

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

FORM 10-K

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

OR

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

Commission File Number: 001-37406

**CORINDUS VASCULAR ROBOTICS, INC.**

(Exact name of Registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

30-0687898

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

309 Waverley Oaks Road, Suite 105, Waltham, MA 02452

(Address of principal executive offices)

(508) 653-3335

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class

Common Stock, \$0.0001 par value per share

Name of each exchange on which registered

NYSE MKT

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

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 Exchange 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 Website, 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 the 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.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if 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 stock held by non-affiliates of the registrant, as of June 30, 2015 (the last business day of the registrant's second quarter of fiscal 2015), was approximately \$172,001,000. For purposes of this computation, all officers, directors, and 10% beneficial owners of the registrant are deemed to be affiliates. Such determination should not be deemed to be an admission that such officers, directors, or 10% beneficial owners are, in fact, affiliates of the registrant.

As of February 29, 2016, the registrant had outstanding 118,934,152 shares of common stock, \$0.0001 par value, which is its only class of common stock.

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the registrant's definitive Proxy Statement for its 2016 Annual Meeting of Shareholders, which is expected to be filed with the Securities and Exchange Commission no later than 120 days after the registrant's fiscal year ended December 31, 2015, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

**EXPLANATORY NOTE**

The registrant meets the "accelerated filer" requirements as of the end of its 2015 fiscal year pursuant to Rule 12b-2 of the Securities Exchange Act of 1934, as amended. However, pursuant to Rule 12b-2 and SEC Release No. 33-8876, the registrant (as a smaller reporting company transitioning to a larger reporting company system based on its public float as of June 30, 2015) is not required to satisfy the larger reporting company requirements until its first quarterly report on Form 10-Q for the 2016 fiscal year and is thus eligible to check both the "Accelerated Filer" and "Smaller Reporting Company" boxes on the cover of this Form 10-K.

CORINDUS VASCULAR ROBOTICS, INC.  
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FOR THE YEAR ENDED DECEMBER 31, 2015

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CorPath<sup>®</sup> is a registered trademark of our company. This Annual Report may also contain trademarks and trade names of other companies.

This Annual Report includes market and industry data that we obtained from periodic industry publications, third-party studies and surveys, government agency sources, filings of public companies in our industry, and internal company surveys. Industry publications and surveys generally state that the information contained therein has been obtained from sources believed to be reliable. Although we believe the foregoing industry and market data to be reliable at the date of the report, this information could prove to be inaccurate as a result of a variety of matters.

## **PART I**

### **CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K and the information incorporated by reference in this Annual Report contain forward-looking statements that involve substantial risks and uncertainties. For example, statements regarding our operations, financial position, business strategy, product development, and other plans and objectives for future operations, and assumptions and predictions about future product development and demand, research and development, marketing, expenses and sales are all forward-looking statements. These statements may be found in the items of this Annual Report entitled “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” as well as in this Annual Report generally. These statements are generally accompanied by words such as “intend,” “anticipate,” “believe,” “estimate,” “target,” “project,” “potential,” “continue,” “forecast,” “predict,” “plan,” “may,” “will,” “could,” “would,” “should,” “expect,” or the negative of such terms or other comparable terminology.

We have based these forward-looking statements on our current expectations and projections about future events. We believe that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to us on the date hereof, but we cannot assure you that these assumptions and expectations will prove to have been correct or that we will take any action that we may presently be planning. These forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, research and product development uncertainties, regulatory policies and approval requirements, competition from other similar businesses, market and general economic factors, and the other risks discussed in Item 1A of this Annual Report. This discussion should be read in conjunction with the consolidated financial statements and notes thereto included in this Annual Report.

We have identified some of the important factors that could cause future events to differ from our current expectations and they are described in this Annual Report in the section entitled “Risk Factors” that you should review carefully. Please consider our forward-looking statements in light of those risks as you read this Annual Report. If one or more of these or other risks or uncertainties materialize, or if our underlying assumptions prove to be incorrect, actual results may vary materially from what we project. We do not undertake to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

### **EXPLANATORY NOTE**

Unless the context otherwise requires, the terms “Company,” “we,” “us,” or “our” refer to Corindus Vascular Robotics, Inc., a Nevada corporation, together with our subsidiaries, Corindus, Inc., a Delaware corporation, and Corindus Security Corporation, a Delaware corporation. Where appropriate, content related only to Corindus, Inc., a Delaware corporation, is referenced as Corindus, Inc.

### **MARKET, INDUSTRY AND OTHER DATA**

Unless otherwise indicated, information contained in this Report concerning our industry and the markets in which we operate, including information regarding our general expectations and market position, market opportunity and market size, is based on information from various sources and on assumptions that we have made based on such information and other similar sources and on our knowledge of the markets for our products. This information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such information. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors and could differ materially from those expressed in the programs, assumptions and estimates made by third parties and by us.

## ITEM 1. BUSINESS.

### Overview

We design, manufacture and sell precision vascular robotic-assisted systems for use in interventional vascular procedures (the “CorPath<sup>®</sup> System”). Our first and current product, the CorPath 200 System, is the only vascular robotic system cleared by the U.S. Food and Drug Administration (“FDA”) to bring precision and accuracy to stent placement in percutaneous coronary intervention (“PCI”) procedures. During the procedure, the interventional cardiologist sits at a radiation-shielded interventional cockpit to advance stents and guidewires with millimeter-by-millimeter precision. The interventional cockpit allows the physician greater control and the freedom from wearing heavy lead protective equipment that causes musculoskeletal injuries. The CorPath System brings robotic precision to radial and complex PCI procedures to help optimize clinical outcomes and minimize the costs associated with complications of improper stent placement with manual PCI procedures. While we are initially cleared for and are targeting PCI procedures, we believe our technology platform has the capability to be developed in the future for other segments of the vascular market, including peripheral vascular, neurointerventional and other more complex cardiac interventions such as structural heart. As of December 31, 2015, we have installed 38 CorPath Systems, including two CorPath Systems in hospitals outside of the U.S.

### Corporate History

Our Company was incorporated under the laws of the State of Nevada on May 4, 2011 under the name “Your Internet Defender Inc.” On August 12, 2014, we closed (the “Closing”) a reverse acquisition transaction (the “Acquisition”) in which we acquired Corindus, Inc. and Corindus Security Corporation as wholly owned subsidiaries. Immediately following the Closing, the business of Corindus, Inc. became our sole focus. We subsequently changed our name to Corindus Vascular Robotics, Inc. and increased our authorized capital stock to 260,000,000 shares (250,000,000 shares of common stock, \$0.0001 par value per share, and 10,000,000 shares of preferred stock, \$0.0001 par value per share).

On May 28, 2015, we completed a public offering by issuing 12,650,000 shares of its common stock at \$3.80 per share in exchange for proceeds of \$44,392,000 net of underwriting discounts, commissions and other offering costs. In connection with the public offering, our common stock was approved for listing on the NYSE MKT, where it commenced trading on May 29, 2015 under the symbol “CVRS”. The Company’s common stock was previously traded on the OTCQB as provided by OTC Markets Group, Inc. under the symbol “CVRS.”

### Percutaneous Coronary Intervention History and Development

PCI, sometimes known as coronary angioplasty, is a non-surgical technique used to open stenotic (narrowed or blocked) coronary arteries found in coronary artery disease. Coronary arteries supply the heart muscle with blood. PCI requires the use of a cardiac catheterization suite (sometimes called a cath lab) with special equipment, x-ray capability and trained personnel. Usually, access to the patient’s heart and major blood vessels is obtained percutaneously through the femoral artery in the groin area. The artery is punctured through the skin with a special needle. Under x-ray guidance, a guide catheter is introduced through the femoral artery up to the aorta (large artery from the heart) and then gently advanced into the blocked coronary artery. The catheter and its devices are passed through the inside of the artery into an area of coronary artery narrowing or blockage. At the leading tip of this catheter, several different devices (such as a balloon, stent or cutting device) can be deployed. A balloon is used to open the coronary artery and restore blood flow. Usually at that time, a stent (a mesh-like tube that holds open the artery) is placed to maintain good blood flow through the damaged area.

PCI is the single highest-volume vascular intervention, with more than 2.5 million procedures performed on a global basis annually according to J.P. Morgan’s 2014 Interventional Cardiology Market Model. PCI can be used to relieve or reduce angina, prevent heart attacks and alleviate congestive heart failure and allows some patients to avoid open heart surgery, which often involves an extensive procedure and a long rehabilitation period.

The first PCI procedure, then known as percutaneous transluminal coronary angioplasty, was performed in Zurich in September 1977 by Andreas Gruentzig, a Swiss radiologist. The early procedures had limited success due to risks associated with the use of large guide catheters that could easily rupture the vessel, no availability of guidewires and large balloon catheters with low burst pressure points. From 1977 to 1986, guide catheters, guidewires and balloon catheter technology were improved, with slimmer profiles and increased tolerance to higher inflation pressure. Stents, first introduced in 1986, are now used in most coronary interventions. The utility of stents has substantially increased procedural safety and success, thus significantly reducing the need for emergency coronary artery bypass surgery.

## **Occupational Hazards of Catheterization Labs**

While there has been significant innovation in the devices and diagnostic tools used in interventional cardiology procedures, the way the manual procedures are generally performed by physicians has remained virtually unchanged since the first procedure by Dr. Gruentzig over 35 years ago. In order to perform the procedure, a physician stands by the patient who is lying on the cath lab table. The physician wears cumbersome and heavy protective apparel containing lead to block exposure to the ionizing radiation of x-rays used in the procedure and thereby combat its adverse effects. Already under bodily strain, the physician must deliver constant x-ray exposures to view the different vessels, which provides visual guidance for manual manipulation of interventional devices inside the patient's heart. In addition to these physical demands, the current manual methods of performing PCI procedures make it difficult for physicians to visualize and estimate the length of the blocked lesion that requires the treatment, often leading to improper device selection and poor placement accuracy.

Interventional cardiologists who perform vascular interventional procedures face life-threatening risks from excessive radiation exposure, may suffer significant occupational hazards and must overcome procedural challenges when performing traditional coronary interventions. The chronic ionizing x-ray radiation exposure to the physician's eyes associated with traditional PCI can cause posterior lens opacities, early cataracts and cancer malignancies. Orthopedic injuries from standing for long periods of time while wearing heavy radiation protection are also common, as are chronic pain complaints and missed physician workdays. In light of these risks, several professional societies and governmental agencies worldwide have called for reductions in radiation to improve catheterization laboratory safety.

Research shows that interventional cardiologists experience among the highest levels of radiation exposure of any medical professional, which leads to increased risk for cancer and cataract formation in addition to increased levels of orthopedic strain from the use of heavy protective garments required to block such exposure. In a study of 36 physicians (of which 28 were interventional cardiologists) with brain tumors potentially linked to radiation exposure over their careers, 86% had left-sided tumors, indicating a correlation with the physician's position at the cath lab table. Additionally, in a survey of interventional cardiologists conducted by the Society for Cardiovascular Angiography and Interventions, 42% reported spine problems (compared to the average rate in the general population of 2.3%) and 28% reported hip, knee or ankle problems and 33% were limited in their practices by these problems. Many hospitals will not allow female interventional cardiologists to practice during pregnancy, while others require them to wear lead protective gear with twice the typical thickness to protect from radiation exposure.

We believe that the future of interventional procedures, where the physician sits inside the cath lab within a radiation-shielded interventional cockpit, will be greatly improved through the use of advanced robotic tools that provide (i) enhanced safety for the catheterization lab staff relative to radiation exposure, (ii) improved patient procedures through advanced precision, dexterity and visualization for the physician and (iii) an economically compelling solution for the hospital. We are pioneering the use of precision vascular robotics to achieve these goals and to improve the way that minimally invasive vascular interventions are performed.

## **Our Precision Robotics System**

We design, manufacture and sell our CorPath System for use in radial and complex interventional vascular procedures to bring precision and accuracy of the only FDA-cleared vascular robotic system to facilitate stent placement for PCI procedures by allowing a physician to measure, manipulate and advance devices with robotic precision. Additionally, our CorPath System allows the physician to perform PCI procedures with a control panel console located within an interventional cockpit. While we are initially approved for and are targeting PCI procedures, we believe our technology platform has the capability to be developed to address many segments of the vascular market in the future, including peripheral, vascular, neurointerventional and other more complex cardiac interventions such as structural heart.

The CorPath System enables the precise, robotic-assisted control of coronary guidewires and balloon/stent devices from the safety of a radiation-shielded interventional cockpit. The CorPath System consists of two components: a bedside unit and an interventional cockpit. The radiation-shielded cockpit features a simple-to-use console to precisely control the movement of guidewires and balloon/stent catheters. Using joysticks and touch-screen controls, the physician is able to measure lengths of portions of anatomy to help in selecting the appropriate stent. At the bedside, the CorPath System's robotic drive and sterile, single-use cassette ("CorPath Cassette") translate the physician's commands into precise movements and manipulations of the coronary stents and catheters. The CorPath Cassette provides a single-use sterile interface with standard PCI guidewires and devices. The CorPath System empowers physicians with precise sub-millimeter measurement and 1mm advancement accuracy. By optimizing stent selection and positioning, the CorPath System enables the deliberate advancement of devices, provides the ability to lock the guidewire and balloon/stent in place during device deployment and helps to ensure that there are no unintended wire/device movements during the procedure.

The CorPath System allows the interventional cardiologist to perform the procedure while seated in an ergonomic and comfortable position in a radiation-shielded cockpit positioned as close as a few feet away from the patient. Our radiation-shielded cockpit provides a reduction in radiation exposure for the primary operator as compared to levels found at the traditional table position for manual procedures. The cockpit allows the physician to control the procedure while seated outside of the radiation field without the need for heavy protective wear. The Percutaneous Robotically-Enhanced Coronary Intervention Study (the "PRECISE Study") published in the Journal of American College of Cardiology Journal, which we sponsored, demonstrated a 95% reduction in radiation exposure to the primary operator. The CorPath System also provides physicians with visualization of the procedure through the eye-level placement of monitors in the cockpit. These improvements can greatly reduce physician fatigue and could potentially extend a physician's medical career. A photo of our CorPath 200 System appears below.

#### **The CorPath 200 System**



#### **Overview of Industry and Market**

##### *Vascular Market*

We developed vascular robotic technology to provide physicians with protection from the occupational hazards of the cath lab and to provide them with robotic precision while executing vascular procedures. Our initial indication for use of the CorPath System is for PCI procedures, radial and complex. We believe our technology can be applied to various vascular clinical applications and markets, including peripheral, vascular, neurointerventional and structural heart, and we may decide to pursue these markets in the future.

##### *Coronary Market (PCI)*

Our current target market is all cardiac cath labs in the U.S. The IMV 2013 Cardiac Cath Lab Market summary report estimates that there are more than 3,250 cath lab rooms in the U.S. performing PCI procedures, which represents approximately 40% of the global market of more than 8,000 PCI cath lab rooms. According to the J.P. Morgan 2014 Interventional Cardiology Market report, there are over 2.5 million PCI procedures performed worldwide each year and approximately 940,000 procedures performed each year in the U.S. The portion of the U.S. cath lab rooms qualifying as customers likely to purchase our product is difficult to ascertain because potential customers are determined by our sales team on a case-by-case basis and is somewhat subjective based on the priorities of each individual facility. Cath lab patient volume has decreased over the past several years, leading to increased competition for patients.

### *Peripheral Vascular Market*

According to Millenium Research Group's 2013 report on U.S. Markets for Peripheral Devices, approximately 1.7 million peripheral vascular procedures are performed annually worldwide (approximately 40% of those in the U.S.) and the annual procedure volumes are expected to grow to over 2.3 million procedures worldwide by 2018. While some peripheral procedures are conducted in cath labs that also conduct PCI procedures, IMV's 2012 Interventional Angiography Lab Market summary report estimates that there are over 3,500 non-PCI peripheral vascular labs worldwide which represent incremental CorPath System placement opportunities beyond PCI.

### *Neurointerventional Market*

Medtech Insight's 2011 report on U.S. Markets for Neurosurgical and Neurointerventional Surgical Products estimates that 395,000 neurointerventional procedures are performed each year, 160,000 in the U.S. and 235,000 internationally, and that the annual volume will grow to an estimated 720,000 worldwide procedures by 2018. The number of incremental, dedicated system worldwide sales opportunities exceeds 400 labs, with 40% in the U.S. and 60% outside the U.S. ("International").

### *Structural Heart Market*

The number of structural heart procedures has been growing and is expected to continue to grow significantly, with an estimated 40,000 worldwide procedures currently performed annually (25% U.S., 75% International) expected to grow to an estimated 120,000 annual structural heart procedures by the year 2018, according to a 2013 clinical report in the Journal of the American College of Cardiology.

### **Our Business Model**

Our business model involves the launching of coronary robotic-assisted intervention programs in hospitals which include the sale of a durable robotic system and a repeat consumable. After the program launch and the sale and installation of the CorPath System in a cath lab, we provide customer support through training and sales of our CorPath Cassette, which provides a sterile interface with standard PCI guidewires and devices. The CorPath Cassette is consumed and replaced for each new patient procedure. The use of the CorPath Cassettes represents opportunity for recurring revenue for each PCI procedure using the CorPath System. We also sell service contracts providing various levels of ongoing service. Over time, we expect to have follow-on sales related to the CorPath System to offer and install robotic system upgrades with more features and new applications.

Our current product line is marketed and sold by our direct sales team that calls on interventional cardiologists, catheterization lab departments and executive administrators in hospitals across the U.S. to launch coronary robotic-assisted intervention programs and drive sales of our CorPath System and our CorPath Cassette. We employ two different types of sales representatives in the field. Our Regional Sales Managers ("RSMs") focus on selling CorPath Systems and our Clinical Account Managers ("CAMs") focus on clinical training and selling the CorPath Cassettes as well as associated disposable accessories, which are designed to maintain a sterile environment when using our products in a cath lab.

The RSMs are responsible for identifying potential customers in the more than 3,250 cath lab rooms performing PCI in the U.S. that desire to launch a coronary robotic-assisted intervention program and purchase a CorPath System. The RSMs may sell the CorPath System as a capital sale or through third-party financed leasing or rental programs. In limited circumstances, we will enter into strategic CorPath System utilization agreements, where we will sell CorPath Cassettes under a CorPath Utilization Program ("CUP"), which is a multi-year arrangement that involves the placement of a CorPath System at a customer's site free of charge and the customer agrees to purchase a minimum number of cassettes each month at a premium over the regular price. The RSMs are also responsible for selling service contracts for the CorPath System. The RSMs are supported by our marketing department, which provides them with leads and sales opportunities garnered through direct marketing activities at interventional cardiology conferences, online webinars, regional seminars and trade journal advertising. Our marketing department also provides the RSMs with the sales tools and marketing resources to help persuasively convey the value proposition of the CorPath System.

Our CAMs focus their efforts on selling our CorPath Cassettes and other associated disposable accessories designed to maintain a sterile environment when using our products in a cath lab. They are responsible for increasing their account sales through new orders and repeat consumable sales within their specific accounts. The CAMs build important relationships throughout the CorPath System installed base accounts, including with the interventional cardiologists, the cath lab technologists, nurses, cath lab directors, schedulers, purchasers and administrators. The CAMs are responsible for ongoing training and development of the CorPath System installed base accounts to build successful CorPath robotic programs and expand its usage across physicians. The CAMs are also responsible for ensuring purchase orders are obtained and that appropriate inventory levels are maintained on site.

#### Driving Utilization of the CorPath System

Following the launch of the coronary robotic-assisted intervention program and the initial sale of a CorPath System to a hospital, we provide enhanced training to the primary physicians and cath lab techs responsible for launching the program and then work to secure an increase in the number of cases performed over time. Subsequently, we expand training to the next group of physicians who use the system. We consistently focus our efforts to make sure that the system is well integrated into the customer's everyday workflow within the cath lab. Dedicated sales and marketing efforts support awareness and use of the CorPath System. Utilization support comes both from encouraging the use of the system within customer accounts and by providing materials to educate general cardiologists and patients on the availability of the CorPath System at the customer site and in their geographical area.

The CorPath System uses a proprietary single-use sterile cassette, which is the source of recurring revenue as use of the CorPath System continues and increases. After a CorPath System is installed and initial training is complete, we provide ongoing support in order to increase customers' familiarity with system features and benefits with the goal of increasing usage of the CorPath System.

#### **Service Revenue**

One year of customer support and warranty is included with the sale of each CorPath System. Thereafter, we sell service contracts under which we continue to provide support after the one-year period. We anticipate that service beyond the basic warranty will become an increasingly important additional source of revenue.

#### **Our Growth Strategy**

Our goal is to ensure that the coronary robotic-assisted intervention program and the use of the CorPath System becomes the standard of care for interventional procedures by providing unsurpassed protection for cath lab staff and being the leading precision robotic technology for patient procedures. We are working with selected customers around the country to establish CorPath System centers of excellence. These centers allow us to bring prospective customers to visit a hospital and cath lab that has previously installed a CorPath System. The site visit will allow the prospective customer the opportunity to see the system installed and in use. It provides the opportunity to discuss the benefits of the system with the hospital staff, including interventional cardiologists, technologists and administrators, and view the work flow of the system in a real life clinical setting. We have successfully conducted such visits at several sites around the country and will continue to expand in the future.

We intend to establish our Company and technology as the brand that cares about and supports the physician and cath lab staff by leading the industry in providing solutions that address and remedy their occupational hazards. By promoting safety and providing awareness of occupational hazards in the cath lab and supporting education about solutions, we hope to become the preferred source for customers seeking to improve the safety of their operations.

A second prong of our growth strategy is to expand into new clinical segments. In addition to our objective to make the CorPath System the premier standard for PCI procedures, we may decide to pursue additional vascular interventional applications for our vascular robotic-assisted technology. Our closest adjacent opportunity is in peripheral vascular procedures performed by interventional cardiologists, vascular surgeons and interventional radiologists. These procedures treat vascular disease in non-coronary areas like the patient's legs. These procedures are often quite lengthy and they expose physicians to x-ray radiation for extended periods of time. The peripheral vascular procedure market has been growing rapidly and is projected to grow at a compound annual growth rate, or CAGR, of 5.9% based on iData's October 2013 Research Report: "US Markets for Peripheral Vascular Devices and Accessories."



Further expansion into neuro-interventional procedures to treat stroke, brain aneurysms and other diseases of the head and neck could allow us to leverage precision robotic-assisted tools into these highly accurate procedures which are very well reimbursed.

Another area of future growth is the emerging market of structural heart procedures. This market segment is experiencing rapid growth due to the advent of new catheter-delivered medical devices that are replacing open surgical procedures. One of the most prominent new devices in this market is the transcatheter aortic valve. The transcatheter aortic valve replacement (“TAVR”) procedure requires very complex integration of a variety of imaging modalities and precise deployment of the device. Our interventional cockpit and robotic-assisted control could potentially provide significant benefits to the execution of TAVR procedures.

Any of these potential applications would require additional clinical trials and various levels of research, engineering, software development, product development, system modifications and regulatory approvals.

An integral part of our growth strategy is to expand commercialization beyond the U.S. marketplace. Opportunities outside of the U.S. represent over 60% of the global procedure volume and are growing at a rate faster than the U.S. market. We intend to expand into and penetrate these new geographical international markets over time by leveraging our product development, clinical research and regulatory approvals gained in the U.S. Our initial international target markets include the Middle East, Northern Europe and Japan. Our current CE Mark for the CorPath System should allow for an easier entry into European and Middle Eastern markets. In 2015, we initiated marketing activities related to the preliminary investigation of the Japanese market and had several meetings with various physicians and regulatory bodies.

#### **Research and Development**

We have built a leading research and development (“R&D”) team comprised of experienced medical device engineers and robotics engineers dedicated to the development of sophisticated robotics systems, including hardware, software, algorithms and radiation shielding and sterile devices to assist physicians in the performance of interventional procedures. We expect our R&D investment to continue to expand the capabilities of our technology to provide more robotic-assisted capabilities for interventional physicians. Additional programs may include the expansion into new clinical areas, such as peripheral vascular, neurointerventional and structural heart procedures, and the ability to manipulate a wider range of devices.

In addition to expanding the capabilities of the CorPath System, we will continue to invest in the design of system manufacturability improvements which we expect to result in a smaller and lower cost system and cassette. The engineering function will use Design for Manufacturability and Assembly (“DFMA”) processes in an effort to reduce costs. DFMA is the combination of two methodologies: Design for Manufacture, which means the design for ease of manufacture of the parts that will form a product, and Design for Assembly, which means the design of the product for ease of assembly. DFMA is used as the basis for concurrent engineering studies to provide guidance to the design team in simplifying the product structure to reduce manufacturing and assembly costs and to quantify improvements. DFMA is a component of lean manufacturing.

Research and development expense amounted to approximately \$4.8 million, \$6.6 million and \$10.0 million for the years ended December 31, 2013, 2014 and 2015, respectively.

#### **Clinical Studies**

We are dedicated to continually advancing robotic-assisted PCI through the publication of clinical data supporting the CorPath System’s value and applicability. We are working with several leading institutions to conduct clinical research activities to further collect evidence regarding the applicability and benefits of robotic-assisted procedures. We are committed to collaboration with prominent interventional cardiologists to build evidence for the benefits of robotic-assisted PCI. We intend to continue to pursue opportunities to develop further evidence for the benefits of the CorPath System in practice. An important component to making the CorPath System the standard of care in the cath lab will be to demonstrate the clinical benefits and applicability of the CorPath System and the advancement of robotic-assisted procedures.

### *First in Man Trial*

In April 2011, we sponsored the *First in Man Trial for the CorPath Robotic-assisted PCI System*, which was published in the Journal of the American College of Cardiologists. This clinical study enrolled eight patients with coronary artery disease who required a PCI procedure at the Corbic Research Institute in Envigado, Colombia. All patients were treated for a single de novo coronary lesion up to 25mm in length located in a vessel 2.5-4.0 mm in diameter. The procedure was successfully completed in all eight patients utilizing the CorPath System to advance coronary guidewires and perform the intervention, and there were no reported device or procedure-related complications or major adverse events. Operator radiation exposure was 97% lower with the use of the CorPath System in comparison with levels found at the standard table position.

### *CorPath PRECISE Study*

We sponsored the PRECISE Study aimed to evaluate the safety and effectiveness of the clinical and technical performance of the CorPath System in the delivery and manipulation of coronary guidewires and stent/balloon devices for use in PCI procedures. We sponsored the PRECISE Study under Investigational Device Exemption ("IDE") approval from the FDA to obtain 510(k) clearance. The PRECISE Study was a prospective, single-arm, multi-center, non-randomized study of the CorPath System. We enrolled 164 patients who were evaluated at nine clinical sites (eight in the U.S.). The PRECISE Study was conducted under Principal Investigators Dr. Giora Weisz, MD Associate Professor of Medicine at Columbia University Medical Center and Chairman of Cardiology, Shaare Zedek Medical Center, Jerusalem, Israel, and Dr. Joseph Carrozza, Chief of Cardiovascular Medicine at St. Elizabeth's Medical Center in Boston. Physicians participating in the study did not receive any direct financial compensation. Results of the PRECISE Study were published in the April 2013 issue of the Journal of the American College of Cardiology and reported a successful PCI completion with use of the CorPath System in 162 of the 164 cases. In each of the two cases in which the PCI procedure was not completed, the interventionalist left the CorPath cockpit to complete the procedure manually, resulting in an incomplete use of the CorPath System. The average radiation exposure to the cardiovascular interventionalist decreased by 95.2% in comparison with levels measured at the location where manual procedures are normally conducted during standard interventions. The overall rate of clinical procedure success was 97.6%, with 100% of patients achieving post-procedure stenosis of less than 30% (as evaluated by a Core Laboratory), and 97.6% of patients had an absence of Major Adverse Cardiac Events ("MACE"). The four MACE events that did arise in the PRECISE Study were cardiac enzyme elevations without symptoms. There were no device-related complications.

### *CorPath PRECISION Registry*

In 2013, we initiated the PRECISION registry, a multicenter post-market registry for the evaluation of the CorPath System's effectiveness in PCI procedures. PRECISION aims to collect data on real-world use of the CorPath System. We are interested in learning about the patterns of the CorPath System's use, safety and effectiveness from an all-comers' perspective. There are currently 15 sites participating in the PRECISION registry, which is being conducted under the leadership of Dr. Giora Weisz. Each site achieves approval to participate in the PRECISION registry from its hospital Institutional Review Board as part of their regular clinical research approval process. We plan to continue to add to the PRECISION registry new sites which are capable of conducting clinical research. Data for the registry is collected and monitored through industry-standard clinical research procedures.

### *Robotically-Assisted Peripheral Intervention for peripheral arterial Disease Study (RAPID)*

The Robotically-Assisted Peripheral Intervention for peripheral arterial Disease (RAPID) Study to evaluate the safety and performance of the CorPath 200 System for use in percutaneous vascular interventions, was completed in 2015. The CorPath System is currently indicated by the FDA for PCI only. The RAPID trial was a single-arm, single center study conducted at the Medical University of Graz in Graz, Austria. The RAPID trial was led by Prof. Dr. Marianne Brodmann, MD, a leading researcher within the university's Division of Angiology, in combination with Prof. Dr. Hannes Deutschmann, of the Medical University of Graz Department of Radiology, and study chairman, Dr. Ehtisham Mahmud, director, Sulpizio Cardiovascular Center-Medicine, UC San Diego. The trial was a prospective, single-arm, single-center study that enrolled 20 subjects to assess the safety and effectiveness of the CorPath System in recanalizing lower extremity arterial blockages during peripheral angioplasty procedures. Results of the RAPID Study were presented in a major cardiology conference. The PAD presentation (Rutherford Classification) was primarily severe (60%) or moderate (30%) claudication. A total of 29 lesions located in the superficial femoral (89.7%) or popliteal (10.3%) arteries were treated. Device technical success and clinical procedural success was 100%. Three minor procedure-related adverse events, all access site hematomas, were reported. There were no device-related complications.

The Staff Exposure to X-ray during PCI: CorPath vs. Manual: An Observational Study to compare cardiac catheterization staff and physician radiation exposure in robotic-assisted PCI with the CorPath 200 System vs. that in manual PCI was completed in 2015. This observational study was led by Dr. Paul T. Campbell, MD, a leading interventional cardiologist at Carolinas Medical Center – NorthEast, Concord, NC. The trial was a prospective, randomized, dual-arm, single-center study that enrolled 30 patients. This observational study showed a significant reduction in physician radiation exposure, and reduction in staff radiation exposure in the robotic-assisted PCI arm compared to the manual PCI arm.

#### **Our Current Product Line**

Our flagship and current product, the CorPath 200 System, brings the precision and accuracy of robotic technology to PCI procedures performed in an interventional cath lab. The CorPath System is intended for use in the remote delivery and manipulation of coronary guidewires and rapid exchange balloon/stent catheters during PCI procedures. There is no contraindication for the use of the product in PCI procedures.

The CorPath System enables the precise, robotic-assisted control of coronary guidewires and balloon/stent devices from the safety of a radiation-shielded, ergonomic interventional cockpit. The CorPath System consists of two components: a bedside unit and an interventional cockpit. The radiation-shielded cockpit features a simple-to-use control console to precisely control the movement of guidewires and balloon/stent catheters. The bedside unit translates the physician's commands into precise movements and manipulations of the coronary stents and catheters contained in a single-use cassette.

The CorPath Cassette provides a sterile interface with standard PCI guidewires and devices and is replaced for each new patient procedure.

In July 2012, we received 510(k) clearance for the CorPath System and initiated a limited commercial launch in the U.S. While we are initially targeting PCI procedures, we believe our open platform technology is capable of addressing all segments of the vascular market, including peripheral, vascular, neurointerventional and other more complex cardiac interventions such as structural heart (subject to securing appropriate regulatory approvals).

In October 2015, we received 510(k) clearance for our robotic-assisted CorPath System to be used during percutaneous coronary interventions performed via radial access. The 510(k) clearance was based on results of a clinical trial conducted at Spectrum Health, Grand Rapids, Michigan, and St. Joseph's Hospital Health Center, Syracuse, New York.

#### **Products in Development**

Our product is tailored to maximize penetration and adoption of our CorPath System technology while providing the best clinical outcomes to our customers and their patients. Our vision for the future is to provide physicians with a complete tool box to robotically perform any interventional procedure desired. We are seeking to expand our penetration within PCI to more complex cases. As we see robotics as the center of the lab, we will continue to integrate other technologies into our robotic system to enable a complete solution for physicians. In order to accomplish this goal, we may investigate proprietary devices, imaging integration and electronic medical record integration while continuing to optimize the workflow in the lab and the remote program we have launched.

#### **Installed CorPath Systems and Backlog**

As of December 31, 2015, there were 36 CorPath Systems installed in hospitals across the U.S. and two installed at international locations. Physicians and their teams in these locations have received training and procedures are currently being performed. Currently these sites have between one to three primary physician CorPath System users. CAM's visit installed sites regularly to support current users and also to expand usage to new targeted users.

## Intellectual Property

Our success depends, in part, on our ability to obtain patents, maintain trade secret protection and operate without infringing the proprietary rights of others. Our intellectual property (“IP”) portfolio covers aspects of our CorPath System and Cassettes, as well as other technology that we have under development, and is one of the means by which we attempt to protect our competitive position. We rely primarily on a combination of know-how, trade secrets, patents, trademarks and contractual restrictions to protect our products and to maintain our competitive position. We are seeking other ways to protect our intellectual property through various legal mechanisms in relevant jurisdictions.

Our researchers and engineers work closely with our patent counsel to protect their inventions and intellectual property with patents issued around the world. We believe that we are building an extensive intellectual property portfolio to protect the fundamental scope of our technology, including our robotic technology, navigational methods, procedures, systems and consumable devices.

We currently own a total of 30 patents and have 53 pending patent applications. Of these, we had 14 issued U.S. patents and 32 pending U.S. patent applications and 16 granted foreign patents and 17 pending foreign applications. The granted foreign patents are in France, Germany, Italy, Israel, the Netherlands and the United Kingdom. The pending applications are in Europe (through applications filed in the European Patent Office), India and Japan. Additionally, there are four Patent Cooperation Treaty applications pending. Our granted patents begin expiring in 2018, and continue to expire through 2030.

Our patents cover, among other things, technology related to robotic control of interventional devices, and the control of the CorPath System, including, but not limited to, the graphical and user interface, function and design of the CorPath Cassette, image-guided navigation for catheter-based interventions, measurement of the length of a structure, and radiation-protected work stations.

In addition to our existing patent coverage, we continue to invest in product development and new IP to further enhance the capabilities of the CorPath System for PCI and other vascular applications. Relative to our current and future portfolio, we believe it will be costly and technically difficult to reverse engineer our products.

We intend to actively protect our intellectual property with patents, trademarks, trade secrets or other legal avenues for the protection of intellectual property. We intend to aggressively prosecute, enforce and defend our patents, trademarks and proprietary technology. The loss, by expiration or otherwise, of any one patent may have a material effect on our business. Defense and enforcement of our IP rights can be expensive and time consuming, even if the outcome is favorable to us. It is possible that the patents issued or licensed to us will be successfully challenged. For example, a court may find that we are infringing on validly issued patents of third parties or that we may have to alter or discontinue the development of our products or pay licensing fees to take into account patent rights of third parties.

As we continue to develop proprietary intellectual property, we will expand our protection by applying for patents on future technologies. While we seek broad coverage under our patent applications, there is always a risk that an alteration to the process may provide sufficient basis for a competitor to avoid infringement claims. In addition, patents expire and we cannot provide any assurance that any patents will be issued from our pending application or that any potentially issued patents will adequately protect our intellectual property.

## Sales and Marketing

We market, sell and support our products in the U.S. through our direct sales force of RSMs with support from our CAMs who provide training and clinical support to our customers. Our direct sales force is the primary distribution channel for CorPath System sales.

We have a direct sales force, clinical sales and support team and headquarters-based marketing team. Our sales and marketing program includes two important steps: selling CorPath Systems to the customer and then leveraging our installed base of systems to drive recurring sales of cassettes and service.

Sales targeting is based on segmentation to identify customers who are likely to purchase and utilize the CorPath System and customers who are likely to be influencers in their region which will help fuel further growth. All hospitals with cath lab rooms that perform PCI procedures are potential customers for a CorPath System. The portion of the approximately 3,250 cath lab rooms in the U.S. that will qualify as customers likely to purchase a CorPath System is difficult to ascertain because potential customers are determined by our sales team on a case-by-case basis and is somewhat subjective based on the priorities of each individual physician and hospital facility. We believe customers that are likely to purchase our product meet a critical criteria profile including (i) an awareness of the dangers faced by interventional cardiologists due to radiation and ergonomic issues in the cath lab, (ii) a practice volume large enough to economically support the CorPath System, (iii) hospital financial health that allows for the capital or operational expenditure for a CorPath System and (iv) regional competitiveness that demands the implementation of new technology.

Our sales effort begins with the interest of an influential physician; and, therefore, our marketing efforts are primarily directed toward interventional cardiologists. Our primary marketing objective is to raise awareness about the CorPath System and its features and benefits among our target customers.

Marketing awareness activities target two strategies:

- 1) General awareness – build knowledge and understanding of the value that the CorPath System brings to the cardiology community, focused initially on awareness from interventional cardiologists; and
- 2) Targeted awareness – using data analysis to identify a target segment of customers (hospitals and physicians) for additional marketing and sales focus.

#### *Physician Benefits*

The cath lab is a hazardous work environment where interventional cardiologists are exposed to radiation on a daily basis. Physicians face two significant risks in the cath lab: damaging radiation exposure despite the use of heavy lead protective aprons and orthopedic strain due to wearing such protective garments while working in ergonomically compromising positions. Each of The International Agency for Research on Cancer (part of the World Health Organization) and the U.S. Environmental Protection Agency independently recognize that ionizing radiation, such as x-rays, can cause cancer and have classified such radiation as a “known carcinogen.” The primary method recommended to partially protect oneself from radiation exposure in the cath lab environment entails wearing more than 20 pounds of lead while leaning over a patient’s table, which leads to interventionalist disc disease of the spine as well as knee, hip and neck injuries. Our CorPath System can limit these risks as evidenced by the results from our PRECISE Study, which demonstrated a 95% reduction in exposure to radiation obviating the need to wear lead during the procedure.

#### *Clinical Benefits for Patients*

Although more than 940,000 PCI procedures are performed annually in the U.S., interventionalists continue to face challenges of poorly selected or misplaced stents. Currently, PCI procedures are performed by interventional cardiologists who approximate lesion length using techniques of subjective visual estimation and tactile feel to position the stent. Published data from the Impact of Stent Deployment Procedural Factors on Long-Term Effectiveness and Safety of Sirolimus-Eluting Stents (“STLLR”) trial in 2008, a study designed to specifically examine PCI stent placement accuracy, shows that nearly 50% of coronary stent placements are not accurately positioned within the lesion using this technique. The clinical impact of longitudinal geographic miss includes complications such as re-occlusion that compels repeat intervention. The CorPath System presents a new option to interventional cardiologists with the potential to optimize clinical outcomes by providing enhanced visualization, precise anatomical measurement and improved control for optimal stent positioning. Using the CorPath System, physicians can (i) consistently measure the anatomy with sub-millimeter accuracy, helping them to choose the correct stent for each patient, (ii) move the guidewire straight into the vessel at the proper angle, potentially leading to a shortened procedure for the patient, (iii) view an enhanced, close-up view of the patient’s vessels and arteries for the entire procedure and (iv) hold the guidewire and balloon/stent in place during device deployment, helping to ensure no unintended wire/device movements during the procedure which could adversely affect the patient.

#### *Hospital Benefits*

Hospitals face increasing pressure to maintain or grow cath lab procedure volumes. By offering a differentiated service, such as robotic-assisted PCI, we can help a facility grow its business. As demonstrated with robotic surgery, hospitals that adopt and promote the technology can benefit in the form of additional patients and procedures.

## Target Customers

### *The Interventional Cardiologist*

The physician is a key decision maker in the evaluation and adoption of new technologies in the interventional cath lab. There are approximately 5,200 active interventional cardiologists in the United States, according to a 2013 article in the Catheterization and Cardiovascular Interventions journal, who are estimated to perform in the aggregate more than 940,000 PCI procedures per year. Interventional cardiologists tend to incorporate technology into their practice and are very focused on products that improve patient care and clinical outcomes. Additionally, interventional cardiologists experience unique occupational risk from their work environment, with the largest exposure to radiation of any medical professionals. To offset this risk, interventionalists wear heavy lead protection exposing them to a higher risk of orthopedic injuries and resulting pain.

The CorPath System allows physicians to measure anatomy with sub-millimeter accuracy and manipulate the interventional device in 1mm increments and with precise 30-degree rotational movements. The capability to accurately control and deliver treatment, using a guidewire and stent of their choice, allows physicians to optimize their PCI procedures and potentially provide better clinical outcomes for their patients. Specifically, the robotic precision can potentially minimize longitudinal geographic miss which has been demonstrated in the STLLR trial to correlate to a 2.3 times greater chance of needing to revascularize the target vessel in the first post-procedure year.

In addition, because physician safety is a growing concern (e.g., studies have shown an increased presence of left-sided brain tumors due to occupational radiation exposure), the ability of the CorPath System to reduce the level of occupational radiation will continue to be a key marketing message. The safety aspect of the device may be a key selling feature as more physicians become employed by healthcare groups which will need to address these concerns to avoid potential workers' compensation claims and reduce insurance costs. Thus, messaging to physicians will focus on the ability of robotic-assisted PCI to improve procedures that can potentially lead to better clinical outcomes and the protection of physicians from radiation and orthopedic issues.

### *The Hospital Administrator*

In this era of economic pressure, purchasing decisions by hospitals must be carefully evaluated to ensure an associated cost benefit. In the case of our products, hospital administrators must be convinced of both the clinical benefit and the economic benefit of having procedures performed using the CorPath System.

Cath lab patient volume has decreased over the past several years which has led to increased competition for patients. Recent data has shown that sites that adopt robotic-assisted surgical procedures, such as prostatectomy, have been able to attract increased patient volumes. Similarly, by using the CorPath System to promote technological leadership in the field of advanced robotics, hospitals can more easily attract and retain physicians while also increasing patient volume.

Customers purchasing our elective Comprehensive Continuity Support program have access to our valuable CorPath Hospital Marketing Program. This broad-based program is a tool kit designed to assist our customer hospitals in launching their own CorPath Vascular Robotic Program using the CorPath System as a tool to market the hospital's quality and commitment to patient care and innovation. The tool kit contains both the programmatic and content elements designed to (i) plan, initiate, and execute public relations and outreach campaigns, (ii) influence and change referral patterns to improve market share in the hospital's catchment area, (iii) promote the benefits of our innovative robotic technology to hospital personnel and patients, and (iv) develop substantial community awareness of the technology and the physicians employing it.

## Product Acquisition Models

Our typical hospital customer purchases the CorPath System through the hospital's capital equipment process and subsequently purchases CorPath Cassettes on an as-needed basis. We have introduced a program for our customers to finance their purchase and are able to seamlessly facilitate a lease or rental for our customers with a third-party financing company. We have also provided a limited number of strategic CUPs, which allow customers to use the CorPath System free of charge in exchange for paying a premium price for the consumables. As of December 31, 2015, we have ten CUPs, which expire at various dates between September 2016 and December 2018. Our revenues recognized under the CUPs were 30.4% and 36.8% for the years ended December 31, 2014 and 2015, respectively, of total revenues from the sale of consumables and 5.9% and 9.1% of our total revenues for the years ended December 31, 2014 and 2015, respectively.

**Competition**

We currently do not face any direct competition for robotic-assisted PCI as the CorPath System is the only FDA-cleared device for this indication. We have some indirect competition in regard to other interventional procedures. There are three companies which make vascular robotic systems for electrophysiology procedures; Hansen Medical, Catheter Robotics and Stereotaxis. Hansen Medical also has a system used for peripheral vascular procedures. If the indications for use of the CorPath System expand in the future, they may become a direct competitor for those procedures. Our primary focus today is on converting customers from the traditional manual PCI procedure to the CorPath System PCI procedure.

The medical device industry, however, is very competitive and subject to significant technological changes. Our potential competitors may develop products, treatments or procedures that are similar, more advanced, safer or more effective than ours. We expect to face competition from many different sources with respect to our existing products and products that we may seek to develop or commercialize in the future.

**Seasonality**

Our CorPath System sales and purchase order cycle may typically take from 6 to 15 months due to the capital budgeting cycle and approval process at each hospital. Because it is a capital item, such a purchase generally requires the approval of senior management of hospitals, and sometimes their parent organizations, purchasing groups, and/or government bodies, as applicable. In addition, hospitals may delay or accelerate purchases of the CorPath System in conjunction with timing of their capital budget timelines. As a result, while it is difficult for us to precisely predict the exact timing of CorPath purchases, we believe that our sales may tend to be heaviest during the third month of each fiscal quarter and heavier in the fourth fiscal quarter than in the other quarters.

Timing of PCI procedures and changes in the PCI procedure market could directly affect the timing of the purchase of our products by hospitals. It is likely that adoption of our products will be more challenging in the third quarter of each year when new interventional fellows join the staff at several of our hospital customer sites. As they are untrained with respect to cath lab skills and patients' cases, they may be devoted to their manual training techniques rather than use of the CorPath System. In the longer term, this risk should be mediated by the limited number of fellows programs relative to hospitals performing PCI procedures.

**Customer Service**

Our goal is 100% customer satisfaction by consistently delivering superior customer experiences before, during, and after the sale. To achieve this goal, we maintain a headquarters-based customer support service team supplemented by our field-based CAMs. Our customer support service team primarily handles all order processing for consumables to ensure that new orders arrive before inventories are depleted. We are committed to providing prompt service for repairs to equipment in order to keep customer uptime at maximum levels. Our CAMs are field-based and are at customer sites on a regular basis to support their needs including on-going training in and outside of the lab. All of our customer service representatives receive regular training so that they can effectively and efficiently field questions from current and prospective customers.

**Our Return Policy; Guarantee**

Neither our equipment, once purchased and installed, nor our single-use cassettes, are returnable or refundable. We stand behind the quality of our products. We value frequent communication with and feedback from our customers in order to continue to improve our offerings and services.

By minimizing stent utilization, the use of the CorPath System has the potential to bring significant clinical, safety and financial benefits to a hospital. To demonstrate our commitment to the benefits of our robotic CorPath System, we offer our hospitals a unique, stent utilization efficiency program called the CorPath One Stent Program. For each eligible CorPath System procedure in which a second unplanned stent is used, we currently provide a credit to the hospital of \$1,000 to be used toward the purchase of additional cassettes. These credits have not been significant to date.

## **Raw Materials for Our Products**

We acquire all raw materials for our products from a group of third-party suppliers. These suppliers may be manufacturers of custom components or distributors of commodity, off-the-shelf, components. Whenever possible, secondary sources for the materials are identified and maintained on our Approved Supplier List. To be included on our Approved Supplier List, suppliers must pass the requirements of our documented Supplier Approval Process.

## **Availability of and Dependence upon Suppliers**

We own all of the designs of all of the custom components used in our product. This allows us to source components which minimize risk of patent infringement or risk of sale to any other manufacturer. We are able to source components at any supplier that has the technical capability to manufacture them. Some of the items we use are off-the-shelf components which can be sourced on the open market and have very little risk in terms of supply and design change. We continually review our supply base for cost and delivery capacity and make adjustments as necessary.

## **Manufacturing of Our Products**

The CorPath System and CorPath Cassettes are manufactured in accordance with the FDA's Current Good Manufacturing Practices ("CGMPs") for medical devices. Our product was cleared by the FDA in 2012 for commercial sale using the 510(k) process and our Waltham, Massachusetts facility is the registered with the FDA as the place of manufacture.

With the exception of our cockpit, which is manufactured by an outside source, all of our manufacturing is categorized as light assembly and is performed by trained personnel in our facility. The single-use cassette is manufactured in an International Organization for Standardization ("ISO") Class 8 clean room. This room is monitored, controlled, and operated according to ISO Class 8 and associated FDA guidelines. Finished products are stored in our facility and shipped directly to the customer. No special environmental controls are required for the storage of our product.

## **Quality Control for Our Products**

A quality assurance team establishes procedures for process control and tests products at various stages of the manufacturing process to ensure we meet product specifications and that our finished products are manufactured in compliance with FDA Quality System Regulations ("QSR"). We inspect incoming components and finished goods per established procedures. Prior to shipment of the product to customers, the quality assurance team reviews our manufacturing record, to ensure it meets established process control requirements and product specifications.

Our quality procedures are designed to meet current FDA regulations and ISO 13485 for compliance with CE Mark requirements. Our production requirements are established to meet product specifications cleared by the FDA and ensure safety of the patients and performance expected by the end users. Our quality system is routinely audited by an internal auditor team and annually assessed by BSI Group for Quality Management System ("QMS") and CE certification. BSI Group is an independent entity, which assesses the compliance of the QMS to ISO 13485 and CE Mark requirements and, upon establishing compliance, provides CE certification (the "Notified Body").

## **Government Regulation**

### *U.S. Medical Device Regulation*

Our products and operations in the U.S. are subject to extensive and rigorous regulation by the FDA. The FDA regulates the development, testing, manufacturing, labeling, storage, record-keeping, promotion, marketing, distribution and service of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), medical devices are classified into one of three classes (Class I, Class II or Class III), depending on the degree of risk associated with each medical device and the extent of regulatory controls needed to ensure the device's safety and effectiveness. Our current products are Class II medical devices.

Class II medical devices are those that are subject to general controls and, frequently, additional special controls, such as premarket or specific labeling guidelines, as specified by the FDA. Class II devices also typically require premarket review and clearance by the FDA, which is accomplished through the submission of a 510(k) premarket notification before the device may be marketed in the U.S. As part of the 510(k) notification process, the FDA may require the following:



- Development of comprehensive product description and indications for use.
- Completion of extensive preclinical tests and/or preclinical animal studies, all performed in accordance with the FDA's Good Laboratory Practice ("GLP") regulations.
- Comprehensive review of predicate devices and development of data supporting the new product's substantial equivalence to one or more predicate devices.
- If appropriate and required, certain types of clinical trials (IDE submission and approval may be required for conducting a clinical trial in the U.S.).

Clinical trials involve use of the medical device on human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices ("GCPs") which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. A protocol with predefined end points, an appropriate sample size and pre-determined patient inclusion and exclusion criteria, is required before initiating and conducting clinical trial. The protocol is reviewed and approved by the participating hospital's Institutional Review Board ("IRB") before the clinical trial can be initiated at the site. Additionally, the IRB must monitor the study until complete. Any subsequent protocol amendments must be submitted and approved by the IRB.

- Assuming successful completion of all required testing, a detailed 510(k) application is submitted to the FDA requesting clearance to market the product. The application includes all relevant data from pertinent preclinical and clinical trials, together with detailed information relating to the product's manufacturing controls and proposed labeling, and other relevant documentation.
- A 510(k) clearance letter from the FDA will authorize commercial marketing of the device for one or more specific indications for use.
- After regulatory clearance, we are required to comply with a number of post-clearance requirements, including, but not limited to, complaint handling and Medical Device Reporting, trending and relevant corrective actions. Also, quality control and manufacturing procedures must continue to conform to QSR requirements. The FDA periodically inspects manufacturing facilities to assess compliance with QSRs, which imposes extensive procedural, substantive, and record keeping requirements on medical device manufacturers. In addition, changes to the manufacturing process are strictly regulated, and, depending on the change, validation activities may need to be performed. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with QSRs and types of regulatory controls.

While not anticipated, future FDA inspections and Notified Body audits may identify compliance issues at our facilities that may potentially disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a device or failure to comply with applicable requirements may result in restrictions on manufacturing and distribution of the device, including withdrawal/recall of the device from the market, or FDA-initiated or judicial action that could delay or prohibit further marketing. Newly identified safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and/or contraindications, and also may require the implementation of other risk management measures.

After a device receives FDA 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a premarket approval application ("PMA"). The FDA requires each manufacturer to make the determination of whether a modification requires a new 510(k) notification or PMA in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance or PMA for a particular change, the FDA may retroactively require the manufacturer to seek 510(k) clearance or PMA. The FDA can also require the manufacturer to cease U.S. marketing and/or recall the modified device until additional 510(k) clearance or PMA approval is obtained.

The FDA and the Federal Trade Commission (“FTC”) also regulate the advertising claims of our products to ensure that the claims we make are consistent with our regulatory clearances, that there is scientific data to substantiate the claims and that our advertising is neither false nor misleading. In general, we may not promote or advertise our products for uses not within the scope of our intended use statement in our clearances or make unsupported safety and effectiveness claims. Many regulatory jurisdictions outside of the U.S. have similar regulations to which we would be subject. Our manufacturing processes are required to comply with the FDA’s cGMP requirements contained in its QSR and associated regulations and guidance. The QSR covers, among other things, the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping, installation and service of a company’s products. The QSR also requires maintenance of extensive records which demonstrate compliance with FDA regulation, the manufacturer’s own procedures, specifications and testing as well as distribution and post-market experience. Compliance with the QSR is necessary to receive FDA clearance or approval to market new products and is necessary for a manufacturer to be able to continue to market cleared or approved product offerings in the U.S. A company’s facilities, records, and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA, which may issue reports known as Forms FDA 483 or Notices of Inspectional Observations which list instances where the FDA inspector believes the manufacturer has failed to comply with applicable regulations and/or procedures. If the observations are sufficiently serious or the manufacturer fails to respond appropriately, the FDA may issue Warning Letters, which are notices of intended enforcement actions against the manufacturer; or United Letters, which are used for less serious violations that may not rise to the level of regulatory significance. These enforcement actions could include legal actions, including fines and total shutdown of production facilities, seizure of product, prohibition on export or import and criminal prosecution. Such actions may have further indirect consequences for the manufacturer outside of the U.S., and may adversely affect the reputation of the manufacturer and the product. In the U.S., routine FDA inspections usually occur every two years, and may occur more often for cause.

We intend to submit 510(k) applications for our next generation devices and for any new indications for use of our existing products. The applications may rely upon published literature and/or the findings of safety and effectiveness based on pre-clinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product or for new claims for the cleared product.

#### *Foreign Medical Device Regulation*

In order for us to market our products in other countries, we must comply with extensive safety and quality regulations in other countries. These regulations, including the requirements for approvals, clearance or grant of CE Certificates and Declaration of Conformity and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval, clearance or CE Certificates of Conformity (or equivalent) in any foreign country in which we plan to market our products may harm our ability to generate revenue and harm our business.

The primary regulatory environment in Europe is that of the European Economic Area (the “EEA”), which is comprised of the 28 Member States of the European Union (“EU”), Iceland, Liechtenstein and Norway. In the EEA, our devices are required to comply with the Essential Requirements defined in Annex I to the EU Medical Devices Directive (applicable in the non-EU EEA Member States via the Agreement on the European Economic Area). We are also required to ensure compliance with the relevant quality system requirements defined in the Annexes to the Medical Devices Directive. Compliance with these requirements entitles us to affix the CE mark to our medical devices, without which they cannot be commercialized in EEA. To demonstrate compliance with the Essential Requirements defined in Annex I of the Medical Devices Directive to obtain the right to affix the CE mark to our medical devices, and thus be permitted to market our medical devices on the EEA market, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. With the exception of low risk medical devices (Class I devices with no measuring function and which are not sterile), in relation to which the manufacturer may issue a CE Declaration of Conformity based on a self-assessment of the conformity of its products with the Essential Requirements defined in the Medical Devices Directive, a conformity assessment procedure requires the intervention of an EU accredited organization. This is an organization designated by the competent authorities of an EEA country to conduct conformity assessments. Depending on the relevant conformity assessment procedure, the accredited organization may audit and examine products’ Technical File and/or the quality system for the manufacture, design and final inspection of our devices before issuing a CE Certificate of Conformity. This Certificate demonstrates substantive compliance with the relevant Essential Requirements laid down in Annex I of the Medical Devices Directive or the relevant quality system requirements defined in the Annexes to the Directive and constitutes the basis for manufacturers to issue their mandatory Declaration of Conformity. Companies compliant with ISO requirements such as “EN ISO 13485: 2012 Medical devices — Quality management systems — Requirements for regulatory purposes” benefit from a presumption of conformity with the relevant quality system requirements defined in the Annexes to the Medical Devices Directive. The Notified Body issues a CE Certificate of Conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements and quality system requirements. In 2011, we received CE Certificate of Conformity from our Notified Body permitting us to affix the CE mark and market our CorPath 200 System in the EEA. If we modify existing products or develop new products in the future, including new devices, it may be necessary to notify our Notified Body and go through a conformity assessment procedure before having the right to affix the CE mark to such products. We will be subject to regulatory audits, currently conducted annually, in order to maintain any CE Certificates of Conformity that have been issued by our Notified Body. We cannot be certain that we will be able to obtain CE Certificates of Conformity for new or modified products. We continually strive to maintain our quality system to comply with the regulatory requirements defined in the Medical Device Directive and EN ISO 13485 for the CE Certificate of Conformity that we have received. We will evaluate regulatory approval in other foreign countries on an opportunistic basis.

### Third Party Coverage and Reimbursement

The U.S. government and health insurance companies together are responsible for hospital and physician reimbursement for virtually all covered interventional procedures. Governments and insurance companies generally reimburse hospitals and physicians for procedures considered medically necessary. The Centers for Medicare & Medicaid Services (“CMS”), administers the Medicare and Medicaid programs (the latter, along with applicable state governments). Many other third-party payors model their reimbursement methodologies after the Medicare program. As the single largest payor, this program has a significant impact on other payors’ payment systems.

Generally, reimbursement for professional services performed at a facility by physicians is reported under billing codes issued by the American Medical Association (“AMA”), known as Current Procedural Terminology (“CPT”) codes. Physician reimbursement under Medicare generally is based on a fee schedule and determined by the relative values of the professional service rendered. In addition, CMS and the National Center for Health Statistics (“NCHS”) are jointly responsible for overseeing changes and modifications to billing codes known as ICD-9-CM procedural codes used by hospitals to report inpatient procedures. For Medicare, CMS generally reimburses hospitals for services provided during an inpatient stay based on a prospective payment system that is determined by a classification system known as Medicare-Severity Diagnostic Related Groupings (“MS-DRGs”). MS-DRGs are assigned using a number of factors including the principal diagnosis, major procedures, discharged status, patient age and complicating secondary diagnoses among other things. Hospital outpatient services, reported by CPT codes, are assigned to clinically relevant Ambulatory Payment Classifications (“APCs”) used to determine the payment amount for services provided.

On October 1, 2008, CMS and NCHS issued a new family of ICD-9-CM procedure codes for “Robotically Assisted Procedures.” The purpose of the ICD-9-CM family of procedure codes is to gather data on robotic assisted surgical procedures. Effective October 1, 2014, ICD-9-CM procedure code 1743 was implemented for Percutaneous Robotic Assisted Procedure(s). A surgical procedure, completed with or without robotic assistance, continues to be assigned to the clinically relevant MS-DRG.

Governments and insurance companies carefully review and increasingly challenge the prices charged for medical products and surgical services. Reimbursement rates from private companies vary depending on the procedure performed, the third-party payor, contract terms, and other factors. Because both hospitals and physicians may receive the same reimbursement for their respective services, with or without robotics, regardless of actual costs incurred by the hospital or physician in furnishing the care, including for the specific products used in that procedure, hospitals and physicians may decide not to use our products if reimbursement amounts are insufficient to cover any additional costs incurred when purchasing our products.

Domestic institutions typically bill for the primary procedure that includes our products to various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans. Because our CorPath System has been cleared for commercial distribution in the U.S. by the FDA, coverage and reimbursement by payors are generally determined by the medical necessity of the primary procedure. While PCI procedures are typically reimbursed by third-party payors, currently, there is no incremental reimbursement provided for robotic-assisted PCI. Therefore, using the CorPath System and consumable cassettes without an incremental reimbursement will initially increase the up-front cost of the PCI procedure and the cath lab operation based on the cost of the CorPath System and also consumable cassettes. This lack of incremental reimbursement from third-party payors for procedures performed with our products, or lack of coverage by governmental and private payors’ policies of interventional procedures performed using our products, may make us unable to generate the revenues necessary to support our business.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, “the PPACA”), was signed into law and makes changes that are expected to significantly impact healthcare providers, insurers, pharmaceutical and medical device manufacturers. One of the principal aims of the PPACA is to expand health insurance coverage to any Americans who are currently uninsured. The consequences of these significant coverage expansions on the sales of our products are currently unknown. The PPACA contains a number of provisions designed to generate the revenues necessary to fund this coverage expansion, including, but not limited to new fees or taxes on certain health-related industries, including medical device manufacturers. Beginning in 2013, medical device manufacturers are required to pay an excise tax (or sales tax) of 2.3% on certain U.S. medical device revenues. Under this provision, we have incurred an excise tax of approximately \$104,000 cumulatively through December 31, 2015 which is reflected in our operating expenses. At the present time the excise tax is suspended due to the operation of a provision in the Consolidated Appropriations Act of 2016, signed into law on December 18, 2015 but that two-year suspension period ends on December 31, 2017. However, there is no guarantee that the excise tax will continue to be suspended by congressional action after this two-year moratorium ends, so we would expect to become subject to the 2.3% medical device tax again beginning on January 1, 2018.

The PPACA also has provisions to study the comparative effectiveness of health care treatments and strategies. It remains unclear how this research will influence future Medicare coverage and reimbursement decisions, as well as influence other third-party payor coverage and reimbursement policies. As Congress and state governments determine how to implement the PPACA, the full impact of the PPACA on the medical device industry and the sale of our products are currently unknown. The PPACA, as well as other federal or state health care reform measures that may be adopted in the future, could have a material adverse effect on our business. The taxes imposed by PPACA and the expansion in the U.S. government’s role in the healthcare industry may result in decreased profits, lower reimbursement from payors for procedures that use our products and/or reduced procedural volumes, all of which may adversely affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers.

Any regulatory or legislative developments in domestic markets that eliminate or reduce reimbursement rates for procedures performed using our products could harm our ability to sell our products or cause downward pressure on the prices of our products, either of which would affect our ability to generate the revenues necessary to support our business.

#### **Properties**

Our principal offices and manufacturing facilities are located at 309 Waverley Oaks Road, Suite 105, Waltham, Massachusetts 02452. On October 24, 2012, Corindus, Inc. entered into a lease with Beaver Group, LLC for a term of approximately five years for 26,402 square feet of office and manufacturing space (the “Lease”). Over the term of the Lease, we pay an average monthly cost of \$46,000 which includes base rent, common area fees, taxes and insurance. Terms of the Lease provide for an option to extend the Lease for an additional five-year period. Our management believes that the leased premises are suitable and adequate to meet current needs.

#### **Employees**

As of February 29, 2016, we have 64 full-time employees. Additionally, from time to time, we hire temporary or contract employees. None of our employees are covered by a collective bargaining agreement and we are unaware of any union organizing efforts. We have never experienced a major work stoppage, strike or dispute. We consider our relationship with our employees to be good.

#### **Subsidiaries**

Our subsidiaries are Corindus, Inc., which is our operating company, and Corindus Security Corporation, which holds and invests the proceeds of the issuance of certain securities.

## Corporate Information

We are a Nevada corporation. Our corporate headquarters and manufacturing facilities are located at 309 Waverley Oaks Road, Suite 105, Waltham, Massachusetts 02452. Our telephone number is 508-653-3335 and our fax number is 508-653-3355. We maintain a website at <http://www.corindus.com>.

## Available Information

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to such reports filed or furnished pursuant to section 13(a) or 15(d) of the Securities Exchange Act of 1934, as well as section 16 reports on Form 3, 4, or 5, are available free of charge on our Internet website as soon as is reasonably practicable after they are filed or furnished with the SEC. Our Code of Conduct and Ethics and the charters for the Audit Committee, the Nominating and Governance Committee and the Compensation and Management Development Committee of our Board of Directors are also available on our Internet website. The Code of Conduct and Ethics and charters are also available in print to any shareholder upon request. Requests for such documents should be directed to Brett Prince, Marketing Department, at 309 Waverley Oaks Road, Suite 105, Waltham, Massachusetts 02452. Our Internet website and the information contained on it or connected to it are not part of nor incorporated by reference into this Form 10-K. Our filings with the SEC are also available on the SEC's website at <http://www.sec.gov>.

## ITEM 1A. RISK FACTORS.

Investing in our common stock or any other security that may be issued by us involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Report, before making an investment decision. If any of the following risks actually occur, our business, financial condition or results of operations could suffer. In that case, the trading price of our shares of Common Stock could decline, and you may lose all or part of your investment. You should read the section entitled "Forward-Looking Statements" above for a discussion of what types of statements are forward-looking statements, as well as the significance of such statements in the context of this Report.

### Risks Related to our Financial Position

*We have incurred significant operating losses since inception and anticipate that we will incur continued losses for the foreseeable future.*

We have incurred recurring net losses, including net losses of approximately \$24.5 million and \$28.8 million for the years ended December 31, 2014 and December 31, 2015, respectively. As of December 31, 2015, we had an accumulated deficit of approximately \$113.6 million. We have generated limited revenue and have funded our operations to date primarily from sales of capital stock and debt. We expect to incur substantial additional losses over the next few years primarily related to our research and development and commercialization activities. As a result, we may never achieve or maintain profitability unless we successfully commercialize our CorPath System. If we are unable to make required payments under any of our obligations for any reason, our creditors may take actions to collect their debts, including foreclosing on our intellectual property that collateralizes our obligations. If we continue to incur substantial losses and are unable to secure additional financing, we could be forced to discontinue or curtail our business operations, sell assets at unfavorable prices, refinance existing debt obligations on terms unfavorable to us, or merge, consolidate, or combine with a company with greater financial resources in a transaction that might be unfavorable to us.

*Until we reach profitability and generate operating cash flows to grow the business, we will need to continue to raise additional funding. We may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs, commercialization efforts and growth strategy.*

We will need additional funding for establishing and expanding our sales and marketing infrastructure and for future product development and we may be unable to raise capital when needed or on attractive terms, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We have funded operations primarily through the issuance of capital stock and debt. As of December 31, 2015, we had an accumulated deficit of approximately \$113.6 million. On May 28, 2015, the Company completed a public offering by issuing 12,650,000 shares of its common stock at \$3.80 per share in exchange for proceeds of \$44.4 million, net of underwriting discounts, commissions and other offering costs. As of December 31, 2015, we had approximately \$42.7 million in cash, cash equivalents and marketable securities. In order to carry out our business and implement our strategy in the future, we anticipate that we will need to obtain additional financing from time to time through additional debt or equity offerings. There can be no assurances, however, that additional funding will be available on terms acceptable to us, if at all.

Should we raise additional funds by issuing equity securities, our stockholders will experience immediate dilution. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any additional debt or equity financing that we close may contain terms, such as liquidation and other preferences, which are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. If additional financing is not available when required or is not available on acceptable terms, we may be unable to fund expansion, successfully promote our brand name, develop or enhance our services, take advantage of business opportunities, or respond to competitive pressures or unanticipated requirements, any of which could seriously harm our business and reduce the value of your investment.

*We currently owe approximately \$8.0 million under a loan agreement and we can give no assurance that we will be able to satisfy our obligations under the loan agreement at the maturity date.*

On June 11, 2014, we entered into a Loan and Security Agreement pursuant to which the lender agreed to make an aggregate of approximately \$10 million available to us under two \$5 million secured promissory notes (the "Secured Promissory Notes"). The initial note for approximately \$5 million was made on June 11, 2014 (the "Initial Note") and the second note for approximately \$5 million was made on December 31, 2014 (the "Second Note"). The Secured Promissory Notes are repayable over a term of 27 months which began on July 1, 2015. The Initial Note bears interest at a rate equal to the greater of (w) 11.25% or (x) 11.25% plus the Wall Street Journal Prime Rate, less 3.25%. The Second Note bears interest at a rate equal to the greater of (y) 9.95% or (z) 9.95% plus the Wall Street Journal Prime Rate, less 3.25%. The Secured Promissory Notes include additional interest payments of \$125 thousand each due no later than October 1, 2017, which is accreted over the term of the loans. There is no assurance that we will have the funds available to meet our principal and interest payment obligations under the Secured Promissory Notes or that we will be able to satisfy covenants or other obligations under the Secured Promissory Notes. Our covenants under the loan arrangement include certain restrictions with respect to subsequent indebtedness, liens, loans and investments, asset sales, and share repurchases and other restricted payments, subject to certain exceptions. The arrangement also includes financial reporting obligations. An event of default under the Loan and Security Agreement includes, but is not limited to, breach of covenants, insolvency, and occurrence of any default under any agreement or obligation of the Company. In addition, the Loan and Security Agreement contains a customary material adverse effect clause which states that in the event of a material adverse effect, an event of default would occur and the lender has the option to accelerate and demand payment of all or any part of the loan. A material adverse effect is defined in the Loan and Security Agreement as a material change in our business, operations, properties, assets or financial condition or a material impairment of our ability to perform all obligations under this Loan and Security Agreement.

*Changes in our effective tax rate may harm our results of operations.*

A number of factors may harm our future effective tax rates including, but not limited to, the following:

- the jurisdictions in which profits are determined to be earned and taxed;
- the resolution of issues arising from tax audits with various taxing authorities;
- change in valuation of our deferred tax assets and liabilities;
- increases in expenses not deductible for tax purposes;
- changes in available tax credits and deductions;
- changes in share-based compensation; and
- changes in tax laws or the interpretation of such tax laws and changes in generally accepted accounting principles.

Because we have incurred losses to date, we have not recorded any income tax provision thus far. At December 31, 2015, we had U.S. federal and state net operating loss carryforwards of approximately \$83.0 million and \$56.6 million, respectively, that can be carried forward and offset against future taxable income. These net operating loss carryforwards will begin to expire in 2028. Utilization of net operating losses may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986, as amended, and similar state provisions. This limitation may result in the expiration of net operating losses before utilization. We have not yet determined whether any changes in ownership have triggered any such limitations. There can be no assurance that we will utilize the entire amount of our net operating loss carryforwards.

## Risks Related to Our Business and Industry

*We are completely dependent on the success of our CorPath System, which has a limited commercial history. If our CorPath System fails to gain or loses market acceptance, our business will suffer.*

We commercially introduced our CorPath System in July 2012, and expect that sales of our CorPath System will account for the majority of our revenue for the foreseeable future. Because of its recent commercial introduction, the CorPath System has limited product and brand recognition. Demand for the CorPath System has not increased as quickly as we expected and we do not know if we will be successful over the long term in generating increased demand for the use of our products. Failure of our CorPath System to significantly penetrate current or new markets would negatively impact our business, financial condition and results of operations.

*We operate in a competitive industry and if our competitors have products that are marketed more effectively or develop products, treatments or procedures that are similar, more advanced, safer or more effective than ours, our commercial opportunities will be reduced or eliminated and our business will be harmed.*

Our potential competitors may develop products, treatments or procedures that are similar, more advanced, safer or more effective than ours. The medical device industry is very competitive and subject to significant technological and practice changes. We expect to face competition from many different sources with respect to our existing products and products that we may seek to develop or commercialize in the future.

Competing against large established competitors with significant resources may make establishing a market for any products that we develop difficult which would have a material adverse effect on our business. Our commercial opportunity could also be reduced or eliminated if our competitors develop and commercialize products, treatments or procedures that are safer, more effective, are more convenient or are less expensive than our existing products or any product that we may develop. Many of our potential competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we may have. Mergers and acquisitions in the medical device industry market may result in even more resources being concentrated among a smaller number of our potential competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These companies 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 complementary to, or necessary for, our programs.

*If institutions or physicians are unable to obtain coverage and reimbursement from third-party payors for procedures using our products, or if reimbursement is insufficient to cover the costs of purchasing our products, we may be unable to generate sufficient sales to support our business.*

In the U.S., hospitals generally bill for the services performed with our products to various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans. Currently, there is no incremental reimbursement provided for robotic-assisted PCI. Therefore, using the CorPath System and consumable cassette without an incremental reimbursement will initially increase the up-front cost of the PCI procedure and the cath lab operation based on the cost of the CorPath System and also consumable cassettes. This lack of incremental reimbursement from third-party payors for procedures performed with our products, or lack of coverage by governmental and private payors' policies of interventional procedures performed using our products, could deter hospitals from purchasing our products and may make us unable to generate the revenues necessary to support our business.

*The commercial success of our products will depend upon the degree of market acceptance by hospitals and physicians. Should we not achieve market acceptance, we will not be able to generate the revenue necessary to support our business.*

The CorPath System is a new technology that represents a fundamentally new way of performing PCI procedures, however, it competes with established treatment options for PCI procedures. Achieving physician, patient and third-party payor acceptance of the CorPath System as a preferred method of performing vascular procedures will be crucial to our success. If our products fail to achieve market acceptance, hospital customers will not purchase our products and we will not be able to generate the revenue necessary to support our business. We believe that acceptance by hospitals, physicians and third-party payors regarding the benefits of procedures performed using our products will be essential for acceptance of our products by patients. Physicians will not recommend the use of our products unless we can demonstrate that they produce results comparable or superior to existing PCI techniques. Even though we have proven the effectiveness of our products through clinical trials, physicians may elect not to use our products for any number of other reasons. For example, cardiologists may continue to recommend conventional PCI techniques simply because it is already widely accepted. In addition, physicians may be slow to adopt our products because of the perceived liability risks arising from the use of new products and the uncertainty of reimbursement from third-party payors, particularly in light of ongoing health care reform initiatives. We expect that there will be a learning process involved for physicians and their surgical teams to become proficient in the use of our products. Market acceptance could be delayed by the time required to complete this training. We may not be able to rapidly train physicians and their surgical teams in numbers sufficient to generate adequate demand for our products.

Development and awareness of our brand will largely depend upon our success in increasing our customer base. In order to attract and retain customers and to promote and maintain our brand in response to competitive pressures, management plans to significantly increase our sales and marketing budgets, particularly for our field sales force. If we are unable to economically promote or maintain our brand, our business, results of operations and financial condition could be severely harmed.

***The successful use of our CorPath System depends in part on physician skill and experience. If we are unable to train physicians on the proper use of our system, we may experience a high risk of product liability.***

The successful use of our CorPath System depends in part on the physician's skill and experience. We train users on the proper techniques in using our system to achieve the intended outcome. Because of the acute nature of PCI procedure, we are unable to have a company representative attend cases using the CorPath System. As the number of users of our system increases, it is possible that the level of training that we are accustomed to providing will be insufficient and some physicians may not be willing to invest the time required to become properly trained with our procedure. We may find that physicians who are less skilled in the use of interventional devices will increasingly use the CorPath System, potentially leading to a higher rate of device failure, injury, negative publicity and an increased risk of product liability. We may be subject to claims against us even if the apparent injury is due to the actions of others. Any litigation that may occur based on physician error in the use of our products and our potential inability to train physicians to use our CorPath System may lead to inadequate demand for our products and have a material adverse impact on our business, financial condition and results of operations.

***Our future success is dependent upon expanding our technology platform to other segments. Our potential inability to expand our technology platform beyond PCI may adversely affect our ability to increase our revenues.***

Currently, our only users are interventional cardiologists in PCI procedures. We are dependent on our ability to expand our technology platform and sell our products to other vascular markets in the future, including peripheral, vascular, neurointerventional and other more complex cardiac interventions such as structural heart. The techniques used in our procedure are similar to those used by not only our current user base of interventional cardiologists, but also to those used by other specialists who are generally trained in interventional techniques. Our revenue growth will depend on our ability to obtain approval to sell our CorPath System into these other markets and to sell our products to their physicians and their affiliated hospitals. Convincing physicians to dedicate the time and energy necessary for adequate training in the use of our system is challenging, and we cannot provide any assurance that we will be successful in these efforts, if we receive approval. In addition, we do not have significant experience in selling our products to other specialists. They may require, among other things, additional clinical evidence supporting patient and physician benefits, training in a manner to which we are not accustomed or other resources that we do not readily have available or are not cost effective for us to provide. If we are unable to expand into other markets, growth of our sales will be limited and our revenue will be adversely impacted.

***Decreasing cath lab patient volume could adversely affect our business, financial condition or results of operations.***

Our current target market consists of the estimated 3,250 cath lab rooms in the U.S. that perform PCI procedures, which we estimate represents 40% of the global market of more than 8,000 PCI cath lab rooms. U.S. cath lab patient volume has decreased over the past several years, leading to increased competition for patients. If U.S. cath lab patient volume continues to decrease, it may become more difficult for us to grow revenue and increase market share and could adversely affect our business, financial condition or results of operations. In addition, revenue from the sale of our consumable cassettes to cath labs which already have a CorPath System installed is dependent on how often the systems are utilized. If the utilization rate decreases, our revenues, financial condition and results of operations could be adversely impacted.



***Our products face the risk of technological obsolescence, which, if realized, could have a material adverse effect on our business.***

The medical device industry is characterized by rapid and significant technological change. There can be no assurance that third parties will not succeed in developing or marketing technologies and products that are more effective than ours or that would render our technology and products obsolete or noncompetitive. Additionally, new, less invasive surgical procedures and medications could be developed that replace or reduce the importance of current procedures that use or could use our products. Accordingly, our success will depend in part upon our ability to respond quickly to medical and technological changes through the development of new products. Product development involves a high degree of risk, and we cannot assure you that our new product development efforts will result in any commercially successful products.

***We may experience long and variable capital sales cycles and/or seasonality in our business which may cause fluctuations in our financial results.***

Our CorPath System may have a lengthy sales and purchase order cycle because it is a major capital item and such a purchase generally requires the approval of senior management of hospitals, their parent organizations, purchasing groups, and/or government bodies, as applicable. In addition, hospitals may delay or accelerate system purchases in conjunction with timing of their capital budget timelines. As a result, it is difficult for us to predict the length of capital sales cycles and, therefore, the exact timing of capital sales. We believe that our sales may tend to be heaviest during the third month of each fiscal quarter, and lighter in the third and first fiscal quarters and heavier in the fourth fiscal quarter. Timing of PCI procedures and changes in the PCI procedure market could directly affect the timing of the purchase of our products by hospitals.

The above factors may contribute to fluctuations in our quarterly operating results and it is possible that in some future quarters our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our stock would likely decrease. These fluctuations, among other factors, also mean that you will not be able to rely upon our operating results in any particular period as an indication of future performance. In addition, the introduction of new products could adversely impact our sales cycle as customers take additional time to assess the benefits and costs of such products.

***If defects are discovered in our products, we may incur additional unforeseen costs, hospitals may not purchase our products and our reputation may suffer.***

Our products incorporate mechanical parts, electrical components, optical components and computer software, any of which can contain errors or failures, especially when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after commercial shipment. Because our products are designed to be used to perform complex medical procedures, we expect that our customers will have an increased sensitivity to such defects. We cannot provide any assurances that our products will not experience component aging, errors or performance problems in the future. If we experience flaws or performance problems, any of the following could occur:

- delays in product shipments;
- loss of revenue;
- delay in market acceptance;
- diversion of our resources;
- damage to our reputation;
- product recalls;
- regulatory actions;
- increased service or warranty costs; or
- product liability claims.

***In the future, we may be subject to product liability and negligence claims relating to the use of our products that could be expensive, divert management's attention and harm our business.***

Our business exposes us to significant risks of product liability claims, which are inherent to the medical device industry, including product liability exposure related to the testing of our CorPath System in human clinical trials. Because our CorPath System is designed to be used in complex surgical procedures, defects could result in a number of complications, including serious personal injury or death. Claims could be brought against us if use or misuse of our CorPath System causes, or merely appears to have caused, personal injury or death. Product liability claims may be brought by individuals or by groups seeking to represent a class.

While we have and intend to maintain product liability insurance, our coverage may not be sufficient to cover claims that may be made against us and we may be unable to maintain such insurance. Additionally, we have entered into various agreements where we indemnify third parties for certain claims relating to our products. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnification obligations. We are not currently subject to any product liability claims; however, future product liability claims against us, regardless of their merit, may result in negative publicity about us that could ultimately harm our reputation and could have a material adverse effect on our business, financial condition, results of operations.

***We may be subject to product recalls that could negatively affect our business.***

We may be subject to product recalls, withdrawals or seizures if any of our products are believed to cause injury or are subject to serious malfunctions or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale or distribution of our products. A recall, withdrawal or seizure of any of our products could materially and adversely affect consumer confidence in our brand and lead to decreased demand for our products. In addition, a recall, withdrawal or seizure of our products would require significant management attention, would likely result in substantial and unexpected expenditures and could materially and adversely affect our business, financial condition or results of operations.

***Our business may be affected by unfavorable publicity or lack of consumer acceptance.***

We are highly dependent upon consumer acceptance of the safety, efficacy and quality of our products. Consumer acceptance of a product can be significantly influenced by scientific research or findings, national media attention and other publicity about product use. A product may be received favorably resulting in high sales associated with that product that may not be sustainable as consumer preferences change. Future scientific research or publicity could be unfavorable to our industry or to any of our products and may not be consistent with earlier favorable research or publicity. A future research report or publicity that is perceived by our consumers as less than favorable or that may question earlier favorable research or publicity could have a material adverse effect on our ability to generate revenue. Adverse publicity in the form of published scientific research, statements by regulatory authorities or otherwise, whether or not accurate, that associates the use of our product with adverse effects, or that questions the benefits of our product or a similar product, or that claims that our products are ineffective, could reduce market acceptance of our products and could result in decreased product demand and could have a material adverse effect on our business, reputation, financial condition or results of operations.

***We could be subject to significant, uninsured liabilities.***

In the future, we may not continue to maintain certain existing insurance coverage or adequate levels of coverage. Premiums for many types of insurance have increased significantly in recent years, and depending on market conditions and our circumstances, in the future, certain types of insurance such as directors' and officers' insurance or products liability insurance may not be available on acceptable terms or at all.

***We may encounter manufacturing problems or delays that could result in lost revenue.***

Manufacturing our products is a complex process. We may encounter difficulties in scaling up or maintaining production of our products, including:

- problems involving production yields;
- quality control and assurance;
- component supply shortages;
- import or export restrictions on components, materials or technology;
- shortages of qualified personnel; and
- compliance with state and federal regulations.

If demand for our products exceeds our manufacturing capacity, we could develop a substantial backlog of customer orders. If we are unable to maintain larger-scale manufacturing capabilities, our ability to generate revenues will be limited and our reputation in the marketplace could be damaged.

***We depend on limited or single source suppliers and vendors for components and services used in the manufacture of our products, and the partial or complete loss of these suppliers or vendors could cause customer supply or production delays and a substantial loss of revenues.***

We depend on limited or single source suppliers for certain key components, and limited vendors for certain services, used to manufacture our products, making us susceptible to quality issues, shortages and price changes. Any of these limited or single source suppliers or vendors could stop producing or supplying our components or stop performing services used to manufacture our products, cease operations or be acquired by, or enter into exclusive arrangements with, one or more potential competitors. As a result, these suppliers and vendors could stop providing components or services to us at commercially reasonable prices, or at all. Because there are a limited number of suppliers and vendors that manufacture the components and provide the services used to manufacture our products, it may be difficult to quickly identify alternate suppliers or vendors or to qualify alternative components or services on commercially reasonable terms, and our ability to satisfy customer demand may be adversely affected, which could result a substantial loss of revenue.

***Disruption of critical information systems or material breaches in the security of our systems could harm our business customer relations and financial condition.***

Information technology helps us operate efficiently, interface with customers, maintain financial accuracy and efficiency and accurately produce our financial statements. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology infrastructure we could be subject to transaction errors, processing inefficiencies, the loss of customers, business disruptions or the loss of or damage to intellectual property through security breach. If our data management systems do not effectively collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies or human error, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Any such impairment could materially and adversely affect our financial condition, results of operations, cash flows and the timeliness with which we report our internal and external operating results.

Our business requires us to use and store personally identifiable information (“PII”) of our customers, employees and business partners. This may include names, addresses, phone numbers, email addresses, contact preferences, tax identification numbers and payment account information. We require user names and passwords in order to access our information technology systems. We also use encryption and authentication technologies to secure the transmission and storage of data. These security measures may be compromised as a result of third-party security breaches, employee error, malfeasance, faulty password management or other irregularity, and result in persons obtaining unauthorized access to our data or accounts. Third parties may attempt to fraudulently induce employees or customers into disclosing user names, passwords or other sensitive information, which may in turn be used to access our information technology systems.

We devote significant resources to network security, data encryption and other security measures to protect our systems and data, but these security measures cannot provide absolute security. We may experience a breach of our systems and may be unable to protect sensitive data. The costs to us to eliminate or alleviate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and our efforts to address these problems may not be successful and could result in unexpected interruptions, delays, cessation of service and may harm our business operations. Moreover, if a computer security breach affects our systems or results in the unauthorized release of PII, our reputation and brand could be materially damaged and use of our products and services could decrease.

***Failure to manage growth effectively could prevent us from achieving our goals.***

Our growth strategy may impose a significant burden on our administrative and operational resources. Our ability to effectively manage growth depends on our ability to substantially expand the capabilities of our administrative and operational resources and to attract, train, manage and retain qualified management and other personnel. Our failure to successfully manage growth could result in our sales not increasing commensurately with capital investments. Our inability to successfully manage growth could materially adversely affect our business.

***Any failure to adequately expand our direct sales force will impede our growth. If we are unable to attract, hire and retain qualified sales and management personnel, the commercial opportunity for our products may be diminished.***

We expect to be substantially dependent on a direct sales force to attract new business and to manage customer relationships. We plan to expand our direct sales force and believe that there is significant competition for qualified, productive direct sales personnel with advanced sales skills and technical knowledge of our industry. Our ability to achieve significant growth in revenue in the future will depend, in large part, on our success in recruiting, training and retaining sufficient direct sales personnel. Recent hires and planned hires may not become as productive as expected and we may be unable to hire sufficient numbers of qualified individuals in the future in the markets where we do business. If we are unable to hire and develop sufficient numbers of productive sales personnel, our business prospects could suffer.

As of December 31, 2015, our sales force consisted of 8 and 9 regional sales managers and clinical account managers, respectively. We may not be able to attract, hire, train and retain qualified sales and sales management personnel. If we are not successful in our efforts to maintain and grow a qualified sales force, our ability to independently market and promote our products may be impaired. Even if we are able to effectively maintain a qualified sales force, our sales force may not be successful in commercializing our products.

*To successfully market and sell our CorPath System internationally, we must address many issues with which we have little or no experience.*

To date, we have primarily marketed our CorPath system domestically in the United States. Over the long term, we intend to grow our business internationally, and to do so we will need to attract distributors or expand our sales operations to effectively sell our CorPath System internationally. Distributors may not commit the necessary resources to market and sell our CorPath System in accordance with our expectations. If future distributors do not perform adequately, or we are unable to locate distributors for particular geographic areas, we may not realize expected long term international revenue growth. International sales are subject to a number of risks, including:

- varying coverage and reimbursement processes and procedures;
- difficulties in staffing and managing foreign operations;
- reduced protection for intellectual property rights in some countries;
- export restrictions, trade regulations and foreign tax laws;
- fluctuating foreign currency exchange rates;
- foreign certification and regulatory requirements;
- lengthy payment cycles and difficulty in collecting accounts receivable;
- customs clearance and shipping delays;
- political and economic instability; and
- preference for locally produced products.

If one or more of these risks is realized, it could require us to dedicate significant resources to remedy the situation, our plan to expand internationally may fail and our financial performance may suffer as a result.

*If we fail to attract and retain key personnel, or to retain our executive management team, we may be unable to successfully develop or commercialize our products.*

Our success depends in part on our continued ability to attract, retain and motivate highly qualified managerial personnel. We are highly dependent upon our executive management team. The loss of the services of any one or more of the members of our executive management team could delay or prevent the successful completion of some of our development and commercialization objectives.

Recruiting and retaining qualified sales and marketing personnel is critical to our success. We may not be able to attract and retain these personnel on acceptable terms. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may also be employed by other companies and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

## **Risks Related to Intellectual Property**

*If we are unable to obtain and maintain protection for intellectual property relating to our technology and products, the value of our technology and products will be adversely affected.*

Our success will depend in part on our ability to obtain and maintain protection for the intellectual property covering or incorporated into our technology and products. The patent situation in the field of medical devices involves complex legal and scientific questions. We rely upon patents, trade secret laws and confidentiality agreements to protect our technology and products. We may not be able to obtain patent rights relating to our technology or products and pending patent applications to which we have rights may not issue as patents or if issued, may not issue in a form that will be advantageous to us. Even if issued, any patents issued to us may be challenged, narrowed, invalidated, held to be unenforceable or circumvented. Changes in either patent laws or in interpretations of patent laws in the United States may diminish the value of our intellectual property or narrow the scope of our patent protection.

*Trademark protection of our products may not provide us with a meaningful competitive advantage.*

We use trademarks on our products and believe that having distinctive marks is an important factor in marketing them. Distinctive marks may also be important for any additional products that we successfully develop and commercially market. If we initiate legal proceedings to seek to protect our trademarks, the costs of these proceedings could be substantial and it is possible that our efforts could be unsuccessful.

*We may in the future be a party to patent litigation and administrative proceedings that could be costly and could interfere with our ability to sell our CorPath System.*

Litigation related to infringement and other intellectual property claims, with or without merit, is unpredictable, can be expensive and time consuming and can divert management's attention from our core business. If we lose this kind of litigation, a court could require us to pay substantial damages, and prohibit us from using technologies essential to our CoPath System, any of which would have a material adverse effect on our business, results of operations and financial condition. If relevant patents are upheld as valid and enforceable and we are found to infringe, we could be prevented from selling our CorPath System unless we can obtain a license to use technology or ideas covered by such patents or are able to redesign our CorPath System to avoid infringement. We do not know whether any necessary licenses would be available to us on satisfactory terms, if at all, or whether we could redesign our CorPath System or processes to avoid infringement.

Competing products may also appear in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, we could be prevented from marketing our CorPath System in one or more foreign countries.

## **Risks Related to Regulatory Matters**

*Recently enacted healthcare legislation reforming the U.S. healthcare system, as well as future reforms, may have a material adverse effect on our financial condition and results of operations.*

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, "the PPACA"), was signed into law which makes changes that are expected to significantly impact healthcare providers, insurers, pharmaceutical and medical device manufacturers. One of the principal aims of the PPACA as currently enacted is to expand health insurance coverage to approximately 32,000,000 uninsured Americans. The consequences of these significant coverage expansions on the sales of our products are unknown and speculative at this point.

The PPACA contains a number of provisions designed to generate the revenues necessary to fund the coverage expansions, among other things. This includes new fees or taxes on certain health-related industries, including medical device manufacturers, regardless of whether the companies are profitable. Beginning in 2013, medical device manufacturers were required to pay an excise tax (or sales tax) of 2.3% of certain U.S. medical device revenues. Under this provision, we have paid an excise tax of approximately \$0.1 million through December 31, 2015, which tax is reflected in our operating expenses. Though there are some exceptions to the excise tax, this excise tax applies to all or most of our products sold within the U.S. At the present time the excise tax is suspended due to the operation of a provision in the Consolidated Appropriations Act of 2016, signed into law on December 18, 2015 but that two-year suspension period ends on December 31, 2017. However, there is no guarantee that the excise tax will continue to be suspended by congressional action after this two-year moratorium ends, so we would expect to become subject to the 2.3% medical device tax again beginning on January 1, 2018. The PPACA also establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians, and other providers to improve the coordination, quality, and efficiency of certain healthcare services through bundled payment models; and creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

The PPACA provisions on comparative clinical effectiveness research also extend the initiatives of the American Recovery and Reinvestment Act of 2009, known as the stimulus package, which included \$1.1 billion in funding to study the comparative effectiveness of health care treatments and strategies. This stimulus funding was designated for, among other things, conducting, supporting or reviewing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA appropriates additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of health care, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies. The taxes imposed by the PPACA and the expansion in the government's role in the U.S. healthcare industry may result in decreased profits to us, lower reimbursement by payors using our products, and/or reduced medical procedure volumes, all of which may adversely affect our business, financial condition and results of operations.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect that additional state and federal healthcare reform measures may be adopted in the future, any of which could have a material adverse effect on our industry generally and our ability to successfully commercialize our products or could limit or eliminate our spending on certain development projects.

The U. S. government has in the past considered, is currently considering and may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect both private and public reimbursement for healthcare services. State and local governments, as well as a number of foreign governments, are also considering or have adopted similar types of policies. Future significant changes in the healthcare systems in the United States or elsewhere, and current uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products. We are unable to predict whether other healthcare policies, including policies stemming from legislation or regulations affecting our business, may be proposed or enacted in the future; what effect such policies would have on our business; or the effect ongoing uncertainty about these matters will have on the purchasing decisions of our customers.

*We are subject to federal and state laws governing our business practices which, if violated, could result in substantial penalties. Additionally, challenges to or investigations of our practices could cause adverse publicity and be costly to respond to and could otherwise harm our business.*

The Medicare and Medicaid anti-kickback laws, and several similar state laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, prohibit payments or other remuneration that could be considered to induce hospitals, physicians or other potential purchasers of our products either to refer patients or to purchase, lease or order, or arrange for or recommend the purchase, lease or order of healthcare products or services for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. Further, the recently enacted PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal health care fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government or a whistleblower may assert that a claim (including items or services resulting from a violation of the federal anti-kickback statute) constitutes a false or fraudulent claim for purposes of the false claims statutes. These laws may affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians or other potential purchasers of our products. They particularly impact how we structure our sales offerings, including discount practices, customer support, education and training programs, physician consulting and other service arrangements. These laws are broadly written, and it is often difficult to determine precisely how these laws will be applied to specific circumstances. Violating anti-kickback laws can result in civil and criminal penalties, which can be substantial and include exclusion from government healthcare programs for noncompliance. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to defend, and thus could harm our business and results of operations.

The PPACA also imposes new reporting and disclosure requirements on device manufacturers for any “transfer of value” made or distributed to physicians and other healthcare providers. Such information must be made publicly available in a searchable format. In addition, device manufacturers will also be required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an aggregate of approximately \$0.2 million per year (and up to an aggregate of \$1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Device manufacturers were required to begin collecting data on August 1, 2013 and were required to submit reports to the Centers for Medicare & Medicaid Services (“CMS”) by March 31, 2014 and the 90th day of each subsequent calendar year. We submitted our report due March 31, 2014 in a timely manner and believe that we are in compliance with this reporting requirement.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians, including the tracking and reporting of gifts, compensation and other remuneration to physicians. Certain states mandate implementation of commercial compliance programs to ensure compliance with these laws, impose restrictions on device manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment, and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements, increases the possibility that a healthcare company may be found out of compliance of one or more of the requirements, subjecting us to significant civil monetary penalties.

Compliance with complex foreign and U.S. laws and regulations that apply to our potential international operations increases our cost of doing business in international jurisdictions and could expose us or our employees to fines and penalties in the U.S. and/or abroad. These numerous and sometimes conflicting laws and regulations include U.S. laws such as the Foreign Corrupt Practices Act, and similar laws in foreign countries, such as the U.K. Bribery Act of 2010. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business and damage to our reputation. Although we intend to implement policies and procedures designed to ensure compliance with these laws, there can be no assurance that our employees, contractors or agents will not violate our policies.

The Dodd-Frank Wall Street Reform and Consumer Protection Act requires us to track and disclose the source of certain metals used in manufacturing which may stem from minerals (so-called “conflict minerals”) which originate in the Democratic Republic of the Congo or adjoining regions. These metals include tantalum, tin, gold and tungsten. In most cases no acceptable alternative material exists which has the necessary properties. It is not possible to determine the source of the metals by analysis but instead a good faith description of the source of the intermediate components and raw materials must be obtained. The components which incorporate those metals may originate from many sources and we may purchase fabricated products from manufacturers who may have a long and difficult-to-trace supply chain. As the spot price of these materials varies, producers of the metal intermediates can be expected to change the mix of sources used, and components and assemblies which we buy may have a mix of sources as their origin. We do not believe these materials are present in the component parts that we use in our CorPath System, but there can be no assurance that these metals will not be included in our components and assemblies from time to time.

*Our products are subject to a lengthy and uncertain domestic regulatory review process. If we do not obtain and maintain the necessary domestic regulatory authorizations, we will not be able to provide our products in the U.S.*

Our products and operations are subject to extensive regulation in the U.S. by the FDA. The FDA regulates the development, bench and clinical testing, manufacturing, labeling, storage, record-keeping, promotion, marketing, sales, distribution and post-market support and reporting of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In order for us to market our Class II products for use in the U.S., we must first obtain clearance from the FDA pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Clearance under Section 510(k) requires demonstration that a new device is substantially equivalent to another device with 510(k) clearance or grandfathered ("pre-amendment") status or to a device that was reclassified from Class III to Class II or Class I (those are referred to as predicate devices). If we significantly modify our products after they receive FDA clearance, or seek to market them for additional indications for use, the FDA may require us to submit a separate 510(k) or premarket approval application ("PMA") for the modified product before we are permitted to market the products in the U.S. In addition, if we develop products in the future that are not considered to be substantially equivalent to a predicate device, we will be required to obtain FDA approval by submitting a PMA. The FDA may not act favorably or quickly in its review of our 510(k) or PMA submissions or we may encounter significant difficulties and costs in our efforts to obtain FDA clearance or approval, any of which could delay or preclude our sale of new products in the U.S. Furthermore, the FDA may request additional data or require us to conduct further testing, or compile more data, including clinical data and clinical studies, in support of a 510(k) submission.

Regulatory policy affecting our products can change at any time. The changes and their impact on our business cannot be accurately predicted. For example, in 2011, the FDA announced a Plan of Action to modernize and improve the FDA's premarket review of medical devices, and has implemented, and continues to implement, reforms intended to streamline the premarket review process. In addition, as part of the Food and Drug Administration Safety and Innovation Act of 2012, Congress enacted several reforms through the Medical Device Regulatory Improvements and additional miscellaneous provisions which will further affect both pre- and post-approval medical device regulation. Most recently, FDA has been focusing on the cybersecurity risks associated with certain medical devices and encouraging device manufacturers to take a more proactive approach to assessing the cybersecurity risks of their devices both during development and on a periodic basis after the devices are in commercial distribution. These regulatory efforts could lead to new FDA requirements in the future or additional product liability or other litigation risks if one of our products is considered to be susceptible to third-party tampering. Changes in the FDA 510(k) process could make clearance more difficult to obtain, increase delay, add uncertainty and have other significant adverse effects on our ability to obtain and maintain clearance for our products. The FDA may also, instead of accepting a 510(k) submission, require us to submit a PMA, which is typically a much more complex, lengthy and burdensome application than a 510(k) submission. To support a PMA, the FDA would likely require that we conduct one or more clinical studies to demonstrate that the device is safe and effective. In some cases such studies may be requested for a 510(k) as well. We may not be able to meet the requirements to obtain 510(k) clearance or PMA approval, in which case the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended uses of our products as a condition to a 510(k) clearance or PMA approval. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approval of new products we develop, any limitations imposed by the FDA on new product use or the costs of obtaining FDA clearance or approvals could have a material adverse effect on our business, financial condition and results of operations.

In order to conduct a clinical investigation involving human subjects for the purpose of demonstrating the safety and effectiveness of a medical device, a company must, among other things, apply for and obtain Institutional Review Board ("IRB") approval of the proposed investigation. In addition, if the clinical study involves a "significant risk" (as defined by the FDA) to human health, the sponsor of the investigation must also submit and obtain FDA approval of an Investigational Device Exemption ("IDE") application. Our system product is considered a significant risk device requiring IDE approval prior to investigational use. We may not be able to obtain FDA and/or IRB approval to undertake clinical trials in the U.S. for any new devices we intend to market in the U.S. in the future. If we do obtain such approvals, we may not be able to conduct studies which comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations. Certainty that clinical trials will meet desired endpoints, produce meaningful or useful data and be free of unexpected adverse effects, or that the FDA will accept the validity of foreign clinical study data cannot be assured, and such uncertainty could preclude or delay market clearance or authorizations resulting in significant financial costs and reduced revenue.



**If we fail to obtain regulatory clearances in other countries for existing products or products under development, we will not be able to commercialize these products in those countries.**

In order for us to market our products in other countries, we must comply with extensive safety and quality regulations in other countries regarding the quality, safety and efficacy of our products. These regulations, including the requirements for approvals, clearance or grant of Conformité Européenne (“CE”) Certificates of Conformity and the time required for regulatory review, vary from country to country. Failure to obtain regulatory approval, clearance or CE Certificates of Conformity (or equivalent) in any foreign country in which we plan to market our products may harm our ability to generate revenue and harm our business. Approval and CE marking procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval or CE Certificate of Conformity in other countries might differ from that required to obtain FDA clearance. The regulatory approval or CE marking process in other countries may include all of the risks detailed above regarding FDA clearance in the United States. Regulatory approval or the CE marking of a product in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval or a CE Certificate of Conformity in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval or a CE Certificate of Conformity in other countries or any delay or setback in obtaining such approval could have the same adverse effects described above regarding FDA clearance in the United States.

The primary regulatory environment in Europe is that of the European Economic Area (the “EEA”), which is comprised of the 28 Member States of the European Union (“EU”), Iceland, Liechtenstein and Norway. In the European Economic Area (EEA), our devices are required to comply with the Essential Requirements laid down in Annex I to the Medical Devices Directive (applicable in the non-EU EEA Member States via the Agreement on the EEA). We are also required to ensure compliance with the relevant quality system requirements laid down in the Annexes to the Medical Devices Directive. Companies compliant with ISO requirements such as “EN ISO 13485: 2003 Medical devices—Quality management systems—Requirements for regulatory purposes” benefit from a presumption of conformity with the relevant Essential Requirements or the quality system requirements laid down in the Annexes to the Medical Devices Directive. Following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the Essential Requirements and quality system requirements, the Notified Body issues a CE Certificate of Conformity. This Certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related CE Declaration of Conformity. We received a CE Certificate of Conformity for our CorPath System in 2011. We cannot be certain that we will be successful in meeting and continuing to meet the requirements of the Medical Devices Directive in the EEA.

***We may incur liability related to the off-label use or misleading advertising of our products.***

The FDA regulates the promotional labeling for and the Federal Trade Commission (“FTC”) regulates the advertising of our products to ensure that the claims we make are consistent with our regulatory clearances, that there is scientific data to substantiate the claims and that our promotion and advertising is neither false nor misleading. The off-label marketing or false advertising of our products may harm our image in the marketplace, result in injuries that lead to product liability suits, which could be costly to our business, or result in costly investigations and sanctions from the FDA and other regulatory bodies if we are deemed to have engaged in off-label promotion or false advertising.

***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 United States 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 (“HIPAA”) and the HITECH Act of 2009, which expanded the application of those rules. 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 of the use or disclosure. If we are found to be in violation of the privacy rules under HIPAA/HITECH (or other applicable federal or state laws), 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.

***Complying with FDA regulations is a complex process, and our failure to comply fully could subject us to significant enforcement actions.***

Because our products are commercially distributed, numerous quality and post-market regulatory requirements apply, including the following:

- continued compliance to the FDA Quality System Regulations (“QSR”), which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the development and manufacturing process, as well as to take into account newly emerging risks associated with a medical device such as cybersecurity vulnerabilities;

- labeling regulations;
- the FDA’s general prohibition against false or misleading statements in the labeling or promotion of products for unapproved uses;
- stringent complaint reporting and Medical Device Reporting regulations, which requires that manufacturers keep detailed records of investigations or complaints against their devices and to report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- adequate use of the Corrective and Preventive Actions process to identify and correct or prevent significant systemic failures of products or processes or in trends which suggest same; and
- the reporting of Corrections and Removals, which requires that manufacturers report to the FDA recalls and field corrective actions taken to reduce a risk to health or to remedy a violation of the FDCA that may pose a risk to health.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with regulatory requirements. If the FDA finds that we have failed to comply, it can institute a wide variety of regulatory or enforcement actions, ranging from inspectional observations (Form FDA 483) to a public Warning Letter to more severe civil and criminal sanctions including the seizure of our products and equipment or a ban on the import or export of our products. Our failure to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our financial condition and results of operations.

Any modification or change of medical devices cleared for market requires the manufacturer to make a determination whether the change is significant enough to require new 510(k) clearance. We have created labeling, advertising and user training for our CorPath System to describe specific procedures that we believe are fully within the scope of our existing 510(k) indications for use stated in our 510(k) clearances. We cannot assure that the FDA would agree that all such specific procedures are within the scope of the existing general clearance or that we have compiled adequate information to support the safety and efficacy of using the CorPath System for all such specific procedures.

***If our manufacturing facilities do not continue to meet federal, state or other manufacturing standards, we may be required to temporarily cease all or part of our manufacturing operations, distribution of our products and/or recall our products which would result in significant product delivery delays and lost revenue.***

Our manufacturing facilities are subject to periodic inspection by regulatory authorities and our operations will continue to be regulated and inspected by the FDA and other regulatory agencies for compliance with Current Good Manufacturing Practices (“CGMP”) requirements contained in the QSR and other regulatory requirements. For any CorPath Systems shipped internationally, we are also required to comply with the International Organization for Standardization (“ISO”) quality system standards as well as European Directives and norms in order to produce products for sale in the EU. In addition, many countries such as Canada and Japan have very specific additional regulatory requirements for quality assurance and manufacturing. If we fail to continue to comply with CGMP requirements, as well as ISO or other regulatory standards, we may be required to cease all or part of our operations until we comply with these regulations.

#### **Risks Related to our Common Stock**

***If our stock price declines, our common stock may be subject to delisting from the NYSE MKT.***

Our common stock was approved for listing on the NYSE MKT and commenced trading on May 29, 2015 under the symbol “CVRS”. Our common stock is currently trading at a price of less than \$2.00 per share. We currently meet the continued listing standards of NYSE MKT. However, we cannot assure you that we will be able to continue to comply with the minimum bid price and the other standards that we are required to meet in order to maintain a listing of our common stock on the NYSE MKT. Our failure to continue to meet these requirements may result in our common stock being delisted from the NYSE MKT. If our common stock is delisted, this would, among other things, substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

*The price of our common stock could be highly volatile due to a number of factors, which could lead to losses by investors and costly securities litigation.*

We cannot predict the extent to which investor interest in our Company will lead to the development of an active trading market on the NYSE MKT or any other exchange that we may trade on in the future. Prior to listing on the NYSE MKT, our common stock traded on the OTCQB in limited volumes. The trading price of our common stock on the OTCQB and the NYSE MKT has been highly volatile and is likely to continue to be highly volatile in response to a number of factors including, without limitation, the following:

- fluctuations in price and volume due to investor speculation and other factors that may not be tied to our financial performance;
- performance by us in the execution of our business plan;
- financial viability;
- actual or anticipated variations in our operating results;
- announcements of developments by us or our competitors;
- market conditions in our industry;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- adoption of new accounting standards affecting our industry;
- additions or departures of key personnel;
- introduction of new products by us or our competitors;
- sales of our common stock or other securities in the open market;
- regulatory developments in both the United States and foreign countries;
- performance of products sold and advertised by licensees in the marketplace;
- economic and other external factors;
- period-to-period fluctuations in financial results; and
- other events or factors, many of which are beyond our control.

The stock market is subject to significant price and volume fluctuations. In the past, and several recent situations, following periods of volatility in the market price of a company's securities, securities class action litigation has been initiated against such company. Litigation initiated against us, whether or not successful, could result in substantial costs and diversion of our management's attention and resources, which could harm our business and financial condition.

*If we are unable to successfully maintain our internal controls over financial reporting or if additional material weaknesses are discovered in our internal accounting procedures, the accuracy and timing of our financial reporting may be adversely affected, which may adversely affect investor confidence in us and, as a result, the value of our common stock.*

In connection with the audit of our 2014 consolidated financial statements, our senior management, including our Chief Executive Officer and Chief Financial Officer, noted a material weakness in our controls relating to our accounting for overhead costs which affected inventories and property and equipment. Specifically, our cost accounting and reserve estimate processes lacked adequate levels of monitoring and review controls to identify and correct inventory valuation errors in a timely manner, which was primarily the result of an insufficient number of qualified accounting resources to ensure adequate technical review of inventory accounting issues during the financial statement close process. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Any failure to develop or maintain effective internal controls over financial reporting or difficulties encountered in maintaining or improving our internal controls over financial reporting could harm our operating results and prevent us from meeting our reporting obligations. Moreover, effective internal controls, particularly those related to revenue recognition, are necessary for us to produce reliable financial reports and are important to helping prevent financial fraud. If we cannot provide reliable financial reports or prevent fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information, and the trading price of our common stock could drop significantly. In addition, investors relying upon this misinformation could make an uninformed investment decision, and we could be subject to sanctions or investigations by the Commission or other regulatory authorities or to stockholder class action securities litigation.

We cannot assure you that measures taken this past year to remediate the material weakness described above will prevent future material weaknesses in this area. We also cannot assure you that we have identified all of our existing control deficiencies or that we will not in the future have additional material weaknesses.

*We are an “emerging growth company” as defined in the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.*

For so long as we remain an “emerging growth company” as defined in the JOBS Act, we may take advantage of certain exemptions from various requirements applicable to public companies that are not “emerging growth companies” including:

- the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;
- the “say on pay” provisions (requiring a non-binding shareholder vote to approve compensation of certain executive officers) and the “say on golden parachute” provisions (requiring a non-binding shareholder vote to approve golden parachute arrangements for certain executive officers in connection with mergers and certain other business combinations) of the Dodd-Frank Wall Street Reform and Protection Act, or Dodd-Frank Act, and some of the disclosure requirements of the Dodd-Frank Act relating to compensation of our chief executive officer;
- the requirement to provide detailed compensation discussion and analysis in proxy statements and reports filed under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and instead provide a reduced level of disclosure concerning executive compensation; and
- any rules that the Public Company Accounting Oversight Board may adopt requiring mandatory audit firm rotation or a supplement to the auditor’s report on the financial statements.

We may take advantage of these exemptions until we are no longer an “emerging growth company.” We would cease to be an “emerging growth company” upon the earliest of: (i) the fifth year after the first sale of our securities as a public reporting company on January 18, 2012; (ii) the first fiscal year after our annual gross revenues are \$1.0 billion or more; (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the end of the second quarter of that fiscal year.

We currently take advantage of some, but not all, of the reduced regulatory and reporting requirements that will be available to us so long as we qualify as an “emerging growth company.” For example, we have irrevocably elected not to take advantage of the extension of time to comply with new or revised financial accounting standards available under Section 102(b) of the JOBS Act. Our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an “emerging growth company,” which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. Likewise, so long as we qualify as an “emerging growth company,” we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and may decline.

***Our Board of Directors may issue and fix the terms of shares of our preferred stock without stockholder approval and we are subject to Nevada law, each of which may delay or prevent a change in control of our Company.***

Our Articles of Incorporation, as amended, authorize the issuance of up to 10,000,000 shares of Preferred Stock, \$0.0001 par value per share, with such designation rights and preferences as may be determined from time to time by the Board of Directors. Our Board of Directors is empowered, without stockholder approval, to issue shares of Preferred Stock with dividend, liquidation, conversion, voting or other rights which could adversely affect the voting power or other rights of the holders of our common stock. In the event of such issuances, the Preferred Stock could be used, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of our Company.

The “business combination” provisions of Sections 78.411 to 78.444, inclusive, of the Nevada Revised Statutes (the “NRS”), generally prohibit a Nevada corporation with at least 200 stockholders of record from engaging in various “combination” transactions with any interested stockholder for a period of two years after the date of the transaction in which the person became an interested stockholder, unless the transaction is approved by the board of directors prior to the date the interested stockholder obtained such status or the combination is approved by the board of directors and thereafter is approved at a meeting of the stockholders by the affirmative vote of stockholders representing at least 60% of the outstanding voting power held by disinterested stockholders, unless (a) the combination was approved by the board of directors prior to the person becoming an interested stockholder or (b) the transaction by which the person first became an interested stockholder was approved by the board of directors before the person became an interested stockholder. After the expiration of two years after the person becomes an interested stockholder, a Nevada corporation subject to the statute may not engage in a combination with an interested stockholder unless either (a) or (b) above are satisfied or the combination is approved after expiration of such two year period by a majority of the voting power held by disinterested stockholder; or the consideration to be paid in the combination is at least equal to the highest of: (i) the highest price per share paid by the interested stockholder within the two years immediately preceding the date of the announcement of the combination or in the transaction in which it became an interested stockholder, whichever is higher, (ii) the market value per share of common stock on the date of announcement of the combination and the date the interested stockholder acquired the shares, whichever is higher or (iii) for holders of preferred stock, the highest liquidation value of the preferred stock, if it is higher. The NRS business combination provisions may have the effect of discouraging, delaying or preventing a change in control of our Company.

***Future sales by our stockholders may negatively affect our stock price and our ability to raise funds in new stock offerings.***

Sales of our common stock in the public market could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable or at all. Of the 118,832,441 shares of common stock issued and outstanding as of December 31, 2015, approximately 38,150,684 shares are freely tradable without restriction by stockholders who are not our affiliates. We issued an aggregate of 73,360,287 shares of common stock to the former shareholders of Corindus, Inc. pursuant to an exemption from the registration requirements of the Securities Act of 1933, and such shares are “restricted securities” as defined in Rule 144. In addition to being subject to restrictions on transfer imposed under federal securities laws, each holder of the newly issued shares entered into a lock-up agreement, which among other things, restricts the sale or transfer of these shares for specified periods. Under the lock-up agreement, each holder was prohibited from selling or disposing of securities of our Company held thereby until August 12, 2015 (the one year anniversary of the closing of the Acquisition) and after the completion of this 12-month lock-up period, such holders are prohibited from selling or disposing of more than 5.0% of securities of our Company held thereby per each rolling 90-day period (beginning with the holder’s first sale of securities following the initial 12-month lock-up period) over the following 12-month period. Our affiliates hold 63,452,513 shares, all of which shares may be resold in the public market only when released from the provisions of a lock-up agreement, when and if registered pursuant to an exemption from registration, or pursuant to the applicable requirements of Rule 144 of the Securities Act of 1933. Although we have no current plans to do so, we may waive the restrictions on transfer under these lock-up agreements in the future. When the shares covered under the lock-up agreements become available for resale, sales of a substantial number of shares of our common stock in the public market, or the perception that these sales could occur, could materially adversely affect the market price of our common stock.

***Insiders have substantial control over the outstanding shares of the Company’s common stock and could delay or prevent a change in corporate control, including a transaction in which the Company’s stockholders could sell or exchange their shares for a premium.***

As of the filing of this Annual Report, our directors and executive officers beneficially own an aggregate of approximately 39% of our outstanding shares of common stock. As a result, our directors and executive officers, if acting together, may have the ability to affect the outcome of matters submitted to stockholders for approval, including the election and removal of directors, and any merger, consolidation or sale of all or substantially all of our assets. In addition, these persons acting together may have the ability to control our management and business affairs. Accordingly, this concentration of ownership may harm the value of our common stock by:

- delaying, deferring or preventing a change in control;
- impeding a merger, consolidation, takeover or other business combination; or
- discouraging a potential acquirer from making an acquisition proposal or otherwise attempting to obtain control.

*We do not expect to pay dividends and investors should not buy our common stock expecting to receive dividends.*

We have never declared or paid any dividends and we do not anticipate that we will declare or pay any dividends in the foreseeable future. Consequently, you will only realize an economic gain on your investment in our common stock if the price appreciates. You should not purchase our common stock expecting to receive cash dividends. Since we do not pay dividends, and if we are not successful in establishing an orderly trading market for our shares, then you may not have any manner to liquidate or receive any payment on your investment. Therefore our failure to pay dividends may cause you to not see any return on your investment even if we are successful in our business operations. In addition, because we do not pay dividends we may have trouble raising additional funds which could affect our ability to expand our business operations.

*Securities analysts may not cover our common stock and this may have a negative impact on our common stock's market price.*

The future trading market for our common stock may depend on the research and reports that securities analysts publish about us or our business. We do not have any control over these analysts. We may face additional risks since we became a public company through an acquisition which, for accounting purposes, was treated as a reverse merger. There is no guarantee that securities analysts will cover our common stock and there may be little incentive to brokerage firms to recommend the purchase of our common stock. If securities analysts do not cover our common stock, the lack of research coverage may adversely affect our common stock's market price, if any. If we are covered by securities analysts who downgrade our stock, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to publish regular reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

*We are likely to raise additional funds, finance acquisitions or develop strategic relationships by issuing capital stock.*

We have financed our operations, and we expect to continue to finance our operations, make acquisitions and develop strategic relationships by issuing equity or convertible debt securities which could significantly reduce the percentage ownership of our existing stockholders. Furthermore, any newly issued securities could have rights, preferences and privileges senior to those of our existing common stock. Moreover, any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. We may also raise additional funds through the incurrence of debt, and the holders of any debt we may issue would have rights superior to your rights in the event we are not successful and are forced to seek the protection of the bankruptcy laws.

*The lack of substantial public company experience of our management team could adversely impact our ability to comply with the reporting requirements of U.S. securities laws.*

Our management team has limited experience in working with public companies which could impair our ability to comply with legal and regulatory requirements such as those imposed by Sarbanes-Oxley Act of 2002. Such responsibilities include complying with federal securities laws and making required disclosures on a timely basis. Our senior management may not be able to implement programs and policies in an effective and timely manner that adequately respond to such increased legal, regulatory compliance and reporting requirements, including the establishing and maintaining internal controls over financial reporting. Any such deficiencies, weaknesses or lack of compliance could have a materially adverse effect on our ability to comply with the reporting requirements of the Securities Exchange Act of 1934 which is necessary to maintain our public company status. If we were to fail to fulfill those obligations, our ability to continue as a public company would be in jeopardy in which event you could lose your entire investment in our Company.

*Our management will be devoting substantial time to comply with regulations and we will incur significant costs as a public company.*

As a public company, we will be subject to certain rules and regulations. In particular, the Sarbanes-Oxley Act and rules subsequently implemented by the Commission impose various requirements on public companies with respect to corporate governance practices. The Sarbanes-Oxley Act requires, among other things, that our management maintain adequate disclosure controls and procedures and internal control over financial reporting. In particular, we must perform system and process evaluation and testing of our internal control over financial reporting to allow management and, as applicable, our independent registered public accounting firm, to report on the effectiveness of our internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our compliance with the foregoing will require us to expend significant management efforts.

Additionally, we will incur significant legal and financial compliance costs associated with our public company reporting requirements, costs associated with applicable corporate governance and accounting requirements. We also expect that these applicable rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

*We may become involved in securities class action litigation that could divert management's attention and harm our business.*

The stock market in general, and the market for medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. These broad market and industry factors may materially harm the market price of our common stock, regardless of our operating performance. In the past, following periods of volatility in the market price of a particular company's securities, securities class action litigation has often been brought against that company. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could materially harm our financial condition and results of operations.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

Our principal offices and manufacturing facilities are located at 309 Waverley Oaks Road, Suite 105, Waltham, Massachusetts 02452. On October 24, 2012, Corindus, Inc. entered into a lease with Beaver Group, LLC for a term of approximately five years for 26,402 square feet of office and manufacturing space (the "Lease"). Over the term of the Lease, we pay an average monthly cost of \$46 thousand which includes base rent, common area fees, taxes and insurance. Terms of the Lease provide for an option to extend the Lease for an additional five-year period. Our management believes that the leased premises are suitable and adequate to meet current needs.

**ITEM 3. LEGAL PROCEEDINGS.**

From time to time, we may become involved in various lawsuits and legal proceedings that arise in the ordinary course of business. Litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that we believe will have a material adverse effect on our business, financial condition or operating results.

**ITEM 4. MINE SAFETY DISCLOSURE.**

Not applicable.

**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.**

**Market Information**

Since May 29, 2015, our common stock has been listed on the NYSE MKT under the symbol "CVRS." Prior to that time, our common stock was quoted on the OTCQB. During the period from December 31, 2012 to June 30, 2014, there were no trades recorded.

The following table sets forth the high and low daily sales prices and the high and low bid information of our common stock as reported by the NYSE MKT and the OTCBQ, as applicable, for each quarter in the fiscal years ended December 31, 2015 and 2014:

	<u>High</u>	<u>Low</u>
<b>2015</b>		
Fourth Quarter	\$ 3.50	\$ 2.50
Third Quarter	\$ 4.31	\$ 2.90
Second Quarter	\$ 4.58	\$ 3.36
First Quarter	\$ 4.25	\$ 4.00
<b>2014</b>		
Fourth Quarter	\$ 4.25	\$ 2.60
Third Quarter	\$ 3.70	\$ 2.60
Second Quarter	*	*
First Quarter	*	*

\*During the period from December 31, 2012 to June 30, 2014, there were no trades recorded.

The over-the-counter market quotations from July 1, 2014 to May 28, 2015 reflect inter-dealer prices, without retail mark-up, mark-down or commission. The high and low bid prices do not necessarily represent actual transactions.

On February 29, 2016, the closing price of a share of our common stock on NYSE MKT was \$1.35.

**Stockholders**

As of February 29, 2016, there were 118,934,152 shares of common stock outstanding, which were held by approximately 118 record holders.

**Dividends**

We have never declared or paid any cash dividend. We do not anticipate that we will declare or pay any dividends in the foreseeable future. Our current policy is to retain earnings, if any, to fund operations, and the development and growth of our business. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will be dependent upon our financial condition, operating results, capital requirements, applicable contractual restrictions, restrictions in our organizational documents, and any other factors that our Board of Directors deems relevant.

**Unregistered Sales of Securities**

Not Applicable.



**Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

During the fourth quarter of the year ended December 31, 2015, neither we nor any "affiliated purchaser," as that term is defined in Rule 10b-18(a)(3) under the Exchange Act, repurchased any of our registered equity securities.

**ITEM 6. SELECTED FINANCIAL DATA.**

The selected financial data set forth below for the years ended December 31, 2013, 2014 and 2015 and historical balance sheet data as of December 31, 2014 and 2015, have been derived from our consolidated financial statements, which can be found elsewhere in this Annual Report. The selected consolidated financial data included below should be read in conjunction with the consolidated financial statements (and notes thereon) and "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in Item 7. The historical balance sheet data as of December 31, 2013 has been derived from financial statements not included in this Annual Report on Form 10-K.

	<b>Fiscal Year Ended December 31,</b>		
	<b>2013</b>	<b>2014</b>	<b>2015</b>
	<b>(in thousands, except share and per share amounts)</b>		
<b>Consolidated Statements of Operations Data:</b>			
Revenue	\$ 896	\$ 2,983	\$ 2,729
Cost of revenue	2,430	4,904	3,724
Gross loss	(1,534)	(1,921)	(995)
Operating expenses:			
Research and development	4,793	6,607	10,033
Selling, general and administrative	8,221	13,002	16,143
Restructuring charges	—	175	—
Total operating expenses	13,014	19,784	26,176
Operating loss	(14,548)	(21,705)	(27,171)
Other income (expense):			
Warrant revaluation	(171)	(2,421)	—
Interest and other income (expense)	28	(415)	(1,592)
Total other expense, net	(143)	(2,836)	(1,592)
Net loss	\$ (14,691)	\$ (24,541)	\$ (28,763)
Net loss per share - basic and diluted <sup>(1)</sup>	\$ (0.20)	\$ (0.29)	\$ (0.25)
Weighted average number of common shares outstanding	73,360,259	84,990,198	113,254,925

<sup>(1)</sup> Basic net loss per share is computed by dividing net loss by the weighted average shares of common stock outstanding for each period. Diluted net loss per share is the same as basic net loss per share since the Company has net losses for each period presented.

	<b>As of December 31,</b>		
	<b>2013</b>	<b>2014</b>	<b>2015</b>
	<b>(in thousands)</b>		
<b>Consolidated Balance Sheet Data:</b>			
Cash, cash equivalents and marketable securities	\$ 9,845	\$ 28,526	\$ 42,666
Total assets	\$ 14,768	\$ 32,836	\$ 47,148
Long-term debt, net of current portion	\$ —	\$ 7,594	\$ 3,677
Total liabilities	\$ 4,728	\$ 13,054	\$ 11,301
Working capital	\$ 11,387	\$ 26,231	\$ 37,988
Accumulated deficit	\$ (60,336)	\$ (84,877)	\$ (113,640)
Total stockholders' equity	\$ 10,040	\$ 19,782	\$ 35,847

## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

*The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results may differ materially from those discussed in the forward-looking statements. Factors that might cause future results to differ materially from those projected in the forward-looking statements include, but are not limited to, those discussed in "Risk Factors" and elsewhere in this Annual Report on Form 10-K. See also "Cautionary Note Regarding Forward-Looking Statements."*

### Overview

Since our inception on March 21, 2002, we have devoted our efforts principally to research and development, business development activities and raising capital. In July 2012, we received clearance from the FDA to market our CorPath System in the United States and shipped our first commercial product under this clearance in September 2012. In 2013, we moved into the growth stage, investing in sales and marketing in order to build the customer base. While we are initially cleared for and are targeting PCI procedures, we believe our technology platform has the capability to be developed in the future for other segments of the vascular market, including peripheral vascular, neurointerventional and other more complex cardiac interventions such as structural heart. As of December 31, 2015, we have installed 38 CorPath Systems, including two CorPath Systems in hospitals outside of the U.S.

In October 2015, we announced that the FDA had given 510(k) clearance for our robotic-assisted CorPath System to be used during percutaneous coronary interventions performed via radial access. The 510(k) clearance was based on results of a clinical trial conducted at Spectrum Health, Grand Rapids, Michigan, and St. Joseph's Hospital Health Center, Syracuse, New York.

Our future capital requirements will depend upon many factors, including progress with developing, manufacturing and marketing our technologies, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, our ability to establish collaborative arrangements, marketing activities and competing technological and market developments, including regulatory changes affecting medical procedure reimbursement, and overall economic conditions in our target markets.

### Public Offering in May 2015

On May 28, 2015, the Company completed a public offering by issuing 12,650,000 shares of its common stock at \$3.80 per share in exchange for proceeds of \$44.4 million, net of underwriting discounts, commissions and other offering costs. In connection with the public offering, the Company's common stock was approved for listing on the NYSE MKT, where it commenced trading on May 29, 2015 under the symbol "CVRS".

### Critical Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, inventory valuation, assumptions used in the valuation of stock-based awards, and valuation allowances against deferred income tax assets. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as "critical" because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate. We use the best information available to us to make our judgments and estimates; however, actual results may be different. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements. It is important that the discussion of our operating results that follows be read in conjunction with the critical accounting policies discussed below.

Additionally, Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. However, we irrevocably chose to “opt out” of such extended transition period and, as a result, we will comply with such new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Once this election is made, it is irrevocable.

#### *Revenue Recognition*

Revenue related to the sale of our products is recognized when persuasive evidence of an arrangement exists, the price to the buyer is fixed or determinable, collectability is reasonably assured, and risk of loss transfers, usually when products are shipped and/or installed and accepted. Our products are sold to customers with no right of return.

We had sold the CorPath System through our exclusive worldwide distributor, Philips Medical Systems Nederland B.V. (“Philips”) from the date we launched our system sales. In November 2013, we amended our distribution agreement with Philips to allow our sales force to sell directly to customers as well. On August 7, 2014, our distribution agreement with Philips expired.

We currently sell our CorPath Systems directly to customers primarily through our internal sales force and to a lesser extent through distributors where we seek opportunities. We will continue to sell CorPath Systems through Philips under a non-exclusive arrangement under mutually agreeable terms on a sale by sale basis until such time we either execute a new distribution arrangement with Philips or we no longer do business with Philips. There is no assurance that we will enter into a new distribution arrangement with Philips or on terms acceptable to us. We also sell through other distributors through purchase orders. We expect to enter into contracts with other distributors in the future.

We are responsible for installation and initial training. We consider all the elements of the sale of the system, including installation and initial training, to be a single unit of accounting in accordance with revenue recognition under U.S. GAAP. Revenue is recognized for the entire arrangement (system, installation and initial training) upon acceptance by the end-user customer.

We sell CorPath Cassettes and accessories to end users and distributors. The revenue from the sale of these products is generally recorded when the items are shipped.

We recognize revenue on multiple-element arrangements in accordance with Accounting Standards Update (“ASU”) 2009-13, Revenue Recognition (Topic 605): Multiple Deliverable Revenue Arrangements, based on the estimated selling price of each element. In accordance with ASU 2009-13, we use vendor-specific objective evidence (“VSOE”), if available, to determine the selling price of each element. If VSOE is not available, we use third-party evidence (“TPE”) to determine the selling price. If TPE is not available, we use our best estimate to develop the estimated selling price.

We provide a one-year warranty on our CorPath Systems for which the cost is accrued at the time of sale.

We sell basic and premium service plans to extend our initial warranty period and provide component upgrades in the event of technological or physical obsolescence. Revenue is allocated based on our best estimate of the selling price of each service. Extended warranty revenue is recognized on a straight-line basis over the life of the service contract and upgrade revenue is recognized with the delivery of the upgrade. Revenues from services administered by us that are not covered by a service contract are recognized as the services are provided. In certain instances, we may sell products together with service contracts.

#### *Income Taxes*

We account for income taxes using the liability method, whereby deferred tax asset and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. We have provided a valuation allowance to reduce deferred tax assets to amounts that are realizable based on uncertainty of future taxable income.

We account for uncertain tax positions using a “more-likely-than-not” threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. Corindus has not had an uncertain tax position to date.

### *Stock-Based Compensation*

We recognize compensation costs resulting from the issuance of stock-based awards to employees as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock award. Stock-based compensation is charged to the respective line items in our statements of operations to which the employee's services are classified. Compensation costs associated with stock-based awards to non-employees are measured at fair value on the date of grant and re-measured at the fair value on the date the awards vest and for those awards that have not vested at the end of each reporting period. We use the Black-Scholes-Merton option pricing model ("Black-Scholes Model") to determine the fair value of the awards. The key assumptions in the Black-Scholes Model include an estimate of the volatility of our stock, the risk-free interest rate, forfeiture rate, and the expected period the stock option will be exercised over.

Prior to the completion of the reverse acquisition in August 2014, the fair value of the Common Stock for purposes of equity incentive awards was determined by our Board of Directors after considering a broad range of factors, including the results obtained from an independent third-party valuation, the illiquid nature of an investment in our Common Stock, our historical financial performance and financial position, our future prospects and opportunity for liquidity events, and recent sale and offer prices of common and preferred stock in private transactions negotiated at arm's length. Subsequent to the reverse acquisition in August 2014, the fair value of our Common Stock is based on trading of our stock on the OTCQB and NYSE MKT.

### *Marketable securities*

We determine the appropriate classification of marketable securities at the time of purchase and reevaluate such designation at each balance sheet date. We have classified all of our marketable securities as "available-for-sale" pursuant to ASC 320, Investments – Debt and Equity Securities. We record available-for-sale securities at fair value, with the unrealized gains and losses included in accumulated other comprehensive income (loss) in stockholders' equity.

We adjust the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity, and include such amortization and accretion in interest and other income (expense). The cost of securities sold is based on the specific identification method. We include interest and dividends on securities classified as available-for-sale in interest and other income (expense).

We review marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations if we have experienced a credit loss, have the intent to sell the marketable security, or if it is more likely than not that we will be required to sell the marketable security before recovery of the amortized cost basis.

### *Inventories*

Inventories are valued at the lower of cost or market using the first-in, first-out (FIFO) method. We routinely monitor the recoverability of our inventories and record the lower of cost or market reserves, or reserves for excess and obsolete inventories, as required. We also monitor the utilization of our production facility and we record the costs of under-utilization of the production facility directly to cost of revenue.

### **Components of Results of Operations**

The following is a description of what comprises each of our significant statement of operations captions:

#### ***Revenues***

We generate our revenues primarily from the sale of the CorPath System, CorPath Cassettes, accessories and service contracts.

### Cost of Revenue

Cost of revenue represents the cost of materials for the CorPath System, CorPath Cassettes and accessories, service labor and labor and overhead of production facilities.

### Research and Development

Research and development expenses consist primarily of salaries and stock based compensation for our research and development, clinical and regulatory employees, and certain operating costs related to research and development and third party contractor costs.

### Selling, General and Administrative

Selling, general and administrative expenses consist primarily of salaries and stock based compensation for our executives and our marketing, finance, legal, human resource, and other administrative employees as well as salaries and commissions of our internal sales force. Selling, general and administrative expenses also include marketing program costs and outside consulting, legal and accounting services, and facilities and other supporting overhead costs. We also included shipping costs for CorPath Systems and CorPath Cassettes and Accessories in selling, general and administrative expense.

### Restructuring Charge

The restructuring charge consisted of a reduction in the general workforce as a result of a cost control initiative launched in January 2014 while we pursued financing alternatives.

### Other Income (Expense)

Other income (expense) represents changes in the warrant revaluation driven by changes in fair value of the underlying redeemable convertible preferred stock into which the warrants were exercisable, as well as interest expense on borrowings under the Company's Loan and Security Agreement, accretion of discounts and amortization of premiums on available-for-sale marketable securities, and interest income.

### Results of Operations

#### Discussion of Year Ended December 31, 2014 compared to Year Ended December 31, 2015:

	Year Ended December 31,		Change
	2014	2015	
	(In thousands)		
Revenue	\$ 2,983	\$ 2,729	\$ (254)
Cost of revenue	4,904	3,724	(1,180)
Gross loss	(1,921)	(995)	926
Operating expenses:			
Research and development	6,607	10,033	3,426
Selling, general and administrative	13,002	16,143	3,141
Restructuring charge	175	—	(175)
Total operating expenses	19,784	26,176	6,392
Operating loss	(21,705)	(27,171)	(5,466)
Other income (expense):			
Warrant revaluation	(2,421)	—	(2,421)
Interest and other income (expense)	(415)	(1,592)	1,177
Total other expense, net	(2,836)	(1,592)	(1,244)
Net loss	\$ (24,541)	\$ (28,763)	\$ (4,222)

## **Revenue**

Revenue decreased from approximately \$3.0 million for the year ended December 31, 2014 to approximately \$2.7 million for the year ended December 31, 2015. This revenue decrease was due primarily to a decrease in CorPath System sales from \$2.2 million during the year ended December 31, 2014 to \$1.8 million during the year ended December 31, 2015. We sold 11 CorPath Systems and eight CorPath Systems during the years ended December 31, 2014 and 2015, respectively, and our average selling price decreased by 4.1% from the year ended December 31, 2014 to the year ended December 31, 2015. Our average selling price of our CorPath System in 2014 included the sale of a CorPath System to an international customer during the second quarter of 2014 at a price substantially higher than our previous pricing. Exclusive of this sale, our average CorPath System price in 2015 increased by 31.9% over 2014. The sales of our CorPath Cassettes and accessories, which represent our sale of consumables, increased from \$0.5 million for the year ended December 31, 2014 to \$0.7 million for the year ended December 31, 2015 due to a larger installed base. The volume and average price of our CorPath Cassettes increased by 91 units and 6.7% from the year ended December 31, 2014 to the year ended December 31, 2015. Revenues under our CUPs represented 30.4% and 36.8% for the year ended December 31, 2014 and 2015, respectively, of our total revenues for the sale of consumables.

We believe the number of systems sold on a quarterly basis will fluctuate due to the unevenness of customer purchasing patterns associated with the early stage of commercialization of our product and market acceptance along with the development of a dedicated and consistent sales force. In 2015, we sold two systems in the first quarter, three in the second quarter, none in the third quarter, and three in the fourth quarter. Additionally, we expect variability in the sales of our consumables until our product receives wider market acceptance.

Given the relatively small number of customers due to the early stage of the Company's commercialization and the price of the CorPath System relative to consumables, customers that purchase a system in a specific period tend to make up a significant percentage of revenue in that period.

## **Cost of Revenue**

Cost of revenue decreased from approximately \$4.9 million for the year ended December 31, 2014 to approximately \$3.7 million for the year ended December 31, 2015, primarily due to fewer sales of CorPath Systems. Cost of revenues for the year ended December 31, 2014 included the effect of under-utilization of our production facilities, as well as approximately \$0.6 million related to inventories produced at a higher cost in 2013 that were subsequently sold in 2014.

Cost of revenue represents the cost of materials for the CorPath System and CorPath Cassettes, as well as labor and overhead at Corindus' production facility. At the Company's current volumes, our cost to manufacture the CorPath System is approximately \$0.2 million and the cost to manufacture cassettes averages approximately \$1 thousand per cassette. We expect these costs to decrease as we obtain economies of scale with respect to purchasing and production and continue to incorporate design enhancements.

## **Gross Loss**

Gross loss decreased from approximately \$1.9 million for the year ended December 31, 2014 to approximately \$1.0 million for the year ended December 31, 2015 based on the changes in revenue and cost of revenue as discussed above. We have not generated enough sales volume of CorPath Systems to offset our manufacturing costs including the effect of the under-utilization of our production facility and have generated a gross loss.

## **Research and Development**

Research and development expenses increased from approximately \$6.6 million for the year ended December 31, 2014 to approximately \$10.0 million for the year ended December 31, 2015. This increase of \$3.4 million is primarily due to investments in the development of the next generation CorPath System, including development of prototype systems, through a combination of incremental employee and consultant related costs, which increased by \$1.9 million, and the purchase of prototype materials, which increased by \$0.9 million.

***Selling, General and Administrative***

Selling, general and administrative expenses increased from approximately \$13.0 million for the year ended December 31, 2014 to approximately \$16.1 million for the year ended December 31, 2015. This increase of \$3.1 million is primarily due to incremental employee-related costs resulting from the expansion of the direct sales force, which increased by \$1.2 million, increased costs associated with consulting and marketing programs and initiatives, which increased by \$0.9 million, and increased presence at tradeshows, which increased by \$0.2 million.

***Restructuring Charge***

We recorded a restructuring charge for the year ended December 31, 2014 of approximately \$0.2 million due to a reduction in the general workforce as a result of a cost control initiative launched while we pursued financing alternatives.

***Other Expense, net***

Other expense, net, decreased from approximately \$2.8 million for the year ended December 31, 2014 to approximately \$1.6 million for the year ended December 31, 2015. The other expense for the year ended December 31, 2014 was primarily a result of the \$2.4 million revaluation of the warrant to purchase preferred stock based on the increase in value of the underlying preferred stock. The warrants to purchase shares of Series A, D and E Redeemable Convertible Preferred Stock were converted into warrants to purchase shares of common stock as a result of the Acquisition on August 12, 2014 and were reclassified to additional paid-in capital with no additional mark to market adjustments. Other expense for the year ended December 31, 2015 was primarily the result of \$1.6 million interest expense on borrowings under the Company's Loan and Security Agreement, as compared to \$0.4 million interest expense for the year ended December 31, 2014.

***Income Taxes***

We have not recorded any benefit related to operating losses due to uncertainty about future taxable income.

***Net Loss***

Net loss increased from approximately \$24.5 million for the year ended December 31, 2014 to approximately \$28.8 million for the year ended December 31, 2015 due to the factors noted above.



	Year Ended December 31,		Change
	2013	2014	
	(In thousands)		
Revenue	\$ 896	\$ 2,983	\$ 2,087
Cost of revenue	2,430	4,904	2,474
Gross loss	(1,534)	(1,921)	(387)
Operating expenses:			
Research and development	4,793	6,607	1,814
Selling, general and administrative	8,221	13,002	4,781
Restructuring charge	—	175	175
Total operating expenses	13,014	19,784	6,770
Operating loss	(14,548)	(21,705)	(7,157)
Other income (expense):			
Warrant revaluation	(171)	(2,421)	2,250
Interest and other income (expense)	28	(415)	443
Total other expense, net	(143)	(2,836)	2,693
Net loss and comprehensive loss	\$ (14,691)	\$ (24,541)	\$ (9,850)

### Revenue

Revenue increased from approximately \$0.9 million for the year ended December 31, 2013 to approximately \$3.0 million for the year ended December 31, 2014. This revenue increase was due primarily to an increase in CorPath System sales from approximately \$0.7 million during the year ended December 31, 2013 to approximately \$2.3 million during the year ended December 31, 2014 resulting from an increase in our sales force. The sales of our CorPath Cassettes and accessories increased from \$0.2 million for the year ended December 31, 2013 to \$0.5 million for the year ended December 31, 2014 due to a larger installed base. We sold six CorPath Systems and 11 CorPath Systems during the years ended December 31, 2013 and 2014, respectively, and our average selling price increased by 84.3% from the year ended December 31, 2013 to the year ended December 31, 2014. In 2014, we sold four systems in the first quarter, two in the second quarter, one in the third quarter, and four in the fourth quarter. Our average selling price of our CorPath System in 2014 included the sale of a CorPath System to an international customer during the second quarter of 2014 at a price substantially higher than our previous pricing. Exclusive of this sale, our average CorPath System price increased by 36.0% over 2013. The volume and average price of our CorPath Cassettes and accessories increased by 540 units and 12.4% from the year ended December 31, 2013 to the year ended December 31, 2014. Revenues under our CUPs represented 18.8% and 30.4% for the year ended December 31, 2013 and 2014, respectively, of our total revenues for the sale of consumables.

Philips, our sole distributor until August 2014 (although we began also selling directly to customers in November of 2013), is a customer that constituted a substantial portion of our revenues. As we have developed our own sales and marketing resources and now sell directly to customers, Philips has increasingly represented a lower percentage of our revenues. Philips accounted for approximately 71% and 11% of our revenues for the years ended December 31, 2013 and 2014, respectively. Our distribution agreement with Philips provided for the sale of our CorPath Systems to Philips at established discounted pricing. Our distribution agreement with Philips expired on August 7, 2014. We sell our CorPath Systems directly to customers primarily through our internal sales force and, to a lesser extent, through distributors where we seek strategic opportunities.

We continue to sell CorPath Systems through Philips on a sale by sale basis under a non-exclusive arrangement under mutually agreeable terms, which may include a continued level of discounted pricing, until such time we either execute a new distribution arrangement with Philips or we no longer do business with Philips. On November 18, 2014, following the termination of the distribution agreement with Philips, we entered into a purchase order with Philips for the purchase of one CorPath System on behalf of an end user, which was sold in the first quarter of 2015, at discounted pricing, which was approximately sixty-five percent (65%) less than the one direct system sale made in the third quarter of 2014 for a sales price of approximately \$352 thousand. There is no assurance that we will enter into a new distribution arrangement with Philips on terms acceptable to us.

**Cost of Revenue**

Cost of revenue increased from approximately \$2.4 million for the year ended December 31, 2013 to approximately \$4.9 million for the year ended December 31, 2014, which included the correction of an immaterial error in the amount of approximately \$0.6 million in 2014 primarily associated with excess overhead costs capitalized in 2013. Cost of revenue represents the cost of materials for the CorPath System and CorPath Cassettes, as well as labor and overhead at Corindus' production facility. At the Company's volumes in 2014, the cost to manufacture the CorPath System was approximately \$0.1 million and the cost to manufacture cassettes averaged approximately \$1 thousand per cassette. The increase in cost of revenues in 2014 reflected increased material costs associated with sales as well as additional labor and overhead costs. In 2014, we wrote inventories down in the amount of \$0.3 million to the lower of cost or market for cassettes as our cost of production exceeded the average selling price. Additionally, we recorded directly to cost of revenue approximately \$1.5 million of overhead costs due to the under-utilization of our production facility, exclusive of the \$0.6 million related to the immaterial correction of the error related to 2013.

**Gross Loss**

Gross loss increased from approximately \$1.5 million for the year ended December 31, 2013 to approximately \$1.9 million for the year ended December 31, 2014. We did not generate enough sales volume of CorPath Systems to offset the costs of our production facility and, therefore, generated a gross loss.

**Research and Development**

Research and development expenses increased from approximately \$4.8 million for the year ended December 31, 2013 to approximately \$6.6 million for the year ended December 31, 2014 due to investments in the development of the next generation CorPath System through a combination of additional employees and outsourced contractor services.

**Selling, General and Administrative**

Selling, general and administrative expenses increased from approximately \$8.2 million for the year ended December 31, 2013 to approximately \$13.0 million for the year ended December 31, 2014, representing an increase of \$4.8 million of which \$2.4 million related to sales and marketing expenses. This increase was due to the expansion of the direct sales force, strategic marketing investments, legal expenses associated with a financing arrangement which was not completed earlier in the year as well as legal, accounting and auditing fees in the amount of \$1.1 million associated with the Acquisition transaction which occurred in August 2014 and the Private Placement transaction that followed.

**Restructuring Charge**

We recorded a restructuring charge for the year ended December 31, 2014 of approximately \$0.2 million due to a reduction in the general workforce as a result of a cost control initiative launched while we pursued financing alternatives.

**Other Expense, net**

Other expense, net, increased approximately \$2.7 million for the year ended December 31, 2014 over the year ended December 31, 2013 due primarily to the revaluation of the warrant based on the increase in value of the underlying Preferred Stock, as well as additional interest expense incurred related to our borrowing arrangement in 2014. The warrants to purchase shares of Series A, D and E Redeemable Convertible Preferred Stock were converted into warrants to purchase shares of Common Stock as a result of the Acquisition and therefore, no additional mark to market adjustments were required.

**Income Taxes**

We have not recorded any benefit related to operating losses due to uncertainty about future taxable income.

## *Net Loss*

Net loss increased from approximately \$14.7 million for the year ended December 31, 2013 to approximately \$24.5 million for the year ended December 31, 2014 due to the factors as noted above.

## **Liquidity and Capital Resources**

We began our medical device business in 2002 and began selling FDA-cleared robotic medical devices in 2012. Our management does not contemplate attaining profitable operations until 2017, nor is there any assurance that such an operating level can ever be achieved. Since inception, we have financed our operations primarily through private sales of capital stock, a public offering of common stock in May 2015 and borrowing arrangements totaling approximately \$155.9 million, as well as limited revenues from the sale of our products.

As of December 31, 2015, we had an accumulated deficit of \$113.6 million and gross borrowings outstanding of \$8.0 million, of which \$4.4 million is contractually due in 2016. As we continue to incur losses and generate negative gross margins, the transition to profitability and positive gross margins is dependent upon achieving a level of revenues adequate to support our cost structure as well as reducing the cost of the product. We may never achieve profitability, and unless and until doing so, it will be necessary for us to attempt to raise additional capital, which may not be available or available on terms acceptable to us.

At December 31, 2015, we had approximately \$42.7 million of cash, cash equivalents and marketable securities. Cash equivalents are comprised of highly liquid money market and certificate of deposit accounts. The marketable securities balance is comprised of certificate of deposit accounts with maturities of three months or greater from the date of purchase and short term government treasury securities. We believe that our working capital of \$38.0 million at December 31, 2015 will provide us the liquidity to meet our operating needs and service our debt for at least the period through December 31, 2016. We will need to raise capital to fund operations and service debt until such time we become cash flow positive, if at all.

On May 28, 2015, we completed a public offering by issuing 12,650,000 shares of our common stock at \$3.80 per share in exchange for net proceeds of approximately \$44.4 million. In connection with the public offering, our common stock was approved for listing on the NYSE MKT and commenced trading on May 29, 2015.

On September 12, 2014, we entered into the Purchase Agreement with multiple investors relating to the issuance and sale of shares of our common stock in a private placement. At the closing of the private placement on September 16, 2014, we sold an aggregate of 10,666,570 shares of common stock at \$2.50 per share for an aggregate purchase price of \$26.7 million, or net proceeds of \$25.5 million. Pursuant to the Purchase Agreement, we registered these shares with the SEC under a registration statement on Form S-1, which was declared effective on January 13, 2015. Among other obligations under the Purchase Agreement, we must use commercially reasonable efforts to keep such registration statement continuously effective with respect to each investor until the earlier of (i) the sale by such investor of such shares or (ii) the date all shares held by such investor may be sold without restriction under Rule 144, including without limitation, any volume and manner of sale restrictions or current public information requirements.

On June 11, 2014, we entered into a Loan and Security Agreement (the "Loan Agreement") pursuant to which the lender agreed to make available to Corindus, Inc. \$10 million in the aggregate under two \$5 million secured promissory notes. The Initial Note was made on June 11, 2014 (the "Initial Note") and the Second Note was made on December 31, 2014 (the Second Note and, together with the Initial Note, the "Secured Promissory Notes"). The Secured Promissory Notes are repayable over a term of 27 months which began on July 1, 2015. The Initial Note bears interest at a rate equal to the greater of (w) 11.25% or (x) 11.25% plus the Wall Street Journal Prime Rate, less 3.25%. The Second Note bears interest at a rate equal to the greater of (y) 9.95% or (z) 9.95% plus the Wall Street Journal Prime Rate, less 3.25%. The borrowings require a final payment in the amount of \$0.3 million in addition to the interest and principal amounts due during the term of the Loan Agreement. The Loan Agreement also contains, among other things, covenants which include certain restrictions with respect to subsequent indebtedness, liens, loans and investments, financial reporting obligations, asset sales, share repurchase and other restricted payments, subject to certain exceptions. In addition, the Loan and Security Agreement contains a customary material adverse effect clause which states that in the event of a material adverse effect, an event of default would occur and the lender has the option to accelerate and demand payment of all or any part of the loan. A material adverse effect is defined in the Loan and Security Agreement as a material change in our business, operations, properties, assets or financial condition or a material impairment of our ability to perform all obligations under this Loan and Security Agreement. Future principal payments under the borrowing arrangement as of December 31, 2015 are as follows (in thousands):

Year ending December 31:

2016	\$	4,373
2017		3,605
	\$	<u>7,978</u>

In summary, our cash flows were:

	Years Ended December 31,		
	2013	2014	2015
	(In thousands)		
Net cash used in operating activities	\$ (15,303)	\$ (18,571)	\$ (27,856)
Net cash used in investing activities	\$ (378)	\$ (122)	\$ (20,793)
Net cash provided by (used in) financing activities	\$ (10)	\$ 37,374	\$ 42,265

**Operating Activities**

Cash used in operating activities was \$27.9 million for the year ended December 31, 2015 compared to \$18.6 million for the year ended December 31, 2014. The \$9.3 million increase in the use of cash was due primarily to the increase in net loss, exclusive of the non-cash warrant revaluation in the prior year, and changes in working capital, including increased use of cash for accounts receivable and inventories as well as an increase in cash used for accounts payable due to the timing of payments.

Cash used in operating activities was \$18.6 million for the year ended December 31, 2014 compared to \$15.3 million for the year ended December 31, 2013. The \$3.3 million increase in the use of cash was due primarily to the increase in net loss, exclusive of the non-cash warrant revaluation, which was due to increased research and development and selling costs to expand the business, offset partially by favorable changes in working capital, including reduced inventory levels as well as an increase in accounts payable due to the timing of payments.

**Investing Activities**

Cash used in investing activities was \$20.8 million for the year ended December 31, 2015 compared to \$0.1 million for the year ended December 31, 2014. The increase in investing activities was primarily due to the use of \$22.8 of the proceeds from our May 2015 public offering for purchases of marketable securities in 2015.

Cash used in investing activities included the purchase of property and equipment in the aggregate amount of approximately \$0.1 million for the year ended December 31, 2014 and approximately \$0.4 million for the year ended December 31, 2013. The decrease was due to fewer required capital investments during the year ended December 31, 2014.

**Financing Activities**

Cash provided by financing activities for the year ended December 31, 2015 was primarily from the completion of our May 2015 public offering in which we issued 12,650,000 shares of our common stock at \$3.80 per share in exchange for net proceeds of \$44.4 million partially offset by \$2.0 million of required principal payments on our long-term debt. Cash provided by financing activities for the year ended December 31, 2014 was primarily from the issuance of shares of our Common Stock in exchange for net proceeds of approximately \$27.5 million in connection with the sale of shares to a private investor and the private placement. We also borrowed approximately \$9.9 million, net, under the Loan Agreement.

## Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements (as that term is defined in Item 303(a)(4)(ii) of Regulation S-K) as of December 31, 2015 that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

## Contractual Obligations

The following table summarizes our contractual cash obligations at December 31, 2015 and the effect such obligations are expected to have on our liquidity and cash flow in future periods:

	Payments Due By Period				
	(In thousands)				
	Total	Less than 1 Year	1 - 3 Years	3 - 5 Years	More than 5 Years
Long-term debt, including estimated interest	\$ 9,045	\$ 5,025	\$ 4,020	\$ —	\$ —
Building lease liability	1,208	573	635	—	—
Other operating lease liabilities	99	47	52	—	—
	<u>\$ 10,352</u>	<u>\$ 5,645</u>	<u>\$ 4,707</u>	<u>\$ —</u>	<u>\$ —</u>

## Recently Issued Accounting Standards

In May 2014, the FASB issued ASU No. 2014-09—Revenue from Contracts with Customers, which amends FASB Accounting Standards Codification Topic 606. ASU 2014-09 provides a single, comprehensive revenue recognition model for all contracts with customers. This standard contains principles for the determination of the measurement of revenue and the timing of when such revenue is recognized. Revenue recognition will reflect the transfer of goods or services to customers at an amount that is expected to be earned in exchange for those goods or services. ASU 2014-09 was scheduled to be effective for annual reporting periods beginning after December 15, 2016, and early adoption was not permitted. In August 2015, the FASB issued ASU No. 2015-14—Revenue from Contracts with Customers: Deferral of Effective Date, which defers the effective date of ASU 2014-09 by one year. ASU 2014-19 is now effective for annual periods after December 15, 2017 including interim periods within that reporting period. Early adoption is permitted, but not before the original effective date. We are currently assessing the impact of this standard to our consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early adoption is permitted. If this standard had been adopted as of December 31, 2015, we believe that we would have concluded that there was not substantial doubt about our ability to continue as a going concern. However, we face certain risks and uncertainties, as further described in Note 1, "Nature of Operations" to the Consolidated Financial Statements, that could have affected this analysis.

In January 2015, the FASB issued Financial Accounting Standards Update—Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items. Subtopic 225-20, Income Statement—Extraordinary and Unusual Items, previously required that an entity separately classify, present, and disclose extraordinary events and transactions. This update is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015 and may be applied prospectively or retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. We do not expect the impact of adoption of this standard to be material.

In February 2015, the FASB issued ASU 2015-02, Consolidation (Topic 810) to address financial reporting considerations for the evaluation as to the requirement to consolidate certain legal entities. ASU 2015-02 is effective for fiscal years and for interim periods within those fiscal years beginning after December 15, 2015. We do not expect the impact of adoption of this standard to be material.

In April 2015, the FASB issued ASU 2015-03, Interest—Imputation of Interest (Subtopic 835-30) as part of the initiative to reduce complexity in accounting standards. The update requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for annual periods beginning after December 15, 2015 and for interim periods within those fiscal years. We do not expect the impact of ASU 2015-03 to be material to our consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Under this accounting guidance, inventory will be measured at the lower of cost and net realizable value and other options that currently exist for market value will be eliminated. ASU 2015-11 defines net realizable value as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. No other changes were made to the current guidance on inventory measurement. The guidance is effective for annual reporting periods and interim periods within those annual reporting periods beginning after December 15, 2016. Early adoption is permitted and the prospective transition method should be applied. We are currently evaluating the impact of ASU 2015-11 on our consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The update addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted only for certain portions of the ASU related to financial liabilities. We are currently evaluating the impact of this standard on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which amends leasing accounting requirements. The new standard requires lessee recognition on the balance sheet of a right-of-use asset and a lease liability, initially measured at the present value of the lease payments. It further requires recognition in the income statement of a single lease cost, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis. Finally, it requires classification of all cash payments within operating activities in the statement of cash flows. It is effective for fiscal years commencing after December 15, 2018 and early adoption is permitted. We are currently evaluating the impact of this standard on our consolidated financial statements.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and marketable securities of \$42.7 million as of December 31, 2015. The cash, cash equivalents and marketable securities as of December 31, 2015 consist of cash in bank deposits, money market funds, certificates of deposit accounts and U.S. government treasury securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investment strategy is primarily in short term securities. Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. We have the ability to hold our fixed income investments to maturity, and therefore we don't expect our operating results to be affected to any significant degree by the effect of a change in market interest rates on our investments.

We pay interest on our outstanding long-term debt at interest rates that fluctuate based upon changes in various base interest rates. The carrying value of our long-term debt, including the current portion, was \$7.7 million at December 31, 2015. See "Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources" and Note 8 — "Long-Term Debt" to the consolidated financial statements for additional information regarding our outstanding long-term debt. The effect of an immediate hypothetical 10% change in variable interest rates would not have a material effect on our consolidated financial statements.

We have generated limited net revenue from operations to date and depend on funds raised through other sources. One possible source of funding is through further equity offerings. Our ability to raise funds in this manner depends upon capital market forces affecting our stock price.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.**

The consolidated financial statements, together with the report of our independent registered public accounting firm, Ernst & Young LLP, appear at page F-1 through F-25 of this Annual Report on Form 10-K.

**ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.**

None.

**ITEM 9A. CONTROLS AND PROCEDURES.**

**Evaluation of Disclosure Controls and Procedures**

As required by Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we carried out an evaluation under the supervision and with the participation of our senior management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2015. Based upon their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective to ensure that material information relating to the Company required to be disclosed by the Company in reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms and to ensure that such information is accumulated and communicated to senior management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and management necessarily was required to apply its judgment in designing and evaluating the controls and procedures.

We continue to review our disclosure controls and procedures, and our internal control over financial reporting, and may from time to time make changes aimed at enhancing their effectiveness and to ensure that our systems evolve with our business.

## **Internal Control over Financial Reporting**

### ***Management's Report on Internal Controls over Financial Reporting***

Our senior management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) promulgated under the Exchange Act as a process designed by, or under the supervision of, our principal executive and principal financial officers, or persons performing similar functions, and effected by our board of directors, senior 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 U.S. GAAP, and includes policies and procedures that:

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

Under the supervision and with the participation of senior management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of the Company's internal control over financial reporting based on the framework in "Internal Control — Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment and the factors discussed below in the section titled, "Remediation of Prior Year Material Weakness in Internal Controls Over Financial Reporting," our senior management has concluded that the internal control over financial reporting was effective as of December 31, 2015.

### ***Remediation of Prior Year Material Weakness in Internal Controls Over Financial Reporting***

As described in Management's Report on Internal Controls Over Financial Reporting in our 2014 Form 10-K filed on March 30, 2015, our senior management concluded that a material weakness existed in our internal controls in 2014 relating to our accounting for overhead costs which affected inventories and property and equipment. Specifically, our cost accounting and reserve estimate processes lacked adequate levels of monitoring and review controls to identify and correct inventory errors in a timely manner, which was primarily the result of an insufficient number of qualified accounting resources to ensure adequate technical review of inventory accounting issues during the financial statement close process. In response, we implemented the following changes in our internal control over financial reporting:

- added finance and accounting capabilities, including a Corporate Controller and compliance consultant with technical accounting expertise to increase quality and timeliness of reviews performed by financial management;
- performed a comprehensive risk assessment process to assess risks and identify, design, implement and evaluate our control activities to address the risks identified, including implementation of monitoring controls related to the design and operating effectiveness of control activities;
- establish procedures to reconcile, validate and review inventory and property and equipment reporting on a routine basis, and in a timely manner;
- reviewed functions performed by finance and operations personnel and redistributed responsibilities to ensure functions were being performed by personnel with the appropriate skill sets; and
- evaluated our training programs and developed additional training programs to ensure proper training of our finance and accounting personnel.

As a result of these changes in internal controls over financial reporting, senior management believes that the material weakness with respect to internal control over financial reporting identified at December 31, 2014 described above was successfully remediated in 2015.

This Annual Report does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. The Company's internal control over financial reporting was not subject to attestation by the Company's independent registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit emerging growth companies, which we are, to provide only management's report in this Annual Report.

**Changes in Internal Control over Financial Reporting**

Except as noted within this Item 9A, there were no changes in our internal control over financial reporting during the quarter ended December 31, 2015 that have materially affected, or that are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION.**

None.

**PART III**

**ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE.**

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2016 Annual Meeting of Stockholders.

**ITEM 11. EXECUTIVE COMPENSATION.**

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2016 Annual Meeting of Stockholders.

**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.**

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2016 Annual Meeting of Stockholders.

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS AND DIRECTOR INDEPENDENCE.**

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2016 Annual Meeting of Stockholders.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.**

The information required by this Item is incorporated herein by reference to the definitive Proxy Statement to be filed pursuant to Regulation 14A of the Exchange Act for our 2016 Annual Meeting of Stockholders.



ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Financial Statements and Financial Statements Schedules

- (1) Financial Statements are listed in the Consolidated Financial Statements Contents on page F-1 of this Annual Report.
- (2) No financial statement schedules are included because such schedules are not applicable, are not required, or because required information is included in the consolidated financial statements or notes thereto.

(b) Exhibits

Exh. No.	Date	Document
2.1	August 5, 2014	Securities Exchange and Acquisition Agreement between Your Internet Defender Inc., and Corindus, Inc. <sup>(3)</sup>
3.1	November 12, 2015	Amended and Restated Bylaws <sup>(8)</sup>
3.2	August 12, 2014	Certificate of Amendment and Restatement of Articles of Incorporation <sup>(3)</sup>
10.1#	September 3, 2008	Employment Agreement between Corindus, Inc. and David M. Handler <sup>(4)</sup>
10.2#	January 21, 2011	Indemnification Agreement between Corindus and Gerard Winkels <sup>(4)</sup>
10.3	October 24, 2012	Lease Agreement <sup>(4)</sup>
10.4	June 11, 2014	Loan and Security Agreement between the Company and Steward Capital Holdings <sup>(7) †</sup>
10.5	June 11, 2014	Warrant to Steward Capital Holdings <sup>(4)</sup>
10.6	June 11, 2014	Intellectual Property Loan Agreement between the Company and Steward Capital Holdings <sup>(7) †</sup>
10.7	June 30, 2014	Resignation of Lisa Grossman <sup>(2)</sup>
10.8	June 30, 2014	Resignation of Gabriel Solomon <sup>(2)</sup>
10.9	June 30, 2014	Loan Agreement between the Company and Lisa Grossman <sup>(2)</sup>
10.10	June 30, 2014	Promissory Note for \$248,831.59 issued to Lisa Grossman <sup>(2)</sup>
10.11	July 2, 2014	Debt Settlement Agreement between the Company and Yitz Grossman <sup>(2)</sup>
10.12#	n/a	Form of Employee Stock Option for 2006 Option Holders <sup>(3)</sup>
10.13#	n/a	Form of Director Stock Option for 2006 Option Holders <sup>(3)</sup>
10.14#	n/a	Form of Employee Stock Option for 2008 Option Holders <sup>(3)</sup>
10.15#	n/a	Form of Officer Stock Option for 2008 Option Holders <sup>(3)</sup>
10.16#	n/a	Form of Director Stock Option for 2008 Option Holders <sup>(3)</sup>
10.17	August 5, 2014	Form of Lock-up Agreement <sup>(3)</sup>
10.18	August 5, 2014	Form of Stock Purchase Agreement for Equity Infusion <sup>(3)</sup>
10.19	August 5, 2014	Form of Private Investor Registration Rights Agreement for Equity Infusion <sup>(3)</sup>
10.20	August 5, 2014	Demand Registration Rights Agreement <sup>(3)</sup>
10.21#	August 12, 2014	2014 Stock Award Plan <sup>(3)</sup>
10.22	August 12, 2014	Interest Transfer Agreement <sup>(4)</sup>
10.23	August 12, 2014	Replacement Warrant to Steward Capital Holdings <sup>(4)</sup>
10.24	August 12, 2014	Replacement Warrant to Narkis Gryp Ltd. <sup>(4)</sup>
10.25	August 12, 2014	Replacement Warrant to Koninklijke Philips Electronics, N.V. <sup>(4)</sup>
10.26	August 12, 2014	Spin-Out Agreement between the Company and Lisa Grossman <sup>(4)</sup>
10.27	August 12, 2014	Repurchase Agreement <sup>(4)</sup>
10.28	September 11, 2014	Securities Purchase Agreement between the Company and certain purchasers, form of <sup>(5)</sup>
10.29	September 15, 2014	Amendment to Securities Purchase Agreement between the Company and certain purchasers, form of <sup>(5)</sup>
10.30	December 22, 2010	Distributor Agreement with Philips Medical Systems Nederland BV <sup>(7) †</sup>
10.31	November 18, 2014	Purchase Order with Philips Medical Systems Nederland BV <sup>(7) †</sup>
10.32#	May 22, 2015	Employment Agreement between Corindus Vascular Robotics, Inc. and David M. Handler <sup>(9)</sup>
10.33#	May 22, 2015	Employment Agreement between Corindus Vascular Robotics, Inc. and David W. Long <sup>(9)</sup>
10.34	n/a	Form of Indemnification Agreement <sup>(10)</sup>
10.35#	February 23, 2016	Employment Agreement between Corindus Vascular Robotics, Inc. and Mark J. Toland <sup>(11)</sup>
21	n/a	<a href="#">Subsidiaries of the Registrant</a> *
23.1	n/a	<a href="#">Consent of Ernst &amp; Young LLP</a> *

<b>Exh. No.</b>	<b>Date</b>	<b>Document</b>
31.1	March 11, 2016	<a href="#">Certification of Chief Executive Officer of Periodic Report pursuant to Rule 13a-14a and Rule 15d-14(a).</a> *
31.2	March 11, 2016	<a href="#">Certification of Chief Financial Officer of Periodic Report pursuant to Rule 13a-14a and Rule 15d-14(a).</a> *
32.1	March 11, 2016	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.</a> * **
32.2	March 11, 2016	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.</a> * **
101.INS	n/a	XBRL Instance Document*
101.SCH	n/a	XBRL Taxonomy Extension Schema Document*
101.CAL	n/a	XBRL Taxonomy Extension Calculation Linkbase Document*
101.DEF	n/a	XBRL Taxonomy Extension Definition Linkbase Document*
101.LAB	n/a	XBRL Taxonomy Extension Label Linkbase Document*
101.PRE	n/a	XBRL Taxonomy Extension Presentation Linkbase Document*

- (1) Incorporated by reference to the corresponding exhibit filed with our Registration Statement on Form S-1 on August 31, 2011.
- (2) Incorporated by reference to the corresponding exhibit filed with our Current Report on Form 8-K on July 7, 2014.
- (3) Incorporated by reference to the corresponding exhibit filed with our Current Report on Form 8-K on August 6, 2014.
- (4) Incorporated by reference to the corresponding exhibit filed with our Current Report on Form 8-K/A on August 15, 2014.
- (5) Incorporated by reference to the corresponding exhibit filed with our Current Report on Form 8-K on September 16, 2014.
- (6) Incorporated by reference to the corresponding exhibit filed with our Current Report on Form 8-K on November 14, 2014.
- (7) Incorporated by reference to the corresponding exhibit filed with our Registration Statement on Form S-1/A on December 8, 2014.
- (8) Incorporated by reference to the corresponding exhibit filed with our Quarterly Report on Form 10-Q on November 13, 2015.
- (9) Incorporated by reference to the corresponding exhibit filed with our Registration Statement on Form S-1/A on May 26, 2015.
- (10) Incorporated by reference to the corresponding exhibit filed with our Current Report on Form 8-K on January 29, 2016.
- (11) Incorporated by reference to the corresponding exhibit filed with our Current Report on Form 8-K on February 26, 2016.

\* Filed herewith.

\*\* This certification is being furnished and shall not be deemed “filed” with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent that the Registrant specifically incorporates it by reference.

† Portions of this exhibit have been omitted pursuant to a request for confidential treatment. Omitted material has been separately filed with the Securities and Exchange Commission.

# Management contract or compensatory plan or arrangement.

**SIGNATURES**

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

DATE: March 11, 2016

CORINDUS VASCULAR ROBOTICS, INC.

By: /s/ Mark J. Toland  
Mark J. Toland  
Chief Executive Officer and President  
Principal Executive Officer

By: /s/ David W. Long  
David W. Long  
Chief Financial Officer and Senior Vice President  
Chief Financial and Accounting Officer

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

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ Mark J. Toland</u> Mark J. Toland	Chief Executive Officer, President and Director (Principal Executive Officer)	March 11, 2016
<u>/s/ David W. Long</u> David W. Long	Chief Financial Officer, Senior Vice President, Treasurer and Secretary (Principal Financial and Accounting Officer)	March 11, 2016
<u>/s/ Jeffrey C. Lightcap</u> Jeffrey C. Lightcap	Chairman	March 11, 2016
<u>/s/ Hillel Bachrach</u> Hillel Bachrach	Director	March 11, 2016
<u>/s/ Jeffrey Gold</u> Jeffrey Gold	Director	March 11, 2016
<u>/s/ David White</u> David White	Director	March 11, 2016
<u>/s/ Gerard Winkels</u> Gerard Winkels	Director	March 11, 2016
<u>/s/ Michael Mashaal</u> Michael Mashaal	Director	March 11, 2016
<u>/s/ Campbell Rogers</u> Campbell Rogers	Director	March 11, 2016

**CORINDUS VASCULAR ROBOTICS, INC.**  
**CONSOLIDATED FINANCIAL STATEMENTS**  
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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Stockholders of  
Corindus Vascular Robotics, Inc.

We have audited the accompanying consolidated balance sheets of Corindus Vascular Robotics, Inc. as of December 31, 2014 and 2015, and the related consolidated statements of operations and comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Corindus Vascular Robotics, Inc. at December 31, 2014 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 11, 2016

**CORINDUS VASCULAR ROBOTICS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
*(In thousands, except share and per share amounts)*

	December 31, 2014	December 31, 2015
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents	\$ 28,526	\$ 22,142
Marketable securities	—	20,524
Accounts receivable	473	878
Inventories, net	1,519	1,329
Prepaid expenses and other current assets	574	591
Total current assets	31,092	45,464
Property and equipment, net	1,284	1,382
Deposits and other assets	222	166
Deferred inventory costs	102	—
Notes receivable due from stockholders	136	136
Total assets	\$ 32,836	\$ 47,148
<b>Liabilities and stockholders' equity</b>		
Current Liabilities:		
Accounts payable	\$ 2,005	\$ 1,538
Accrued expenses	1,137	1,199
Deferred revenue	202	701
Current portion of long-term debt	1,517	4,038
Total current liabilities:	4,861	7,476
Long-term liabilities		
Deferred revenue, net of current portion	531	106
Other liabilities	68	42
Long-term debt, net of current portion	7,594	3,677
Total long-term liabilities:	8,193	3,825
Total liabilities	13,054	11,301
Commitments and Contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, par value \$0.0001 par value; 10,000,000 shares authorized; none issued and outstanding	—	—
Common stock, \$0.0001 par value; 250,000,000 shares authorized; 105,883,157 shares at December 31, 2014 and 118,832,441 shares at December 31, 2015 issued and outstanding	11	12
Additional paid-in capital	104,648	149,489
Accumulated other comprehensive loss	—	(14)
Accumulated deficit	(84,877)	(113,640)
Total stockholders' equity	19,782	35,847
Total liabilities and stockholders' equity	\$ 32,836	\$ 47,148

*The accompanying notes are an integral part of the consolidated financial statements.*

**CORINDUS VASCULAR ROBOTICS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
*(In thousands, except share and per share amounts)*

	Year Ended December 31,		
	2013	2014	2015
Revenue	\$ 896	\$ 2,983	\$ 2,729
Cost of revenue	2,430	4,904	3,724
Gross loss	<u>(1,534)</u>	<u>(1,921)</u>	<u>(995)</u>
Operating expenses:			
Research and development	4,793	6,607	10,033
Selling, general and administrative	8,221	13,002	16,143
Restructuring charge	—	175	—
Total operating expense	<u>13,014</u>	<u>19,784</u>	<u>26,176</u>
Operating loss	<u>(14,548)</u>	<u>(21,705)</u>	<u>(27,171)</u>
Other income (expense):			
Warrant revaluation	(171)	(2,421)	—
Interest and other income (expense)	28	(415)	(1,592)
Total other expense, net	<u>(143)</u>	<u>(2,836)</u>	<u>(1,592)</u>
Net loss	<u>\$ (14,691)</u>	<u>\$ (24,541)</u>	<u>\$ (28,763)</u>
Net loss per share--basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.29)</u>	<u>\$ (0.25)</u>
Weighted-average common shares used in computing net loss per share--basic and diluted	<u>73,360,259</u>	<u>84,990,198</u>	<u>113,254,925</u>
Other comprehensive loss:			
Net loss	\$ (14,691)	\$ (24,541)	\$ (28,763)
Unrealized loss on marketable securities	—	—	(14)
Comprehensive loss	<u>\$ (14,691)</u>	<u>\$ (24,541)</u>	<u>\$ (28,777)</u>

*The accompanying notes are an integral part of the consolidated financial statements.*

**CORINDUS VASCULAR ROBOTICS, INC.**  
**CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY**  
*(In thousands, except share and per share amounts)*

	<u>Common Stock, \$0.0001 Par Value</u>			Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Additional Paid-in Capital			
<b>Balance at December 31, 2012</b>	73,360,162	\$ 7	\$ 70,050	—	\$ (45,645)	\$ 24,412
Issuance of common stock upon exercise of stock options	125	—	—	—	—	—
Issuance costs related to common stock	—	—	(10)	—	—	(10)
Stock-based compensation expense	—	—	329	—	—	329
Net loss	—	—	—	—	(14,691)	(14,691)
<b>Balance at December 31, 2013</b>	73,360,287	7	70,369	—	(60,336)	10,040
Stock-based compensation expense	—	—	377	—	—	377
Reclassification of warrant liability	—	—	5,803	—	—	5,803
Issuance of common stock in connection with reverse acquisition	20,856,300	2	(5)	—	—	(3)
Issuance of common stock to private investor	1,000,000	—	2,000	—	—	2,000
Issuance of common stock in connection with private placement of common stock, net of issuance costs of \$1,179	10,666,570	2	25,485	—	—	25,487
Issuance of warrants to purchase common stock	—	—	619	—	—	619
Net loss	—	—	—	—	(24,541)	(24,541)
<b>Balance at December 31, 2014</b>	105,883,157	11	104,648	—	(84,877)	19,782
Stock-based compensation expense	—	—	505	—	—	505
Issuance of common stock in connection with public offering of common stock, net of issuance costs of \$794	12,650,000	1	44,391	—	—	44,392
Issuance of common stock upon exercise of stock options	340,345	—	76	—	—	76
Common stock withheld to pay statutory minimum withholding taxes on exercise of stock options	(41,061)	—	(131)	—	—	(131)
Change in fair value of marketable securities	—	—	—	(14)	—	(14)
Net loss	—	—	—	—	(28,763)	(28,763)
<b>Balance at December 31, 2015</b>	118,832,441	\$ 12	\$ 149,489	\$ (14)	\$ (113,640)	\$ 35,847

The accompanying notes are an integral part of the consolidated financial statements.



**CORINDUS VASCULAR ROBOTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended December 31,		
	2013	2014	2015
<b>Operating activities</b>			
Net loss	\$ (14,691)	\$ (24,541)	\$ (28,763)
Adjustments to reconcile net loss to net cash flows used in operating activities:			
Depreciation and amortization	607	622	706
Stock-based compensation expense	329	377	505
Write down of inventories	—	341	—
Accretion of interest expense	—	106	625
Accretion on available-for-sale securities	—	—	(13)
Warrant revaluation	171	2,421	—
Changes in operating assets and liabilities:			
Accounts receivable	(23)	(438)	(404)
Due from related party	130	125	—
Prepaid expenses and other current assets	134	(80)	(17)
Deferred inventory costs	—	(102)	102
Inventories	(2,313)	257	(346)
Deposits and other assets	89	24	56
Accounts payable, accrued expenses and other liabilities	329	1,584	(380)
Deferred revenue	(65)	733	73
Net cash used in operating activities	<u>(15,303)</u>	<u>(18,571)</u>	<u>(27,856)</u>
<b>Investing activities</b>			
Purchases of available-for-sale securities	—	—	(22,766)
Maturities of available-for-sale securities	—	—	2,241
Purchase of property and equipment	(378)	(122)	(268)
Net cash used in investing activities	<u>(378)</u>	<u>(122)</u>	<u>(20,793)</u>
<b>Financing activities</b>			
Proceeds from issuance of common stock, net of offering costs	(10)	27,487	44,392
Proceeds from issuance of long term debt and warrants, net of deferred financing costs and discounts	—	9,890	(50)
Proceeds from exercise of stock options	—	—	76
Payments of statutory minimum withholding taxes on stock option exercises	—	—	(131)
Payments on long-term debt	—	—	(2,022)
Other	—	(3)	—
Net cash provided by (used in) financing activities	<u>(10)</u>	<u>37,374</u>	<u>42,265</u>
Net increase (decrease) in cash and cash equivalents	(15,691)	18,681	(6,384)
Cash and cash equivalents at beginning of period	25,536	9,845	28,526
Cash and cash equivalents at end of period	<u>\$ 9,845</u>	<u>\$ 28,526</u>	<u>\$ 22,142</u>
<b>Non-cash Investing and Financing Activities</b>			
Transfer from inventories to property and equipment in the field	\$ 588	\$ 347	\$ 587
Reclassification of warrant liability to stockholders' equity	\$ —	\$ 5,803	\$ —
Deferred public offering costs in accounts payable and accrued expenses	\$ —	\$ 50	\$ —
<b>Supplemental Cash Flow Information</b>			
Interest paid	\$ —	\$ 266	\$ 976

The accompanying notes are an integral part of the consolidated financial statements.

**Corindus Vascular Robotics, Inc.**  
**Notes to Consolidated Financial Statements**  
*In thousands, except share and per share amounts*

**1. Nature of Operations**

*The Company*

Corindus Vascular Robotics, Inc. (the “Company”), a Nevada corporation (formerly named Your Internet Defender, Inc. (“YIDI”)), acquired Corindus, Inc., a privately-held company, in a reverse acquisition on August 12, 2014. The Company’s corporate headquarters and research and development facility are in Waltham, Massachusetts and the Company is engaged in the marketing, sales and development of robotic-assisted catheterization systems (“CorPath System”).

Since its inception on March 21, 2002, the Company has devoted its efforts principally to research and development, business development activities and raising capital. In July 2012, the Company received clearance from the FDA to market its CorPath System in the United States and shipped its first commercial product under this clearance in September 2012. In 2013, the Company moved into the growth stage, investing in sales and marketing in order to build the customer base. While the Company is initially cleared for and is targeting PCI procedures, the Company believes its technology platform has the capability to be developed in the future for other segments of the vascular market, including peripheral vascular, neurointerventional and other more complex cardiac interventions such as structural heart.

In October 2015, the Company announced that the FDA had given 510(k) clearance for its robotic-assisted CorPath System to be used during percutaneous coronary interventions performed via radial access. The 510(k) clearance was based on results of a clinical trial conducted at Spectrum Health, Grand Rapids, Michigan, and St. Joseph’s Hospital Health Center, Syracuse, New York.

The Company’s future capital requirements will depend upon many factors, including progress with developing, manufacturing and marketing its technologies, the time and costs involved in preparing, filing, prosecuting, maintaining and enforcing patent claims and other proprietary rights, its ability to establish collaborative arrangements, marketing activities and competing technological and market developments, including regulatory changes affecting medical procedure reimbursement, and overall economic conditions in its target markets.

*Recent Equity Offerings*

On May 28, 2015, the Company completed a public offering by issuing 12,650,000 shares of its common stock at \$3.80 per share in exchange for proceeds of \$44,392, net of underwriting discounts, commissions and other offering costs. In connection with the public offering, the Company’s common stock was approved for listing on the NYSE MKT, where it commenced trading on May 29, 2015 under the symbol “CVRS”.

*Liquidity*

The Company has incurred losses since inception and has funded its operations primarily through the issuance of capital stock and debt. As of December 31, 2015, the Company had an accumulated deficit of \$113,640, and net borrowings outstanding of \$7,978, of which \$4,373 is contractually due over the next 12 months.

The Company has cash, cash equivalents and marketable securities of \$42,666 and working capital of \$37,988 at December 31, 2015. The Company believes that these available resources will be sufficient to meet the Company’s cash requirements through December 31, 2016, including funding its anticipated losses and scheduled debt maturities. Additionally, the Company is in compliance with its debt covenant requirements as of December 31, 2015 and expects to remain in compliance throughout 2016. As the Company continues to incur losses, transition to profitability is dependent upon achieving a level of revenues adequate to support the Company’s cost structure. The Company may never achieve profitability, and unless and until doing so, intends to fund future operations through additional debt or equity offerings. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, if at all.

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**2. Significant Accounting Policies**

**Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Corindus, Inc. and Corindus Security Corporation, which was created on December 21, 2012 to hold and invest the proceeds from issuance of equity. All intercompany transactions and balances have been eliminated in consolidation. The functional currency of both wholly-owned subsidiaries is the U.S. dollar and, therefore, the Company has not recorded any currency translation adjustments.

In the fourth quarter of 2014, the Company participated in the formation of a not-for-profit, which was established to generate awareness of the health risks linked to the use of fluoroscopy in hospital catheterization. As of December 31, 2015, the Company's Chief Executive Officer and one of its senior executives represented two of the three voting members of the board of directors of the entity. As a result, under the voting model used for the consolidation of related parties, which are controlled by a company, the Company has consolidated the financial statements of the entity, and recognized expenses of \$18 and \$386 for the years ended December 31, 2014 and 2015, respectively. The entity had assets and liabilities of \$56 and \$75, respectively, on the Company's balance sheet at December 31, 2015. The entity did not have any assets or liabilities on the Company's balance sheet at December 31, 2014.

**Segment Information**

The Company operates in one business segment, which is the development, marketing and sales of robotic-assisted vascular interventions. Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. To date, the chief operating decision maker has made such decisions and assessed performance at the company level, as one segment. The Company's chief operating decision maker is the Chief Executive Officer.

Revenues from domestic customers were \$896, \$2,068 and \$2,684 for the years ending December 31, 2013, 2014 and 2015, respectively. Revenues from international customers, primarily in Dubai and Israel, were \$0, \$915 and \$45 for the years ending December 31, 2013, 2014 and 2015, respectively.

**Use of Estimates**

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of assets and liabilities at the date of the financial statements. Such management estimates include those relating to revenue recognition, inventory valuation, assumptions used in the valuation of stock-based awards, and valuation allowances against deferred income tax assets. Actual results could differ from those estimates.

**Cash Equivalents**

The Company considers highly liquid short-term investments, which consists of money market funds and certificates of deposit with original maturity dates of three months or less at the date of purchase, to be cash equivalents. From time to time, the Company's cash balances may exceed federal deposit insurance limits.

**Marketable Securities**

The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company has classified all of its marketable securities at December 31, 2015 as "available-for-sale" pursuant to ASC 320, Investments – Debt and Equity Securities. The Company records available-for-sale securities at fair value, with the unrealized gains and losses included in accumulated other comprehensive loss in stockholders' equity.

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The Company adjusts the cost of available-for-sale debt securities for amortization of premiums and accretion of discounts to maturity. The Company includes such amortization and accretion in interest and other income (expense). The cost of securities sold is based on the specific identification method. The Company includes interest income on securities classified as available-for-sale in interest and other income (expense).

The Company reviews marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations if the Company has experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that the Company will be required to sell the marketable security before recovery of the amortized cost basis.

At December 31, 2015, the balance in the Company's accumulated other comprehensive loss was composed solely of activity related to the Company's available-for-sale securities. There were no realized gains or losses recognized on the maturity of available-for-sale securities during the year ended December 31, 2015, and as a result, the Company did not reclassify any amount out of accumulated other comprehensive loss during that same period.

The aggregate fair value of securities held by the Company in an unrealized loss position for less than twelve months as of December 31, 2015 consists of 13 certificates of deposit and two U.S. Treasuries. The Company has the intent and ability to hold such securities until recovery. As of December 31, 2015, the Company's available-for-sale securities had remaining maturities no greater than one year. The Company determined that there was no material change in the credit risk of the above investments. As a result, the Company determined it did not hold any investments with an other-than-temporary impairment as of December 31, 2015.

The following table summarizes available-for-sale securities held at December 31, 2015:

Description	Amortized Cost	Unrealized Gain	Unrealized Loss	Fair Value
<b>December 31, 2015</b>				
U.S. government treasuries	\$ 15,885	\$ 1	\$ (10)	\$ 15,876
Certificates of deposit	4,653	—	(5)	4,648
<b>Total</b>	<b>\$ 20,538</b>	<b>\$ 1</b>	<b>\$ (15)</b>	<b>\$ 20,524</b>

Certain short-term securities with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheet at December 31, 2015 and are not included in the table above. The Company did not hold any available-for-sale securities at December 31, 2014.

**Fair Value Measurements**

In accordance with ASC 820, Fair Value Measurements and Disclosures, the Company generally defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (exit price). The Company uses a three-tier fair value hierarchy, which classifies the inputs used in measuring fair values. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements), and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

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- *Level 1* – inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- *Level 2* – inputs are inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly. If the asset or liability has a specified (contractual) term, a Level 2 input must be observable for substantially the full term of the asset or liability.
- *Level 3* – inputs are unobservable inputs for the asset or liability in which there is little, if any, market activity for the asset or liability at the measurement date.

The following table sets forth the Company's assets that are measured at fair value on a recurring basis as of December 31, 2015:

Description	Fair value measurement category			
	Total	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
<b>December 31, 2015:</b>				
Assets:				
Cash equivalents	\$ 6,356	\$ 6,107	\$ 249	\$ —
Marketable securities:				
U.S. government treasuries	15,876	15,876	—	—
Certificates of deposit	4,648	—	4,648	—
<b>Total assets</b>	<b>\$ 26,880</b>	<b>\$ 21,983</b>	<b>\$ 4,897</b>	<b>\$ —</b>

The Company's financial instruments of deposits and notes receivable are carried at cost and approximate their fair values given the liquid nature of such items. The fair value of the Company's long-term debt amounted to \$9,111 and \$7,715 at December 31, 2014 and 2015, respectively, based on discounted cash flow analysis, which included Level 3 inputs and fair value approximates recorded amounts.

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**Concentrations of Credit Risk and Significant Customers**

The Company had the following customers that accounted for greater than 10% of its revenues for the year ended December 31, 2014 and 2015, respectively:

Customer	For the Year ended December 31,	
	2014	2015
	Percent of Revenues	Percent of Revenues
A	27%	—
B	12%	—
C	11%	—
D	11%	—
E	10%	—
F	—	13%
G	—	11%
H	—	10%

Additionally, Customer B accounted for 27% of the Company's accounts receivable balance at December 31, 2014, and Customer F accounted for 38% of the accounts receivable balance at December 31, 2015. The Company had one other customer that accounted for 25% of its accounts receivable balance at December 31, 2014, but did not exceed 10% of its revenues in 2014. The Company had one other customer that accounted for 38% of its accounts receivable balance at December 31, 2015, but did not exceed 10% of its revenues in 2015.

The Company had one customer, Philips, who accounted for approximately 71% of its revenues in 2013. The Company had no other customers that accounted for greater than 10% of its revenues in 2013.

The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts, or other hedging arrangements.

**Allowance for Doubtful Accounts**

The Company evaluates the collectability of accounts receivable on a regular basis. The allowance for doubtful accounts, if any, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts and economic factors or events expected to affect future collections experience. The Company's accounts receivable consist primarily of amounts due from large, well-capitalized customers and while the Company reviews their creditworthiness, collectability is generally not an issue. The Company records an allowance for doubtful accounts, when necessary, based on the potential for collectability issues within the customer base. The Company's allowance for doubtful accounts was \$0 at December 31, 2014 and 2015.

**Product Warranty**

Customers are permitted to return defective products under the Company's standard product warranty program. For CorPath Systems, the Company's standard one-year warranty provides for the repair of any product that malfunctions. Return and replacement can only occur if a material breach of the warranty remains uncured for 30 days. A roll-forward of the Company's warranty liability is as follows:

Balance at December 31, 2013	\$ 29
Provision for warranty obligations	96
Settlements	(64)
Balance at December 31, 2014	61
Provisions for warranty obligations	58
Settlements	(51)
Balance at December 31, 2015	\$ 68

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**Inventories**

Inventories are valued at the lower of cost or market using the first-in, first-out (FIFO) method. The Company routinely monitors the recoverability of its inventory and records the lower of cost or market reserves based on current selling prices and reserves for excess and obsolete inventory based on historical and forecasted usage, as required. Scrap and excess manufacturing costs are charged to cost of revenue as incurred and not capitalized as part of inventories. The Company only capitalizes pre-launch inventory when purchased for commercial use and it deems regulatory approval to be probable.

**Property and Equipment**

Property and equipment is carried at cost. Major items and betterments are capitalized; maintenance and repairs are charged to expense as incurred. The Company capitalizes certain costs incurred in connection with developing or obtaining internal-use software. Software costs that do not meet capitalization criteria are expensed as incurred. Demonstration equipment represents internally manufactured capital equipment that is used on-site at trade shows and at customer locations to demonstrate the CorPath System. Field equipment represents internally manufactured capital equipment placed at customer locations under a program that involves the placement of a system at the customer's site and the customer's agreement to purchase a minimum number of cassettes each month. At December 31, 2015, the Company had placed six field equipment units and four units for a customer's evaluation under such arrangements.

Depreciation on the demonstration equipment is charged to selling, general and administrative and the depreciation on the field equipment is charged to cost of revenue. Depreciation is computed under the straight-line method over the estimated useful lives of the respective assets.

Depreciation is provided over the following estimated asset lives:

Machinery and equipment	5 years
Computer equipment	3 years
Office furniture and equipment	5 years
Leasehold improvements	Shorter of life of lease or useful life
Vendor tooling	1.5 - 3 years, based on planned usage
Software	4 years
Demonstration equipment	3 years
Field equipment	3 years

**Impairment of Long-Lived Assets**

The Company's long-lived assets principally consist of property and equipment. The Company continually monitors events and changes in circumstances that could indicate carrying amounts of long-lived assets may not be recoverable. An impairment loss is recognized when expected cash flows are less than an asset's carrying value. Accordingly, when indicators of impairment are present, the Company evaluates the carrying value of such assets in relation to the operating performance and estimated future undiscounted cash flows of the underlying assets. The Company's policy is to record an impairment loss when it is determined that the carrying amount of the asset may not be recoverable. No such impairment changes have been recognized.

**Comprehensive Loss**

Comprehensive loss is comprised of net loss and changes in the unrealized gains and losses on marketable securities. Accumulated other comprehensive loss, a component of stockholders' equity, is comprised of the cumulative unrealized gains and/or losses from the change in fair market value of the Company's marketable securities. Accumulated other comprehensive loss was \$14 as of December 31, 2015.

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**Revenue Recognition**

The CorPath System is a capital medical device used by hospitals and surgical centers to perform heart catheterizations. Use of the CorPath System requires a sterile, single-use cassette (the "CorPath Cassette"), which are sold separately, for each procedure. Products are sold to customers with no rights of return. The Company recognizes revenue on the sale of products when the following criteria are met:

- Persuasive evidence of an arrangement exists
- The price to the buyer is fixed or determinable
- Collectability is reasonably assured
- Risk of loss transfers and the product is delivered.

In each arrangement, the Company is responsible for installation of the CorPath System and initial user training, which services are deemed essential to the functionality of the system. Therefore, the Company recognizes system revenue when the CorPath System is delivered and installed, and accepted by the end user customer.

Each CorPath System is sold with a standard one year warranty, which provides that the CorPath System will function as intended and during that one year period, the Company will either replace the product or a portion thereof or provide the necessary repair service during the Company's normal service hours. The Company accrues for the estimated costs of the warranty once the CorPath System revenue is recognized.

The Company generally enters into multiple element arrangements, which include the sale of a CorPath System with an initial order of CorPath Cassettes, and may include either a basic service plan or a premium service plan. The basic service plan provides for an extended warranty period and the premium service plan provides for the extended warranty as well as component upgrades, when and if they become available during the service plan period. Deliverables, which are accounted for as separate units of accounting under multiple-element arrangements include: (a) the CorPath System, including installation and initial training, which are subject to customer acceptance and (b) the initial shipment of CorPath Cassettes to the customer, and may include either (c) an extended warranty or (d) component upgrades.

The Company recognizes revenue on multiple-element arrangements in accordance with Accounting Standards Update ("ASU") 2009-13, Revenue Recognition (Topic 605): Multiple Deliverable Revenue Arrangements, based on the estimated selling price of each element. In accordance with ASU 2009-13, the Company uses vendor-specific objective evidence ("VSOE"), if available, to determine the selling price of each element. If VSOE is not available, the Company uses third-party evidence ("TPE") to determine the selling price. If TPE is not available, the Company uses its best estimate to develop the estimated selling price ("BESP"). The Company uses BESP to determine the selling price of its systems as well as the basic and premium service plans. BESP is determined based on estimated costs plus a reasonable margin, and has generally been consistent with the price charged to the customer for such products and services. The determination of BESP also considers the price of the service plans charged to customers when such services are sold separately in subsequent transactions. The Company also uses BESP to determine the selling price of the initial order of cassettes, which considers the price at which it charges its customers when the cassettes are sold separately.

Revenue related to basic service plans is recognized on a straight-line basis over the life of the service contract. Revenue related to premium service plans is recognized over the life of the service contract, with consideration given to the expected timing of costs to be incurred related to the delivery of component upgrades. Revenues from accessories are recorded upon delivery and services provided by the Company outside of a basic or premium service contract are recognized as the services are provided.

There are no performance, cancellation, termination, and refund-type provisions under the Company's multiple element arrangements.

On January 21, 2011, the Company entered into a distributor agreement with Philips Medical Systems Nederland, B.V. ("Philips") appointing Philips to be the sole worldwide distributor for the promotion and sale of the Company's CorPath System. Under the agreement, Philips sold the equipment directly to the end user and the Company was responsible for installation and initial training. Revenue was recognized on a net basis based on the amount billed to Philips and upon acceptance of the system by the end-user customer. This agreement with Philips expired on August 7, 2014. The Company continues to sell CorPath Systems through Philips on a sale by sale basis under a non-exclusive arrangement under mutually agreeable terms, which may include a continued level of discounted pricing, until such time the Company either executes a new distribution arrangement with Philips or the Company no longer does business with Philips. At December 31, 2014 and 2015, there were no amounts outstanding from Philips.



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The Company also sells CorPath Cassettes under a CorPath Utilization Program (“CUP”), which is a multi-year arrangement that involves the placement of a CorPath System at a customer’s site free of charge and the customer agrees to purchase a minimum number of CorPath Cassettes each month at a premium over the regular price. The Company records revenue upon shipment of the cassettes based on the selling price of the CorPath Cassettes. The system is capitalized as field equipment in property and equipment and is depreciated on a straight line basis through cost of revenue over the estimated useful life of the system, which generally approximates the length of the CUP program contract, which is typically 36 months.

The Company also offers a One-Stent program to demonstrate its confidence in the CorPath System’s ability to help accurately measure anatomy and precisely place only one stent per lesion. The Company provides eligible customers registered under the program a \$1 credit against future CorPath Cassette purchases for a qualifying CorPath percutaneous coronary intervention (“PCI”) procedure which uses more than one stent per lesion. The estimated cost of honoring the potential obligation under the stent program is recorded as a reduction of revenue at the time of shipment. These costs have not been significant to date.

The Company records shipping and handling costs as a selling expense in the period incurred, and records payments from customers for shipping costs as a reduction of selling expenses. Such amounts have not been material in the periods presented. The Company recorded medical device excise tax in the amount of \$29, \$40 and \$34 for the years ended December 31, 2013, 2014 and 2015, respectively, which is included in selling, general and administrative expenses. At the present time the excise tax is suspended due to the operation of a provision in the Consolidated Appropriations Act of 2016, signed into law on December 18, 2015 but that two-year moratorium ends on December 31, 2017.

**Research and Development**

Costs for research and development are expensed as incurred. Research and development expense consists primarily of salaries, salary-related expenses and costs of contractors and materials.

**Income Taxes**

The Company accounts for income taxes using the liability method, whereby deferred tax asset and liability account balances are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are realizable.

The Company accounts for uncertain tax positions using a “more-likely-than-not” threshold for recognizing and resolving uncertain tax positions. The evaluation of uncertain tax positions is based on factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. The Company evaluates these tax positions on an annual basis. The Company also accrues for potential interest and penalties related to unrecognized tax benefits in income tax expense.

The Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances.

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**Stock-Based Compensation**

The Company recognizes compensation costs resulting from the issuance of stock-based awards to employees and directors as an expense in the consolidated statements of operations over the requisite service period based on a measurement of fair value for each stock award. The awards issued to date have been stock options with service-based vesting periods over two or four years. The Company recognizes compensation costs resulting from the issuance of stock-based awards to non-employees as an expense in the consolidated statements of operations over the service period based on a measurement of fair value for each stock award at each performance date and period end.

Prior to the completion of the reverse acquisition, the fair value of the common stock was determined by the Board of Directors after considering a broad range of factors, including the results obtained from an independent third-party valuation, the illiquid nature of an investment in the Company's Common Stock, the Company's historical financial performance and financial position, the Company's future prospects and opportunity for liquidity events, and recent sale and offer prices of Common and Preferred Stock in private transactions negotiated at arm's length. Subsequent to the completion of the reverse acquisition, the fair value of the Common Stock was obtained from quoted market prices on the OTCQB as provided by OTC Market Groups, Inc. In connection with the public offering in May 2015, the Company's common stock was approved for listing on the NYSE MKT, where it commenced trading under the symbol "CVRS".

The following assumptions were used to estimate the fair value of stock options granted using the Black-Scholes-Merton option-pricing model ("Black-Scholes Model"):

	<b>Years ended December 31,</b>		
	<b>2013</b>	<b>2014</b>	<b>2015</b>
Risk-free interest rate	0.72% to 1.43 %	1.89% to 2.01%	1.54% to 1.97 %
Expected term in years	5.75 to 6.25	6.25	6.08
Expected volatility	80 %	50 %	50%
Expected dividend yield	0 %	0 %	0%

The risk-free interest rate assumption is based upon observed U.S. government security interest rates with a term that is consistent with the expected term of the Company's employee stock options. The expected term is based on the average of the vesting period and contractual term of the Company's options given the lack of historical data available. The Company does not pay a dividend, and is not expected to pay a dividend in the foreseeable future.

Due to a lack of a public market for the Company's Common Stock for an extended period of time, the Company utilized comparable public companies' volatility rates as a proxy of its expected volatility for purposes of the Black-Scholes Model. Stock-based compensation expense is recorded net of estimated forfeitures and is adjusted periodically for actual forfeitures. The Company uses historical data to estimate forfeiture rates. For the years ended December 31, 2013, 2014 and 2015, forfeitures were estimated to be 4.9%, 6.0% and 5.0%, respectively.

**Warrant Liability**

The Company reviews the terms of warrants issued in connection with the applicable accounting guidance and classifies warrants as a long-term liability on the consolidated balance sheets if the warrant may conditionally obligate the Company to transfer assets, including repurchase of the Company's capital stock, at some point in the future. Warrants to purchase shares of redeemable convertible preferred stock met these criteria and therefore required liability-classification. The Company classifies warrants within stockholders' equity on the consolidated balance sheets if the warrants are considered to be indexed to the Company's own capital stock, and otherwise would be recorded in stockholders' equity.

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Liability-classified warrants are subject to re-measurement at each balance sheet date, and any change in fair value is recognized as a component of other income (expense) in the consolidated statements of operations. The Company estimated the fair value of these warrants at issuance and each balance sheet date thereafter using the Black-Scholes Model as described in the stock-based compensation section above, based on the estimated market value of the underlying Redeemable Convertible Preferred Stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying redeemable convertible preferred stock. The fair value of the Redeemable Convertible Preferred Stock was determined by the Board of Directors after considering a broad range of factors, including the results obtained from an independent third-party valuation, the illiquid nature of an investment in the Company's Redeemable Convertible Preferred Stock, the Company's historical financial performance and financial position, the Company's future prospects and opportunity for liquidity events, and recent sale and offer prices of Common and Preferred Stock in private transactions negotiated at arm's length.

The Company had warrants outstanding to purchase shares of Series A, D and E Redeemable Convertible Preferred Stock, which converted into warrants to purchase shares of Common Stock at the date of the Acquisition. Prior to the Acquisition, the warrant instruments required mark-to-market accounting which was recorded in the statements of operations based on their fair values determined using the Black-Scholes Model and the fair value of underlying Preferred Stock. The warrant instruments were re-valued for the last time at the date of the Acquisition and reclassified into stockholders' equity in 2014, and at December 31, 2014 and 2015, the Company did not have a warrant liability.

**Related-Party Transactions**

On January 21, 2011, the Company entered into a distributor agreement with Philips appointing Philips to be the sole distributor for the promotion and sale of the Company's CorPath System. The agreement was terminated on August 7, 2014. The Company continues to sell CorPath Systems through Philips on a sale by sale basis under a non-exclusive arrangement under mutually agreeable terms, which may include a continued level of discounted pricing, until such time the Company either executes a new distribution arrangement with Philips or the Company no longer does business with Philips.

For the years ended December 31, 2013, 2014 and 2015, the Company recorded revenues of \$630, \$315 and \$125, respectively, from shipments to Philips under the distribution agreement. At December 31, 2014 and 2015, there were no amounts outstanding from Philips, resulting from selling activity under the agreement. As of December 31, 2015, Koninklijke Philips, N.V. ("Philips' Parent"), held approximately 15% of the Company's outstanding Common Stock.

**Recent Accounting Pronouncements Not Yet Adopted**

In May 2014, the FASB issued ASU 2014-09—Revenue from Contracts with Customers, which amends FASB Accounting Standards Codification Topic 606. ASU 2014-09 provides a single, comprehensive revenue recognition model for all contracts with customers. This standard contains principles for the determination of the measurement of revenue and the timing of when such revenue is recognized. Revenue recognition will reflect the transfer of goods or services to customers at an amount that is expected to be earned in exchange for those goods or services. ASU 2014-09 was scheduled to be effective for annual reporting periods beginning after December 15, 2016, and early adoption was not permitted. In August 2015, the FASB issued ASU No. 2015-14—Revenue from Contracts with Customers: Deferral of Effective Date, which defers the effective date of ASU 2014-09 by one year. ASU 2014-09 is now effective for annual periods after December 15, 2017 including interim periods within that reporting period. Early adoption is permitted, but not before the original effective date. The Company is currently assessing the impact of this standard to its consolidated financial statements.

In August 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. The amendments in this update will explicitly require a company's management to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures in certain circumstances. The new standard will be effective in the first annual period ending after December 15, 2016. Early adoption is permitted. If this standard had been adopted as of December 31, 2015, the Company believes that it would have concluded there was not substantial doubt about its ability to continue as a going concern. However, the Company faces certain risks and uncertainties, as further described in Note 1, Nature of Operations, that could have affected this analysis.

In January 2015, the FASB issued Financial Accounting Standards Update—Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items. Subtopic 225-20, Income Statement—Extraordinary and Unusual Items, previously required that an entity separately classify, present, and disclose extraordinary events and transactions. This update is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015 and may be applied prospectively or retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The Company does not expect the impact of adoption to be material to its consolidated financial statements.

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In February 2015, the FASB issued ASU 2015-02, Consolidation (Topic 810) to address financial reporting considerations for the evaluation as to the requirement to consolidate certain legal entities. ASU 2015-02 is effective for fiscal years and for interim periods within those fiscal years beginning after December 15, 2015. The Company does not expect the impact of ASU 2015-02 to be material to its consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, Interest—Imputation of Interest (Subtopic 835-30) as part of the initiative to reduce complexity in accounting standards. The update requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 is effective for annual periods beginning after December 15, 2015 and for interim periods within those fiscal years. The Company does not expect the impact of ASU 2015-03 to be material to its consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. Under this accounting guidance, inventory will be measured at the lower of cost and net realizable value and other options that currently exist for market value will be eliminated. ASU 2015-11 defines net realizable value as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. No other changes were made to the current guidance on inventory measurement. The guidance is effective for annual reporting periods and interim periods within those annual reporting periods beginning after December 15, 2016. Early adoption is permitted and the prospective transition method should be applied. The Company is currently evaluating the impact of ASU 2015-11 on its consolidated financial statements.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities. The update addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. ASU 2016-01 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Early adoption is permitted only for certain portions of the ASU related to financial liabilities. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), which amends leasing accounting requirements. The new standard requires lessee recognition on the balance sheet of a right-of-use asset and a lease liability, initially measured at the present value of the lease payments. It further requires recognition in the income statement of a single lease cost, calculated so that the cost of the lease is allocated over the lease term on a generally straight-line basis. Finally, it requires classification of all cash payments within operating activities in the statement of cash flows. It is effective for fiscal years commencing after December 15, 2018 and early adoption is permitted. The Company is currently evaluating the impact of this standard on its consolidated financial statements.

### 3. Inventories

The Company's inventories are valued at the lower of cost or market using the FIFO method and consist of the following:

	<b>December 31,</b>	
	<b>2014</b>	<b>2015</b>
Raw materials	\$ 737	\$ 483
Work in progress	198	79
Finished goods	584	767
	<u>\$ 1,519</u>	<u>\$ 1,329</u>

In the fourth quarter of 2015, the Company reclassified certain of its original equipment manufacturer ("OEM") parts from raw materials to finished goods to be consistent with how all of its OEM parts were being classified. For the year ended December 31, 2014, the inventory balances include a reclassification of \$124 from raw materials to finished goods in order to conform to the current year's presentation.

**Corindus Vascular Robotics, Inc.**  
**Notes to Consolidated Financial Statements**  
*In thousands, except share and per share amounts*

**4. Property and Equipment**

Property and equipment are stated at cost and are being depreciated using the straight-line basis over the assets' estimated useful lives. Depreciation and amortization expense was \$607, \$622 and \$706 for the fiscal years 2013, 2014 and 2015, respectively. Property and equipment consist of the following:

	December 31,	
	2014	2015
Machinery and equipment	\$ 334	\$ 441
Computer equipment	273	286
Office furniture and equipment	355	360
Leasehold improvements	67	70
Vendor tooling	711	715
Software	490	498
Demonstration equipment	633	717
Field equipment	588	1,004
Construction in progress	—	126
	3,451	4,217
Less accumulated depreciation and amortization	(2,167)	(2,835)
Property and equipment, net	\$ 1,284	\$ 1,382

Construction in progress at December 31, 2015 relates to vendor tooling that is currently in the design and testing stage which will be used in the Company's production process.

**5. Notes Receivable**

On June 14, 2010, the Company loaned funds to certain stockholders of the Company for tax payments to be made to the Israel Tax Authority in connection with a tax ruling related to a reorganization that took place in 2008 and the Company received non-interest bearing notes receivable, which documented such loans. Total amount of notes receivable issued was \$145.

The notes receivable are repayable upon the disposition of the Company's Common Stock. Notes receivable in the amount of \$136 were outstanding at both December 31, 2014 and 2015. The Company assessed the notes receivable for impairment and concluded that there was no impairment indicators at December 31, 2014 and 2015. The Company does not believe there is any collection risk associated with the notes receivable at December 31, 2015.

In February 2016, the Company received a payment of \$65 related to this notes receivable balance as one of the stockholders had recently sold some of their shares of the Company's common stock.

**6. Accrued Expenses**

Accrued expenses consist of the following:

	2014	2015
Payroll and benefits	\$ 185	\$ 79
Professional and consultant fees	496	444
Travel expenses	57	113
Product development costs	62	44
Commissions	85	187
Warranty	61	68
Interest	48	71
Other	143	193
	\$ 1,137	\$ 1,199

Certain items classified as "Other" in the prior year, travel expense and interest, were changed to conform with the current year presentation.

**Corindus Vascular Robotics, Inc.**  
**Notes to Consolidated Financial Statements**  
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**7. Long-Term Debt**

On June 11, 2014, the Company entered into a Loan and Security Agreement pursuant to which the lender agreed to make available to the Company \$10,000 in two separate \$5,000 loans under secured promissory notes. The initial note was made on June 11, 2014 in an aggregate principal amount equal to \$5,000 (the "Initial Promissory Note") and is repayable in equal monthly installments of principal and interest over 27 months beginning on July 1, 2015. Prior to July 1, 2015, the Company was required to make interest only payments. The Initial Promissory Note bears interest at a rate equal to the greater of (a) 11.25% or (b) 11.25% plus the Wall Street Journal Prime Rate, less 3.25%, and includes an additional interest payment of \$125 due no later than October 1, 2017, which is accreted over the term of the loan. The effective interest rate of the Initial Promissory Note was 11.50% at December 31, 2015.

On December 31, 2014, the Company borrowed the additional \$5,000 (the "Second Promissory Note") under the Loan and Security Agreement. The Second Promissory note is also repayable in equal monthly installments of principal and interest over 27 months beginning on July 1, 2015. Prior to July 1, 2015, the Company was required to make interest only payments. The Second Promissory Note bears interest at a rate equal to the greater of (a) 9.95% or (b) 9.95% plus the Wall Street Journal Prime Rate, less 3.25%, and also includes an additional interest payment of \$125 due no later than October 1, 2017, which is accreted over the term of the loan. The effective interest rate of the Second Promissory Note was 10.20% at December 31, 2015. The notes are secured by substantially all the assets of the Company.

In connection with the Initial Promissory Note, the Company issued the lender warrants to purchase 177,514 shares of the Company's Common Stock at an exercise price of \$1.41 per share. The fair value of the warrant issued to the lender was determined to be \$230 at the date of issuance, and was recorded as a discount on the debt. Additionally, in connection with the Second Promissory Note, the Company issued the lender warrants to purchase 177,514 shares of the Company's Common Stock at an exercise price of \$1.41 per share. The fair value of the warrant issued to the lender was determined to be \$619 at the date of issuance, and was recorded as a discount on the debt. The Company amortizes the debt discount to interest expense over the term of the debt using the effective interest method.

The Company estimated the fair value of these warrants using the Black-Scholes Model based on the estimated market value of the underlying Common Stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock. The Company used the following assumptions for the valuation of its warrants issued on the following dates:

	June 11, 2014	December 31, 2014
Risk-free interest rate	2.5%	2.17%
Dividend yield	0.0%	0.0%
Expected volatility	50.0%	50.0%
Expected term (years)	10.00	9.44

The Loan and Security Agreement also contains covenants which include certain restrictions with respect to subsequent indebtedness, liens, loans and investments, asset sales and share repurchases and other restricted payments, subject to certain exceptions. The Loan and Security Agreement also contains financial reporting obligations. An event of default under the Loan and Security Agreement includes, but is not limited to, breach of covenants, insolvency, and occurrence of any default under any agreement or obligation of the Company. In addition, the Loan and Security Agreement contains a customary material adverse effect clause which states that in the event of a material adverse effect, an event of default would occur and the lender has the option to accelerate and demand payment of all or any part of the loan. A material adverse effect is defined in the Loan and Security Agreement as a material change in the Company's business, operations, properties, assets or financial condition or a material impairment of its ability to perform all obligations under its Loan and Security Agreement. The Company was not in default of any conditions under the Loan and Security Agreements as of December 31, 2015.

**Corindus Vascular Robotics, Inc.**  
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*In thousands, except share and per share amounts*

Borrowings outstanding, net of unamortized discount of \$414 and \$150 of additional interest payments, amounted to \$7,715 at December 31, 2015. Future principal payments under the borrowing arrangement as of December 31, 2015 are as follows:

Year ending December 31:	
2016	\$ 4,373
2017	3,605
	<u>\$ 7,978</u>

**8. Income Taxes**

There was no federal or state provision for income taxes for the years ended December 31, 2013, 2014 or 2015 due to the Company's operating losses and a full valuation allowance on deferred income tax assets for all periods since inception. All of the Company's loss before provision for income taxes is attributable to its United States operations.

The Company's effective income tax rate differs from the statutory federal income tax rate as follows:

	Years Ended December 31,		
	2013	2014	2015
Statutory U.S. federal rate	34.0%	34.0%	34.0%
State income tax	4.7	1.7	3.7
Permanent items	0.6	(3.8)	(0.4)
Change in taxing status in Massachusetts to a manufacturer	—	(4.9)	—
Other	(0.8)	(0.7)	(0.5)
Change in state tax rate	—	—	0.7
Federal R&D credits	2.0	1.2	1.3
State R&D and other credits	0.5	0.7	0.5
Change in valuation allowance	(41.0)	(28.2)	(39.3)
Total expense (benefit)	—%	—%	—%

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and the related valuation allowance were as follows:

	December 31,	
	2014	2015
Deferred income tax assets:		
Operating loss carryforwards	\$ 20,178	\$ 30,832
Start-up expenditures	2,807	2,711
Property and equipment	46	28
Intangible assets	2,589	—
Stock-based compensation expense	738	788
Research and development credit carryforwards	1,216	1,746
Accrued expenses and other	307	482
Total deferred income tax assets	27,881	36,587
Valuation allowance	(27,881)	(36,587)
Net deferred income tax assets	<u>\$ —</u>	<u>\$ —</u>

**Corindus Vascular Robotics, Inc.**  
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The Company has provided a full valuation allowance against the deferred income tax assets, since it has a history of losses, which are all attributable to the U.S. and currently does not have enough positive evidence required under U.S. GAAP to reverse its valuation allowance. Management does not believe it is more likely than not that its deferred tax assets relating to the loss carryforwards and other temporary differences will be realized in the future. For the years ended December 31, 2014 and 2015, the valuation allowance increased by \$6,912 and \$8,706 respectively, resulting principally from increased operating loss carryforward.

Deferred tax assets relating to tax benefits of employee share-based compensation have been reduced for stock options exercised in periods in which the Company was in a net operating loss (NOL) position. Some exercises resulted in tax deductions in excess of previously recorded benefits based on the stock option value at the time of the grant (windfalls). Although windfalls are reflected in NOL carryforwards in the tax return, the additional tax benefit associated with the windfalls is not recognized until the deduction reduces taxes payable pursuant to U.S. GAAP. Accordingly, since the tax benefit does not reduce the Company's current taxes payable due to NOL carryforwards, these windfall tax benefits are not reflected in the Company's NOLs in deferred tax assets. Windfalls included in NOL carryforwards but not reflected in deferred tax assets as of December 31, 2015 totaled \$850.

At December 31, 2015, the Company had U.S. federal and state net operating loss carryforwards of approximately \$82,989 and \$56,585, respectively, that can be carried forward and offset against future taxable income. These net operating loss carryforwards will begin to expire in 2028. Utilization of net operating losses may be subject to a substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986, and similar state provisions. The annual limitation may result in the expiration of net operating losses before utilization. The Company has determined no ownership changes have occurred to date that would place limitations on the ability to use net loss carryforwards, but will continue to monitor any future shifts in ownership that could cause limitations.

Significant judgment is required in evaluating the Company's tax positions and in determining the Company's provision for income taxes. In the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. As of December 31, 2015, the Company was not under audit in any tax jurisdiction. The U.S. statute of limitations will remain open to examination by the tax authorities until the utilization of net operating loss carryforwards. The Company accrues interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

**9. Stockholders' Equity**

The Company is authorized to issue 250,000,000 shares of common stock. Holders of Common Stock are entitled to vote on all matters and are entitled to the number of votes equal to the number of common shares held. Holders of Common Stock shall be entitled to receive dividends when and if declared by the Board of Directors. No dividends have been declared to date. In certain events, including the liquidation, dissolution or winding up of the Company, the remaining assets of the Company shall be distributed ratably among the holders of Common Stock.

The Company is authorized to issue 10,000,000 shares of preferred stock. As of December 31, 2014 and 2015, the Company had no shares of preferred stock issued or outstanding.

At December 31, 2015, there were 23,569,951 shares of common stock reserved for the potential exercise of warrants (5,207,379) and stock options (8,778,503), and 9,584,069 shares that are available for grant under the 2014 Stock Award Plan.

**10. Stock-Based Compensation**

In connection with the Company's reverse acquisition in August 2014, Corindus exchanged options to purchase shares of its Common Stock for YIDI's options to purchase shares of YIDI's Common Stock (the "Replacement Plan Options"). The 2014 Stock Award Plan is the replacement plan for options previously awarded under the Corindus, Inc. 2006 Umbrella Option Plan and the Corindus, Inc. 2008 Stock Incentive Plan and is the plan under which all future Company options will be issued. The 2014 Stock Award Plan was limited to award issuances which in the aggregate could not exceed 9,035,016 shares, all of which shares will be used for the issuance of the Company stock-based awards, including options to purchase common stock, restricted stock and restricted stock units. Replacement Plan Options are exercisable for up to ten years from the date of original vesting commencement date of the options.

On April 30, 2015, the Company's Board of Directors and shareholders owning a majority of the Company's outstanding shares of common stock approved an increase in the authorized shares of common stock under the 2014 Stock Award Plan from 9,035,016 shares to 18,661,856 shares.



**Corindus Vascular Robotics, Inc.**  
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A summary of the activity under the Company's stock option plans is as follows. Such information has been retrospectively adjusted to give effect to the exchange of stock options that occurred upon the Acquisition.

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding at December 31, 2014	8,678,017	\$ 0.64	6.30	\$ 31,359
Granted	1,454,486	\$ 3.51		
Exercised	(347,392)	\$ 0.28		
Cancelled	(1,006,608)	\$ 0.80		
Outstanding at December 31, 2015	<u>8,778,503</u>	\$ 1.11	5.98	\$ 18,876
Exercisable at December 31, 2015	<u>6,673,104</u>	\$ 0.63	5.01	\$ 17,220
Vested and expected to vest at December 31, 2015	<u>8,673,233</u>	\$ 1.09	5.95	\$ 18,813

Stock-based compensation expense was allocated based on the employees' function as follows:

	Years ended December 31,		
	2013	2014	2015
Research and development	\$ 59	\$ 95	\$ 74
Selling, general and administrative	270	282	431
	<u>\$ 329</u>	<u>\$ 377</u>	<u>\$ 505</u>

The fair value of employee options is estimated on the date of each grant using the Black-Scholes Model. The weighted-average grant date fair value of options granted during the year ended December 31, 2013, 2014 and 2015 were \$0.24, \$0.16 and \$1.80, respectively. As of December 31, 2015, there was approximately \$2,415 of unrecognized compensation cost related to non-vested stock-based compensation arrangements under the 2014 Stock Award Plan. That cost was expected to be recognized over a weighted-average period of 3.38 years.

The total intrinsic value of options exercised in 2015 was \$995.

#### 11. Warrants to Purchase Common Stock

In connection with the Acquisition, the Company exchanged warrants to purchase 201,178 shares of Corindus, Inc. Series A, D and E Redeemable Convertible Preferred Stock at an average exercise price of \$26.63 per share to warrants to purchase 5,029,865 shares of the Company's Common Stock at the average exercise price of \$1.07 per share.

Prior to the Acquisition, the warrants were treated as liability instruments and were measured on a recurring basis at their fair value with inputs categorized as Level 3 in the fair value hierarchy. The resulting gain or loss on revaluation was recorded as other income (expense) in the consolidated statements of operations. The Company estimated the fair value of these warrants using the Black-Scholes Model based on the estimated market value of the underlying Redeemable Convertible Preferred Stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying Redeemable Convertible Preferred Stock.

**Corindus Vascular Robotics, Inc.**  
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The Company revalued the warrants for the final time at the date of the Acquisition, which resulted in a charge of \$2,421 for the year ended December 31, 2014. A roll forward of the warrant liability is as follows:

Balance at December 31, 2013	\$ 3,152
Issuance of warrants in connection with lending arrangement	230
Revaluation of warrants	2,421
Reclassification of warrant liability to stockholders' equity	(5,803)
Balance at December 31, 2014	<u>\$ —</u>

The Company used the following assumptions for the valuation of its warrant liability:

	August 12, 2014
Risk-free interest rate	1.025%
Dividend yield	0.0%
Expected volatility	50.0%
Expected term (years)	3.5

The Company has following warrants outstanding at December 31, 2015:

Exercise Price	Date of Expiration	Number of Warrants
\$1.06	October 11, 2017	4,728,191
\$0.76	May 31, 2017	124,160
\$1.41	May 28, 2020	355,028
		<u>5,207,379</u>

**12. Commitments and Contingencies**

The Company has an operating lease for approximately 26,402 square feet at its corporate headquarters and manufacturing plant in Waltham, Massachusetts, which expires in January 2018 and the Company has an option to extend for an additional five years at market rates or the rates payable in the final years of the term of the lease, whichever is greater. The lease terms include escalating rent payments over the life of the lease and rent expense is recognized over the life of the lease on a straight-line basis. The difference between the amount expensed and actual rent payments are recorded as a deferred rent included within accrued expenses in the consolidated balance sheets. In connection with the lease, the Company is required to maintain a security deposit with its landlord, which declines every six months during the lease until January 2016, at which point the amount remains constant at \$134. The total amount of the security deposit is approximately \$178 at December 31, 2015, of which \$45 is included in prepaid expenses and other current assets. The Company also leases copiers and vehicles under operating leases that expire at various points through 2019.

Total rent expense was \$584, \$577 and \$574 for the years ending December 31, 2013, 2014 and 2015, respectively. At December 31, 2015, the Company's future minimum lease payments are indicated below:

Year ending December 31:	Total Lease Payments
2016	\$ 573
2017	586
2018	49
Total	<u>\$ 1,208</u>

The Company is subject to potential claims from time to time in the ordinary course of business. At December 31, 2015, the Company is not subject to any significant asserted or unasserted claims.

**Corindus Vascular Robotics, Inc.**  
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**13. Net Loss per Share**

Basic net loss per share is computed by dividing net loss by the weighted average shares of common stock outstanding for each period. Diluted net loss per share is the same as basic net loss per share since the Company has net losses for each period presented. The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	<b>Years Ended December 31,</b>		
	<b>2013</b>	<b>2014</b>	<b>2015</b>
Options to purchase Common Stock	8,548,357	8,678,017	8,778,503
Warrants to purchase Common Stock	4,852,351	5,207,379	5,207,379
<b>Total</b>	<b>13,400,708</b>	<b>13,885,396</b>	<b>13,985,882</b>

**14. Restructuring Charge**

During 2014, the Company initiated reductions in workforce to control costs while the Company pursued new financing alternatives. During 2014, the Company recorded \$175 in restructuring charges for severance and related costs, which were paid in 2014.

**15. 401(k) Plan**

The Company has a tax-qualified employee savings and retirement 401(k) plan, covering all qualified employees. Participants may elect a salary deferral up to the statutorily prescribed annual limit for tax-deferred contributions. The Company has not made any matching contributions to date.

**Corindus Vascular Robotics, Inc.**  
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**16. Selected Quarterly Financial Data (Unaudited)**

The following table presents unaudited operating results for each of the Company's quarters in the years ended December 31, 2015 and 2014:

	<b>Fiscal Year 2015 Quarters</b>				
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>	<b>Year</b>
Revenue	\$ 776	\$ 909	\$ 212	\$ 832	\$ 2,729
Cost of revenue	801	941	722	1,260	3,724
Gross profit (loss)	(25)	(32)	(510)	(428)	(995)
Operating expenses	6,747	6,839	6,148	6,442	26,176
Operating loss	(6,772)	(6,871)	(6,658)	(6,870)	(27,171)
Total other expense, net	(397)	(432)	(404)	(359)	(1,592)
Net loss	<u>\$ (7,169)</u>	<u>\$ (7,303)</u>	<u>\$ (7,062)</u>	<u>\$ (7,229)</u>	<u>\$ (28,763)</u>
Net loss per share - basic and diluted	<u>\$ (0.07)</u>	<u>\$ (0.07)</u>	<u>\$ (0.06)</u>	<u>\$ (0.06)</u>	<u>\$ (0.25)</u>

  

	<b>Fiscal Year 2014 Quarters</b>				
	<b>First</b>	<b>Second</b>	<b>Third</b>	<b>Fourth</b>	<b>Year</b>
Revenue	\$ 730	\$ 1,077	\$ 554	\$ 622	\$ 2,983
Cost of revenue	1,383	1,058	793	1,670 <sup>(1)</sup>	4,904
Gross profit (loss)	(653)	19	(239)	(1,048)	(1,921)
Operating expenses	4,949	4,388	5,148	5,299	19,784
Operating loss	(5,602)	(4,369)	(5,387)	(6,347)	(21,705)
Total other income (expense)	1,768	(1,341)	(3,062)	(201)	(2,836)
Net loss	<u>\$ (3,834)</u>	<u>\$ (5,710)</u>	<u>\$ (8,449)</u>	<u>\$ (6,548)</u>	<u>\$ (24,541)</u>
Net loss per share - basic and diluted	<u>\$ (0.05)</u>	<u>\$ (0.08)</u>	<u>\$ (0.10)</u>	<u>\$ (0.06)</u>	<u>\$ (0.29)</u>

<sup>(1)</sup> Includes \$536 from the correction of an immaterial error related to inventory overhead costs that were overstated in the 2013 consolidated financial statements.

**17. Subsequent Events**

The Company has evaluated all events or transactions that occurred after December 31, 2015 through the date of filing of the Form 10-K. In the judgment of management, there were no material events that impacted the consolidated financial statements or disclosures.

**EXHIBIT 21**

**SUBSIDIARIES OF THE REGISTRANT**

- Corindus, Inc., a Delaware corporation and wholly-owned subsidiary
  - Corindus Security Corporation, a Delaware corporation and wholly-owned subsidiary
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EXHIBIT 23.1

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statements (Form S-8 Nos. 333-203107 and 333-206349) pertaining to the 2014 Stock Award Plan of Corindus Vascular Robotics, Inc. of our report dated March 11, 2016, with respect to the consolidated financial statements of Corindus Vascular Robotics, Inc. included in this Annual Report (Form 10-K) of Corindus Vascular Robotics, Inc. for the year ended December 31, 2015.

/s/ Ernst & Young LLP

Boston, Massachusetts  
March 11, 2016

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

I, Mark J. Toland, certify that:

- (1) I have reviewed this Annual Report on Form 10-K of Corindus Vascular Robotics, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements and other financial information included in this report fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 11, 2016

*/s/ Mark J. Toland*

Mark J. Toland  
Chief Executive Officer and President  
Principal Executive Officer

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

I, David W. Long, certify that:

- (1) I have reviewed this Annual Report on Form 10-K of Corindus Vascular Robotics, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- (3) Based on my knowledge, the financial statements and other financial information included in this report fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- (4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- (5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 11, 2016

*/s/ David W. Long*

David W. Long

Chief Financial Officer and Senior Vice President Principal Financial and Accounting 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 of Corindus Vascular Robotics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark J. Toland, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

March 11, 2016

*/s/ Mark J. Toland*

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Mark J. Toland  
Chief Executive Officer and President  
Principal Executive Officer

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request. This certification shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section, and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

EXHIBIT 32.2

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 of Corindus Vascular Robotics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David W. Long, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

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

March 11, 2016

*/s/ David W. Long*

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David W. Long  
Chief Financial Officer and Senior Vice President  
Principal Financial and Accounting Officer

A signed original of this certification has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request. This certification shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to liability under that section, and will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.