



FORM 10-K

CARDICA INC – CRDC

Filed: September 14, 2006 (period: June 30, 2006)

Annual report which provides a comprehensive overview of the company for the past year

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

Form 10-K

(Mark One)

- ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 30, 2006
- OR
- TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .

Commission file number 000-51772

CARDICA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State of Incorporation)

94-3287832
(I.R.S. Employer Identification No.)

900 Saginaw Drive
Redwood City, California 94063
(Address of Principal Executive Offices, including Zip Code)

(650) 364-9975
(Registrant's Telephone Number, Including Area Code)

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, \$0.001 par value
(Title of Class)

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding twelve 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.
Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). YES NO

As of September 1, 2006, the aggregate market value of the registrant's voting and nonvoting common stock held by non-affiliates of the registrant was approximately \$28,911,005, based on the closing price of Cardica's common stock on the Nasdaq National Market on September 1, 2006, of \$5.00 per share.

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Section 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. YES NO

The number of shares of registrant's common stock outstanding on September 1, 2006 was 9,815,693.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission, or SEC, pursuant to Regulation 14A in connection with the 2006 Annual Meeting of Stockholders to be held on November 8, 2006 are incorporated by reference into Part III of this report. Such Proxy Statement will be filed with the SEC within 120 days after the registrant's fiscal year ended June 30, 2006.

CARDICA, INC.
ANNUAL REPORT ON FORM 10-K
For the Year Ended June 30, 2006

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PART I

Item 1. *Business*

Overview

We design and manufacture proprietary automated anastomotic systems used by surgeons to perform coronary artery bypass surgery. In coronary artery bypass grafting procedures, or CABG, veins or arteries are used to construct alternative conduits to restore blood flow beyond narrowed or occluded portions of coronary arteries, “bypassing” the narrowed or occluded portion of the artery that is impairing blood flow to the heart muscle. Our first two products, the C-Port® Distal Anastomosis System, referred to as the C-Port system, and the PAS-Port® Proximal Anastomosis System, referred to as the PAS-Port system, provide cardiovascular surgeons with easy-to-use automated systems to perform consistent, rapid and reliable connections, or anastomoses, of the vessels, which surgeons generally view as the most critical aspect of the bypass procedure. We received 510(k) clearance from the Federal Drug Administration, or FDA, to market our C-Port system in the United States in November 2005. We currently sell the C-Port system in the United States and Europe, and the PAS-Port system in Europe, and in Japan through our distributor, Century Medical, Inc., referred to as Century. Our strategy is to further enhance and leverage our technology to develop additional automated anastomotic systems that facilitate the performance of minimally invasive endoscopic coronary bypass surgery, as well as automated systems to be used in other surgical applications, such as vascular closure.

The current method of performing an anastomosis in a CABG procedure utilizes a tedious and time-consuming hand-sewn suturing technique to connect a bypass graft to the aorta at one end, the proximal end, and to a small-diameter coronary artery at the other end, the distal end. We estimate that approximately 1.2 million of these blood vessel connections are performed annually in the United States. Proper vessel alignment and suture tension among the many individually placed fine stitches are critical for optimal bypass graft blood flow and function. By replacing the hand-sewn sutures with an easy-to-use, highly reliable and consistent automated system, the time required for completing the anastomoses can be reduced. We believe that our automated systems can also improve the quality and consistency of the anastomoses, which we believe will ultimately contribute to improved patient outcomes.

Our C-Port system is used to perform a distal anastomosis, which is the connection of a bypass graft vessel to the coronary artery downstream of the narrowed or occluded coronary artery. The C-Port system received the CE Mark in April 2004, which is required for marketing in the European Union, and 510(k) clearance from the FDA in November 2005, which is required for marketing in the United States. As of June 30, 2006, we had sold over 600 C-Port systems. In addition, we are currently designing the next iteration of our C-Port system, referred to as the C-Port xA system, intended for use in endoscopic coronary bypass surgery.

Our PAS-Port system is used to perform a proximal anastomosis, which is the connection of a bypass graft vessel to the aorta, the source of blood for the bypass. The PAS-Port system received the CE Mark in March 2003 and regulatory approval from Japanese regulatory authorities in January 2004 for distribution in Japan. The PAS-Port system is being sold in Japan through Century. According to Century, the PAS-Port system has been used in Japan in over 130 hospitals and has an estimated 15% market share of all proximal anastomoses performed in beating heart surgery using a vein as the bypass graft. As of June 30, 2006, more than 3,700 PAS-Port systems had been sold in Europe and Japan. In June 2006, we commenced a randomized, prospective clinical trial in 11 centers in the United States and in Europe to study the safety and efficacy of the PAS-Port system.

Industry Background

Coronary Artery Disease

According to the American Heart Association, approximately 13.2 million Americans have coronary artery disease, and approximately 653,000 people in the United States die each year as a result of the disease. Coronary artery disease, sometimes referred to as atherosclerosis, is a degenerative disease resulting from the deposit of cholesterol and other fatty materials on the interior walls of blood vessels, forming a build-up known as plaque. The accumulation of plaque, usually over decades, causes the vessel to become inelastic and progressively narrows the interior of the artery, impairing its ability to supply blood and oxygen to the heart muscle. When there is insufficient

blood flow to the heart muscle, an injury may occur, often resulting in chest pain, or angina, a heart attack or even death. Coronary artery disease is caused by aging and is exacerbated by dietary and environmental factors, as well as by genetic predisposition. As a patient ages, the disease will typically advance and become more diffuse, compromising the coronary artery system more globally and occluding more small-diameter vessels.

Current Treatment Alternatives for Coronary Artery Disease

Physicians and patients may select among a variety of treatments to address coronary artery disease, with the selection often depending upon the stage and severity of the disease and the age of the patient. In addition to changes in patient lifestyle, such as smoking cessation, weight reduction, diet changes and exercise programs, the principal existing treatments for coronary artery disease include the following:

Medical Treatment with Pharmaceuticals

Before the advent of interventional cardiology or bypass surgery, medical treatment with pharmaceuticals was the only form of therapy available to patients with coronary heart disease. In patients with less severe disease, pharmaceuticals remain the primary treatment approach and include drugs such as platelet adhesion inhibitors or drugs that reduce the blood cholesterol or triglyceride levels. The objective for medical treatment with pharmaceutical agents is to reduce the incidence, progression or exacerbation of coronary artery disease and its associated symptoms. For more serious disease, however, pharmacological therapy alone is often inadequate.

Interventional Cardiology Techniques

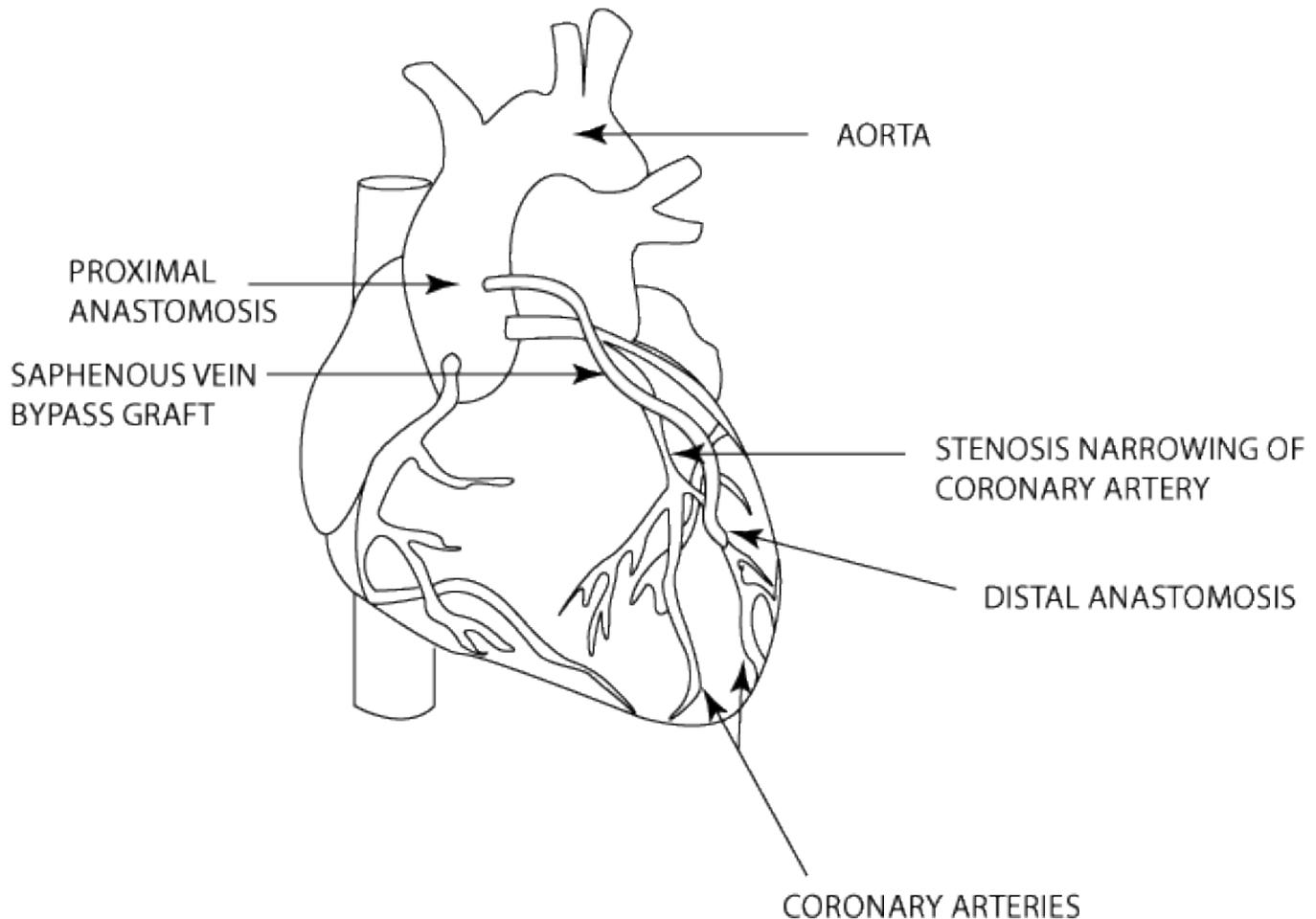
Coronary Angioplasty. Percutaneous transluminal coronary angioplasty, commonly referred to as balloon angioplasty, is a surgical procedure that involves the dilation of the obstructed artery with a balloon catheter. To perform an angioplasty, the surgeon maneuvers a flexible balloon catheter to the site of the blockage in the coronary artery, inflates the balloon, compressing the plaque and stretching the artery wall to create a larger channel for blood flow. The balloon is then deflated and removed. Angioplasty is generally successful in increasing immediate blood flow and, relative to current surgical procedures, offers the benefits of shorter periods of hospitalization, quicker recovery times, reduced patient discomfort and lower cost. However, angioplasty does not always provide prolonged efficacy: independent studies indicate that 25% to 40% of vessels treated with balloon angioplasty return to their pre-treatment, narrowed size, a process known as restenosis, within six months following the procedure. Restenosis is primarily the result of cell proliferation in response to the “injury” caused by the angioplasty procedure.

Stents. High rates of restenosis following treatment by balloon angioplasty led to the introduction of stents, mesh-like metallic tubes that are placed within the narrowed portion of the coronary vessel to hold the vessel open after the angioplasty balloon has been removed. Although clinical outcomes for procedures using stents reflect an improvement over balloon angioplasty alone, the effectiveness of stents is still limited by restenosis, which occurs in about 10% to 35% of cases within six months of the procedure.

Recently, some manufacturers have introduced drug-eluting stents, which incorporate, on the surface of the stent, specially formulated, slow-release drugs designed to prevent restenosis. According to published studies, currently marketed drug-eluting stents have been shown in clinical trials to reduce the rate of restenosis, within the first nine months after placement, to less than 10%. Market adoption of drug-eluting stents has been rapid, and industry observers predict that drug-eluting stents will capture approximately 90% of the stent market within three years.

Despite the advancements and market success of drug-eluting stents and angioplasty therapies, these interventional procedures may be less effective than CABG in addressing diffuse progressive coronary artery disease. In this advanced stage of coronary artery disease, intervention is required for multiple vessels, many of which are less than two millimeters in internal diameter, a diameter unsuited for angioplasty and stenting. In addition, stents have been shown to be difficult to place in patients with coronary lesions in sections with vessel branches and in patients with narrowings in the left main coronary artery.

Bypass Surgery. CABG involves the construction of an alternative path to bypass a narrowed or occluded coronary artery and restore blood flow from the aorta to an area past the occlusion. This procedure can be accomplished using either veins or arteries as bypass grafts. Veins are typically harvested from the patient's leg, while arteries are taken from either the patient's arm (radial artery) or chest wall (mammmary artery). One end of the harvested vessel is then generally attached to the aorta for blood inflow, and the opposite end is attached to the target coronary vessel. If a mammmary artery is used as the bypass graft, it must be dissected from the chest wall, leaving one end in place, while the opposite end is attached to the target vessel, providing uninterrupted blood flow from the arterial circulation. Once in place, these grafts provide sufficient blood flow to bypass the narrowed or occluded portion of the coronary artery. (See Figure Below).



Over the last decade approximately 90% of patients undergoing first time CABG surgery received a mammmary artery as a bypass graft vessel, a graft that does not require a proximal anastomosis, in addition to other bypass grafts such as veins and radial arteries. When the left anterior descending or LAD, artery is obstructed, CABG is most commonly performed by grafting the left internal mammmary artery, or LIMA, to the LAD. When other coronary arteries are obstructed, saphenous vein grafts are typically used as the bypass vessel. A study shows that patients who undergo a CABG procedure typically receive at least three bypass grafts, of which we believe a majority are performed using one artery and two veins as the bypass graft vessels.

Although CABG surgery is generally a highly invasive and even traumatic procedure, an independent study comparing CABG and implantation of conventional stents has shown that CABG is the more effective treatment for coronary artery disease, achieving the best long-term patient outcomes as measured by survival rate and need for intervention. Studies have shown that following CABG, grafts can remain patent, or open, and functional for as long as 10 years in approximately 50% of venous grafts and approximately 90% of arterial grafts. In addition, CABG procedures can be used to treat diffuse, end-stage coronary artery disease states that are not amenable to treatment by angioplasty or stents.

According to an independent analysis by Medtech Insight, a division of Windhover Information, entitled "Emerging U.S. Markets for Myocardial Revascularization, Repair, and Regeneration Products and Technologies," dated November 2004, an estimated 260,000 CABG procedures will be performed in 2005 in the United States, as compared to approximately 280,000 procedures in 2004. We believe that the decrease in CABG procedures is primarily attributable to the increase in other interventional cardiology procedures, including the increased use of drug-eluting stents. The average CABG surgery requires approximately three bypass grafts per patient, and a majority of grafts require an anastomotic connection at both ends of the graft. Assuming an average of

approximately five anastomoses per CABG procedure, we estimate that approximately 1.2 million of these blood vessel connections are performed in connection with CABG procedures annually in the United States. We believe approximately two-thirds of the procedures are performed using veins as the bypass graft.

Types of CABG Procedures

There are currently three types of CABG, two of which are commonly performed:

Conventional On-Pump CABG Procedures. Conventional on-pump CABG procedures are particularly invasive and traumatic to the patient, typically requiring the surgeon to open the patient's chest cavity by splitting the sternum and to place the patient on a pump to circulate the blood throughout the body. Redirecting the blood flow to a pump enables the surgeon to clamp the aorta and stop the heart, which results in a motionless and bloodless field in which the surgeon can perform the difficult and tedious task of manually suturing the small vessels to one another. The absence of blood flow and motion are important factors in ensuring precision and providing positive clinical outcomes; however, the use of a pump for circulation exposes the patient's blood to foreign surfaces, which has been shown to increase the incidence of bleeding and short-term neurocognitive defects. Additionally, stopping the heart may result in impairment or damage to the heart muscle. Moreover, clamping of the aorta has been shown, in clinical studies, to cause the release of particles into the blood stream that may produce blockages in other parts of the body, such as the brain. Blockages in the brain can lead to neurological damage, including strokes. Clamping the aorta also carries the risk of injury to the vessel wall with later bleeding complications. Notwithstanding these potential problems the majority of CABG procedures performed today use this on-pump technique.

Off-Pump CABG Procedures. In 1995, a new method of performing CABG was introduced that avoids the use of external pumps, requiring the surgeon to perform the anastomosis while the heart is beating. The clinical literature suggests that this procedure, termed off-pump coronary artery bypass, or OPCAB, offers several benefits, including reductions in bleeding, kidney dysfunction, short-term neurocognitive dysfunction and length of hospital stay. OPCAB is currently used in approximately 25% of all CABG procedures performed in the United States.

Notwithstanding these advantages, the technical challenges inherent in OPCAB have impeded its widespread adoption. Because the patient's heart is beating during the procedure, the surgeon is required to perform the delicate anastomosis on a target vessel, which could be as narrow as one millimeter in internal diameter, while the vessel is moving with each heart contraction. The technical demands of the procedure, together with the longer learning curve required to achieve surgical proficiency, may also initially adversely affect long-term graft patency and completion of revascularization. In addition, surgeons will still typically be required to place a partially occluding clamp on the ascending aorta to hand suture the proximal vein graft anastomosis. As a result, even in OPCAB procedures, patients still face the risk of the serious adverse effects associated with the application of aortic clamps.

Minimally Invasive Endoscopic Procedures. Recently, a very small number of CABG procedures have been performed using minimally invasive endoscopic procedures to reduce patient trauma. In this approach, the sternum is left intact and the surgery is performed through small access ports. The anastomoses are performed on selected, readily reachable vessels using special surgical instruments, and this procedure requires special surgical skills. Although endoscopic procedures offer the promise of faster post-operative patient recovery times, rapid ambulation, long-term graft patency and a low incidence of adverse outcomes, there are a number of challenges to wide-scale realization of that potential, in particular, the absence of a method to enable surgeons to perform reproducible and effective anastomoses that can be rapidly deployed through small incisions. Currently, it is estimated that fewer than 3% of CABG patients are eligible for minimally invasive endoscopic techniques.

Surgical Techniques for Anastomoses

The current method of performing anastomoses, the most critical aspect of CABG procedures, typically employs tedious and time-consuming hand-sewn placement of individual stitches with a continuous suture to connect the bypass graft to the aorta or coronary vessels. Conventional anastomosis can require ten to 25 minutes to suture, depending upon the size of the vessels. Proper vessel alignment and suture tension among the many individually placed fine stitches are critical for optimal bypass graft blood flow and function. Furthermore, long-

term clinical outcomes may be improved if the anastomosis is “compliant,” that is, if its shape and size can adapt to changes in flow and blood pressure by placement of many single sutures rather than one continuous suture. However, most surgeons prefer the use of a continuous suture because placement of individual sutures may be more technically challenging and time-consuming. Whether the surgeon elects to operate on the patient on- or off-pump, a hand-sewn proximal anastomosis generally requires clamping of the aorta and therefore carries with it the risk of neurological damage and other serious adverse effects. Recently, new technology has been introduced that allows the surgeon to perform hand-sewn proximal anastomoses to the aorta without clamping of the aorta. These facilitating devices temporarily cover the opening in the aortic wall from the inside while the surgeon places the stitches to create the anastomosis and are removed after the anastomosis has been completed to allow blood flow into the bypass graft. We believe these systems, in their current implementations, are not suitable for endoscopic bypass surgery.

The laborious and time-consuming nature of manually applied sutures and the limitations associated with their use, together with advances occurring in coronary surgical procedures, have fueled the need for easy-to-use, fast and highly reliable automated systems to expedite and standardize the performance of anastomoses in CABG procedures. Although a number of companies have attempted to develop automated systems to perform anastomoses, to date only one system, which is for use in performing a proximal anastomosis, is currently commercially available in the United States.

Our Solutions

We design and manufacture proprietary automated anastomotic systems used by surgeons to perform anastomoses during on- or off-pump CABG procedures. We believe that by enabling consistent and reliable anastomoses of the vessels at this most critical step in CABG surgery through a fast, automated process, our products can improve the quality and consistency of these anastomoses, which we believe will ultimately contribute to improved patient outcomes. We have designed our products to meet the needs of surgeons, including:

- *Physiological features.* Our clips use medical grade stainless steel that is identical to that used in conventional coronary stents, which is known to be compatible with the human body (in the absence of allergies to certain components of medical grade stainless steel). Our products minimize trauma to both the graft and target vessel during loading and deployment, thereby reducing the risk of scar formation and associated narrowings or occlusions. Additionally, our PAS-Port system can be used without clamping the aorta, which has been shown to be a cause of adverse events, including neurological complications. In addition, our C-Port system creates compliant anastomoses, which potentially allow the shape and size of the anastomosis to adapt to changes in flow and blood pressure.
- *Handling features.* Our anastomotic systems can create anastomoses more rapidly than hand suturing, resulting in a surgical procedure that can be performed more quickly. For example the PAS-Port system can be set-up and deployed in approximately three minutes compared with approximately ten to 25 minutes for a hand-sewn anastomosis. In addition, the system is easy to use, typically requiring only a few hours of training to become technically proficient in the technique. The C-Port system is compatible with coronary arteries as small as one millimeter in internal diameter, which is typically the lower limit of target vessels considered to be candidates for revascularization. The C-Port system can also be deployed at various angles, allowing access to all coronary targets during both on- and off-pump procedures. Both the C-Port system and the PAS-Port system are designed as integrated products, where all steps necessary to create an anastomosis are performed by a single tool, with one user interface. The need for target vessel preparation is minimal for the PAS-Port system, a feature that is especially important in patients undergoing a second or third coronary bypass procedure with the presence of significant scarring in and around the heart and aorta.
- *Standardized results.* Our products enable consistent, reproducible anastomoses, largely independent of surgical technique and skill set, using a wide range in quality of graft tissues. In comparison with hand-sewn sutures, our systems offer mechanically-governed repeatability and reduced procedural complexity.
- *Reduced costs.* Because our products can help to expedite the CABG procedure, we believe that they may contribute to reduced operating room time and associated expenses, partially offset by the increased cost of our products compared to current alternatives, such as sutures. Additionally, our C-Port system creates

anastomoses rapidly and does not require the interruption of blood flow. It may reduce some of the technical challenges inherent in performing anastomosis in off-pump procedures, which may advance adoption of the off-pump approach. By helping more surgeons perform off-pump CABG, the need for a costly pump may also be reduced or eliminated, thereby potentially reducing the total costs of the procedure. Finally, to the extent complications such as strokes or injury to the heart muscle decrease, post-operative costs of a CABG procedure may be significantly reduced.

Our Strategy

Our goal is to become the leading provider of automated anastomotic systems for cardiac bypass surgeries. Although CABG may offer the most effective treatment for many patients with coronary artery disease, patients are often deterred by the invasiveness and trauma associated with the procedure. As a result, some patients may opt to accept less invasive procedures, such as balloon angioplasty and coronary stent implantation, even though the procedure may result in a less favorable outcome for that patient. For CABG to be a more attractive treatment alternative, surgeons must strive to decrease the invasiveness and trauma associated with current procedures by introducing endoscopic or keyhole surgery for CABG, similar to the success seen in laparoscopic or arthroscopic procedures over the past decade. However, for endoscopic CABG to be widely adopted, several challenges must be overcome, including, most significantly, the development and successful implementation of innovative technology that safely accomplishes the most critical step in this procedure, the anastomosis. We believe that our anastomotic technology will become a key enabling technology for endoscopic CABG.

We believe we must follow a step-by-step process of technology development and market introduction to achieve our goals. In the first step, we must show strong clinical evidence that our products are safe and effective in an open chest setting, an environment in which the surgeon currently feels most comfortable. Anastomotic systems are disruptive technology and, to gain the trust and confidence of cardiac surgeons, we must carefully familiarize them with these systems. If we are successful in this first step of the process and the surgical community has started to adopt this technology in open chest surgery, the second step would involve introducing follow-on products that have been tested in a closed chest setting and have incorporated all the features necessary to safely and effectively perform this type of procedure.

The principal elements of our strategy to achieve our vision and goals include:

- *Driving market adoption of the C-Port and PAS-Port systems.* We intend to drive commercial adoption of our C-Port system and, if cleared or approved by the FDA, our PAS-Port system and future products by marketing them as integrated anastomotic tools for use in both on- and off-pump CABG procedures. We believe clinical data from our product trials and evidence of the cost-effective nature of our systems compared with alternatives will be key factors in driving physician adoption of our products. We intend to continue to seek to obtain persuasive clinical data on patient outcomes, procedure times and costs and quality of outcome through post-marketing studies, registry trials and physician-initiated studies to further drive market adoption.
- *Expanding our sales and marketing effort.* We are building a direct sales force to market and sell the C-Port system in the United States. Our U.S. sales force is initially targeting selected influential surgeons in high volume cardiac surgery centers. Through this effort, we will seek to increase both confidence in and demand for our products. We also intend to increase the number of distributors carrying our products in Europe and Asia. If we obtain FDA clearance or approval of the PAS-Port system or other products in the field of cardiac surgery, the same sales force will be responsible for selling these products.
- *Capitalizing on our proprietary technology to develop next-iteration products for endoscopic cardiac procedures.* We believe that the evolution of endoscopic CABG procedures, which would offer faster post-operative patient recovery times, long-term graft patency and a low incidence of adverse outcomes, could increase the number of CABG procedures performed. To help propel the effort toward more viable cardiac endoscopic procedures, we plan to develop flexible, next-iteration automated anastomotic systems designed to facilitate minimally invasive endoscopic CABG. We have received a grant from the National Institute of Health, or NIH, which will, in part, support us in our efforts to reach the goal of developing products for use in endoscopic surgery.

- *Establishing a strong proprietary position.* As of June 30, 2006, we had 43 issued U.S. patents, 61 additional patent applications in the United States and another six patent applications filed in selected international markets. We plan to continue to invest in building our intellectual property portfolio.
- *Leveraging our core competency to develop innovative products for other surgical applications.* We believe that our core technology, which comprises extensive technological innovations, can be adapted for a variety of surgical applications and disease indications. For example, we are currently developing products for use in other applications, such as vascular closure. We plan to continue to seek market opportunities in related fields to develop additional products that leverage our core strengths in surgical stapling and closure.

Our Products

We have developed three proprietary systems to perform anastomoses, the C–Port system, C–Port xA system and the PAS–Port system. The C–Port system automates a distal anastomosis between the graft vessel and target artery. This system has been studied using veins rather than arteries as the graft vessel and has received FDA 510(k) clearance for the creation of anastomoses between grafts and target vessels generally. The C–Port xA system, developed as an iteration of the C–Port system, has been studied in animals using veins and arteries as the bypass graft vessel, and we submitted a 510(k) application for the C–Port xA system in December 2005. The PAS–Port system automates the performance of a proximal anastomosis between a graft vessel, typically a saphenous vein, and the aorta. A study shows that patients who undergo a CABG procedure typically receive at least three bypass grafts, of which we believe a majority are performed using one artery and two veins as the bypass graft vessels.

C–Port® Distal Anastomosis System

Our C–Port system, which may be used in either on– or off–pump CABG procedures, is designed to perform an end–to–side distal anastomosis by attaching the end of a bypass vein graft to a coronary artery downstream of an occlusion or narrowing. The system uses miniature stainless steel staples to securely attach the bypass graft to the coronary artery. Our C–Port system is effective in creating compliant anastomoses in vessels as small as one millimeter in internal diameter. In addition, the C–Port system has been designed to:

- perform an end–to–side anastomosis without interruption of native coronary blood flow, which is not possible in a conventional hand–sewn anastomosis during off–pump surgery without the use of a temporarily placed vascular shunt;
- be compatible with vein grafts of diameters between 4 millimeters and 6 millimeters and wall thicknesses less than 1.4 millimeters;
- achieve nearly complete alignment of the natural blood lining surfaces of the coronary artery and the vein graft to minimize scarring and potential occlusion of the anastomosis; and
- minimize the amount of foreign material in the blood stream that may cause clotting and subsequent graft failure.

The C–Port system received the CE Mark in April 2004 for marketing in the European Union, and 510(k) clearance from the FDA in November 2005. As of June 30, 2006, we had sold over 600 C–Port systems.

C–Port™ xA Anastomosis System

We have applied for 510(k) clearance of the C–Port xA system for the same intended use as the C–Port system. The C–Port xA system features several modifications designed to improve the safety and reliability of the system, including a change from a spring–driven to a gas release–driven stapling mechanism, optimizing the staple configuration to further stabilize the graft; incorporation of non–traumatic vessel clamps to better position the graft vessel for anastomosis; and incorporation of safety mechanisms to minimize the chance of unintentional staple deployment. The C–Port xA system is also designed to deploy more staples around the periphery of the anastomosis than the original C–Port system to help ensure leak–proof sealing without the need for additional stitches at either end of the anastomosis, as may currently be required with the C–Port system.

PAS–Port® Proximal Anastomosis System

Our PAS–Port system is a fully automated device used to perform an end–to–side proximal anastomosis between a saphenous vein and the aorta. To complete a proximal anastomosis, the cardiac surgeon simply loads the bypass graft vessel into the PAS–Port system, places the end of the delivery device against the aorta and turns the knob on the opposite end of the delivery tool. The device first creates an opening in the aorta and subsequently securely attaches the bypass graft to the aortic wall, using a medical grade stainless steel implant that is formed into its final shape by the delivery tool. The innovative design of the PAS–Port system allows the surgeon to load the bypass graft and rapidly complete the anastomosis, typically in approximately three minutes, with little or no injury to the bypass graft vessel or the aorta.

An important advantage of our PAS–Port system is that, in contrast to conventional hand–sewn proximal anastomoses, the vascular connections created can be performed without clamping the aorta, potentially avoiding the associated risks such as neurological complications. Surgeons use our PAS–Port system in conventional CABG procedures and in OPCAB. While we are not aware of any patients who required additional surgery to correct leakage from an anastomosis performed with our PAS–Port system, the design of the PAS–Port requires an additional stitch intra–operatively to obtain hemostasis (absence of bleeding in the anastomosis site) in approximately 5% to 10% of the deployments. Additional stitches may be required intra–operatively in an individual anastomosis depending on the quality of the target and graft vessels, adequacy of target site preparation and quality of the loading of the graft to the deployment cartridge. We will be working on adaptations to the PAS–Port system for use in endoscopic applications.

The PAS–Port system is approved for sale and marketed in Europe and Japan. As of June 30, 2006, over 3,700 PAS–Port systems had been sold, primarily in Japan. In addition, we have recently obtained conditional approval from the FDA for an Investigational Device Exemption to conduct a prospective, randomized, multi–center and multi–national clinical trial to evaluate the safety and efficacy of the PAS–Port system.

Future Product Programs

Our product research and development efforts are focused on building innovative devices that enhance our current products or leverage our core competency in mechanical clip formation for applications in endoscopic CABG and other medical fields. We currently have active programs to design and develop the following products:

Endoscopic Anastomosis System (C–Port Flex A System)

The C–Port Flex A Anastomosis System, or the C–Port Flex A system, includes modifications to the C–Port xA system that are designed to enable automated anastomoses to be performed as part of robot–facilitated CABG procedures. The C–Port Flex A system includes all the features and benefits of the C–Port xA system and has a flexible, rather than rigid, shaft. The flexible shaft is designed to allow the working end of the device that creates the anastomosis to be inserted through a 12–millimeter diameter port to access the chest cavity and heart. The device would then be loaded with the bypass graft vessel inside or outside the chest cavity and deployed to create the anastomosis to the coronary artery. This product is designed to enable technology for completion of robotically assisted, including endoscopic, CABG surgery through four or five relatively small incisions between the ribs. Avoiding both the incision through the sternum and the use of a pump should significantly reduce patient trauma and accelerate post–operative recovery. We are currently conducting preclinical animal–model studies with the C–Port Flex A, supported in part by a grant from the NIH.

X–Port™ Vascular Access Closure Device

We believe that our proprietary technology used in our automated vascular anastomosis systems may provide an innovative, simple mechanical solution to close the vascular access sites used in interventional vascular procedures. We are currently designing the X–Port™ Vascular Access Closure Device, or X–Port, to address this clinical need.

Similar to our other products, the X–Port consists of a deployment tool and a vascular clip. At the end of an interventional vascular procedure, the surgeon would insert the deployment tool into a standard introducer sheath

and then simply press a button to deploy a micro–stainless steel clip over the opening in the vessel wall, sealing off the vascular access site.

Currently, vascular closure is accomplished by one of two methods, manual compression or alternative vascular closure devices. Simple manual compression, the most frequently used method of closure, is a time–consuming process that requires the patient to lie flat while pressure is manually applied directly to the access site for an average of 25 minutes. Once this initial period of compression is completed, the patient must continue to remain immobile for up to another four to 24 hours, depending upon the amount of anticoagulant drug therapy used during and after the procedure. Manual compression causes patient discomfort, is resource intensive and can increase the duration of the patient’s hospitalization. As a result, a variety of devices have been developed and commercialized to replace manual compression. Most of these products substantially decrease the duration of hospitalization, time to ambulation and, in most instances, patient discomfort.

It is estimated that approximately 8.5 million diagnostic and interventional catheterization procedures will be performed worldwide in 2005. In each of these procedures, the access site must be closed by one of these closure methods. It is estimated that in approximately 45% of these patients a device is employed. The worldwide market for femoral artery closure devices is estimated to be approximately \$500 million in 2005 and is estimated to increase to approximately \$790 million by 2008.

We have targeted this rapidly growing market because we believe that, by integrating many of the desired features into a single product, the X–Port, if it is successfully developed and receives regulatory clearance or approval, may be well–positioned to outperform existing vascular access closure devices. The X–Port is designed to have the following advantages:

- a simple user interface;
- placement through the same introducer sheath used for the interventional procedure;
- minimal amount of foreign material in the vessel wall with only a fraction of this material exposed to blood;
- a low manufactured cost; and
- scalable to various sizes of introducer sheaths.

We are currently conducting preclinical animal–model studies of the X–Port to assess its safety and efficacy.

Agreement with Cook Incorporated

On December 9, 2005, we entered into an agreement with Cook Incorporated, or Cook, to develop the X–Port. Under the agreement, we and Cook will jointly develop the X–Port, under the direction of a Development Committee that includes representatives from each party. Cook receives an exclusive, worldwide, royalty–bearing license, with the right to grant sublicenses, to make, have made, use, sell, offer for sale and import the X–Port for medical procedures in any part of the body. The parties may also agree to perform research on the product in new formats, in which case Cook would reimburse us for work we perform in connection with such research.

During fiscal 2006, we received payments aggregating \$1.0 million that we recorded as development revenue under the agreement. Cook will also pay us up to a total of an additional \$1.0 million in future payments if additional development milestones are achieved. We will receive a royalty based on Cook’s annual worldwide sales of the X–Port, if any. Certain minimum royalty payments are required under the agreement, which may be reduced during time periods in which certain product improvements are being developed because product sales are unexpectedly low for reasons other than Cook’s failure to commercialize diligently the product.

Cook must use commercially reasonable efforts to develop a production version of the product, and to apply for a CE mark and for FDA approval of the product, at its own expense. Additionally, Cook must use commercially reasonable efforts to commercialize the product following regulatory approval. We must supply a certain number of product units for Cook’s use in development of the product. Cook has the right to manufacture the product during later stages of development, and has the obligation to supply the product for commercial purposes. The term of the agreement will expire on December 9, 2025, subject to renewal by mutual agreement between Cook and us. Cook

may terminate the agreement for convenience at any time, and either party may terminate the agreement for uncured material breach by the other party.

If the agreement is terminated either by Cook for convenience, or by us for Cook's material breach, then Cook must pay to us a pro-rated payment for work performed by us under the development plan prior to such termination, not to exceed an amount equal to the milestone payments made during the term of the agreement plus \$300,000. Additionally, in such case, Cook must transfer to us certain technology and regulatory filings and assist us in other respects to enable us to develop, manufacture and commercialize the product, and Cook agrees not to sue us under certain intellectual property rights as necessary to allow us to continue, on our own or with or through third parties, to make, use, sell, offer for sale and import the product anywhere in the world for use in medical procedures in the body. In such case, for five years after such termination (unless a court does not determine that our termination for Cook's breach was proper), Cook cannot grant to any competitor of ours a license under Cook's intellectual property rights to facilitate the competitor in making, using, selling, offering for sale or importing the X-Port or any improvement anywhere in the world for use in medical procedures in the body.

If Cook terminates the agreement for our breach after it has paid to us all of the milestone payments, then Cook's license survives such termination, subject to its continuing obligation to pay royalties to us. If Cook terminates the agreement for material breach by us in failing to meet any of the milestones defined in the agreement, then we must repay the initial fee and the milestone payments, less certain costs we incurred in developing the product.

Cook has the first right to enforce the X-Port intellectual property against third parties, and Cook bears all expenses associated with such enforcement unless we choose to participate. We may undertake such enforcement if Cook permits us to do so. In the event that a third party takes legal action to assert intellectual property rights against us and/or Cook with regard to the X-Port product, then Cook may offset against the total royalty payment due to us a portion of any monies expended by Cook in defending against the action.

Regulatory Status and Clinical Trial Summary

Regulatory Status

International

The C-Port system received the CE Mark in April 2004 and the PAS-Port system received the CE Mark in March 2003. The PAS-Port system also received regulatory approval to be sold in Japan in January 2004. The C-Port xA system received the CE Mark in June 2006. We plan to submit the C-Port xA for regulatory approval in Japan.

United States

We commenced our European pivotal clinical trial to study our PAS-Port system in 2002. In 2001 and 2002, the FDA approved two proximal anastomosis devices for sale in the United States, the Symmetry system developed by St. Jude Medical and the CorLink system developed by Bypass, Inc. and Johnson & Johnson. The design of the pivotal clinical trial for the PAS-Port was based on the trial designs of these two predicate devices. We submitted the results of our pivotal clinical trial for the PAS-Port system to the FDA in an application for 510(k) clearance in 2003. After receiving reports of apparently device-related adverse events with the Symmetry device, the FDA revisited the criteria for a 510(k) clearance of subsequent anastomosis products. The FDA sponsored a special panel meeting on March 19, 2004 to redefine objective performance criteria for safety and efficacy of anastomosis products, which are significantly more rigorous than when we submitted our data. Following redefinition of the objective performance criteria, we resubmitted pooled data from two trials evaluating safety and efficacy of the PAS-Port system to the FDA. In April of 2005, the FDA asked the Circulatory System Devices Panel to consider the data submitted on the PAS-Port system. The panel concurred that vascular anastomotic devices have great potential and the data regarding the PAS-Port system looked promising. The majority of panel members, however, believed that more robust data were required. Following this recommendation from the panel, we withdrew our 510(k) submission. To collect data to address the new criteria, we obtained a conditional approval of an Investigational Device Exemption, or IDE, for a new randomized 220 patient prospective clinical trial to be conducted in 11 sites in

the United States and Europe. We began enrolling patients in this PAS–Port clinical trial in June 2006. We expect to complete enrollment in this trial in 2006 and to complete the 9–month follow up angiograms and to include the results of the clinical trial as part of a 510(k) submission in calendar year 2007.

We commenced our pivotal clinical trial to study our C–Port system in 2003 and submitted the data from this trial in an application for 510(k) clearance in 2004. We received 510(k) clearance from the FDA to market the C–Port system in the United States in November 2005. In December 2005, we submitted an application for 510(k) clearance of the C–Port xA system using the C–Port as a predicate device.

International Clinical Studies

Study	Number and Location of Sites	Enrollment Completion Date	Number of Patients	Objective	Length of Follow-up	Regulatory Status
C–Port Pivotal Trial	5 European Sites	February 2004	133	Determine safety and efficacy of distal anastomotic device	12 months	<ul style="list-style-type: none"> • CE Mark received in Europe • 510(k) clearance obtained in United States
PAS–Port European Pivotal Trial	3 European Sites	September 2002	55	Determine safety and efficacy of proximal anastomotic device	24 months	<ul style="list-style-type: none"> • CE Mark received in Europe • IDE conditionally approved in United States
PAS–Port II Trial	4 European Sites	February 2004	54	Increase data pool for study of safety and efficacy with an improved PAS–Port device	12 months	

We intend to continue to gather additional clinical data for our products to further support our sales and marketing efforts. We believe these studies will primarily consist of registry trials and physician–initiated studies.

Sales and Marketing

Our initial products focus on the needs of cardiovascular surgeons worldwide. We are building a direct sales force initially targeting selected influential surgeons in high volume cardiac surgery centers in the United States to sell our C–Port system. Approximately half of all U.S. CABG procedures are performed at 225 cardiac surgery centers. We plan to selectively target institutions within this group of centers and to conduct intensive focused marketing and training for the C–Port system and for our products that receive FDA clearance or approval in the future. Through this effort, we hope to generate wider demand for our products by training well–respected clinical supporters of our products and leveraging their reputations in the clinical community. In addition, we intend to promote our systems at major medical conventions and through other marketing efforts such as seminars, workshops, brochures and internet–based training. We will also work with our investigators to present the results of our clinical trials at cardiovascular meetings.

We currently distribute our PAS–Port system in Japan through our exclusive distributor, Century Medical, Inc., or Century. In the fiscal year ended June 30, 2006, sales to Century comprised approximately 64% of our total product revenue. Century has a direct sales organization of approximately 16 representatives who are responsible for the development of the anastomotic device market and directly contact cardiac surgeons. Century provides clinical training and support for end–users in Japan. We provide Century with promotional support, ongoing clinical training, representation at trade shows and guidance in Century’s sales and marketing efforts. Our agreement with Century expires in July 2009. The agreement renews automatically for a second five–year term if Century meets certain sales milestones. Either party may terminate this agreement if the other party defaults in performance of material obligations and such default is not cured within a specified period or if the other party becomes insolvent or subject to bankruptcy proceedings. In addition, we may terminate the agreement within 90 days following a change of control by payment of a specified termination fee.

Guidant distributed our products in Europe under a distribution agreement that terminated in September 2004. Guidant accounted for 65% of our total net revenue in fiscal year 2005 and 75% of our total net revenue in fiscal year 2004. The revenue generated from the distribution agreement \$1.0 million, or 50% of fiscal year 2005 revenue and \$0.4 million, or 48% of fiscal year 2004 revenue.

We are currently building a distribution network in Europe for both our PAS–Port and C–Port systems. We have currently engaged SIC Systems as our exclusive distributor in Italy, and we may engage additional distributors in several other European countries; however, we do not anticipate significant product sales from Europe in part because their healthcare systems are difficult to penetrate for new higher cost medical products. We are continuing to sell to selected customers and will continue to evaluate further opportunities to expand our distribution network in Europe and in other parts of the world where the healthcare economics are conducive to the introduction and adoption of new medical device technologies.

Competition

The market for medical devices used in the treatment of coronary artery disease is intensely competitive, subject to rapid change, and significantly affected by new product introductions and other market activities of industry participants. We believe the principal competitive factors in the market for medical devices used in the treatment of coronary artery disease include:

- improved patient outcomes;
- access to and acceptance by leading physicians;
- product quality and reliability;
- ease of use;
- device cost–effectiveness;
- training and support;
- novelty;
- physician relationships; and
- sales and marketing capabilities.

There are numerous potential competitors in the medical device, biotechnology and pharmaceutical industries, such as Boston Scientific Corporation, Edwards Lifesciences Corporation, Guidant Corporation, Johnson & Johnson, Inc., Medtronic, Inc. and St. Jude Medical, that are targeting the treatment of coronary artery disease broadly. Each of these companies has significantly greater financial, clinical, manufacturing, marketing, distribution and technical resources and experience than we have. In addition, new companies have been, and are likely to continue to be, formed to pursue opportunities in our market.

The landscape of active competitors in the market for anastomotic solutions is currently limited. Medtronic, with its recent acquisition of Coalescent Surgical, obtained the only marketed proximal anastomotic system in the United States, the Spyder, which deploys a series of nitinol–based U–Clips to attach a graft to the aorta. Several companies market systems designed to facilitate or stabilize proximal anastomoses, such as Guidant’s Heartstring Aortic Occluder and Novare Surgical Systems’ Enclose anastomotic assist device. St. Jude Medical previously had a commercially available proximal anastomotic system that was marketed both in the United States and Europe; however, St. Jude Medical voluntarily withdrew this product from the market in 2004. Johnson & Johnson has obtained FDA clearance for a proximal system that has been developed by Bypass Inc.

Our C–Port system is the only automated anastomosis device for distal anastomosis cleared for marketing in the United States. The only currently marketed facilitating device for distal anastomosis is the U–Clip, which substitutes clips for sutures, but still requires manual application of typically 12 to 14 individually placed clips per anastomosis by the surgeon.

Currently, the vast majority of anastomoses are performed with sutures and, for the foreseeable future, sutures will continue to be the principal competitor for alternative anastomotic solutions. The sutures used for anastomoses in CABG procedures are far less expensive than automated anastomotic systems, and surgeons, who have been using sutures for their entire careers, may be reluctant to consider alternative technologies, despite potential advantages.

In addition, cardiovascular diseases may also be treated by other methods that do not require anastomoses, including interventional techniques such as balloon angioplasty and use of drug-eluting stents, pharmaceuticals, atherectomy catheters and lasers. Further, technological advances with other therapies for cardiovascular disease such as drugs, local gene therapy or future innovations in cardiac surgery techniques could make other methods of treating this disease more effective or less expensive than CABG procedures.

Our X-Port system, if developed and approved, would compete in the market for femoral artery closure devices. Two large competitors, St. Jude Medical and Abbott Vascular Devices, currently control over 80% of this market. St. Jude Medical's Angioseal vascular closure device, which is licensed from Kensey-Nash, is based on a collagen plug and has the leading market share. Other FDA-cleared products in this market include Abbott Vascular Devices' suture-based Perclose and nitinol-based StarClose devices and Medtronic's Angiolink Stapler. In addition to these large existing and potential competitors, there are a number of venture capital-backed private companies that are developing devices and technologies for this market.

Manufacturing

Our headquarters provides space for our manufacturing operations, sterile products manufacturing, packaging, storage and shipping, as well as for our research and development laboratories and general administrative facilities. We believe that our current facilities will be sufficient to meet our manufacturing needs for at least the next two years.

We believe our manufacturing operations are in compliance with regulations mandated by the FDA and the European Union. Our facility is ISO 13485:2003 certified. In connection with our CE mark approval and compliance with European quality standards, our facility was initially certified in June 2002 and has been inspected annually thereafter.

There are a number of critical components and sub-assemblies required for manufacturing the C-Port and PAS-Port systems that we purchase from third-party suppliers. The vendors for these materials are qualified through stringent evaluation and monitoring of their performance over time. We audit our critical component manufacturers on a regular basis and at varied intervals based on the nature and complexity of the components they provide and the risk associated with the components' failure.

We use or rely upon sole source suppliers for certain components and services used in manufacturing our products, and we utilize materials and components supplied by third parties, with which we do not have any long-term contracts. In recent years, many suppliers have ceased supplying raw materials for use in implantable medical devices. We cannot quickly establish additional or replacement suppliers for certain components or materials, due to both the complex nature of the manufacturing processes employed by our suppliers and the time and effort that may be required to obtain FDA clearance or other regulatory approval to use materials from alternative suppliers. Any significant supply interruption or capacity constraints affecting our facilities or those of our suppliers would affect our ability to manufacture and distribute our products.

Third-Party Reimbursement

Sales of medical products are increasingly dependent in part on the availability of reimbursement from third-party payors such as government and private insurance plans. Currently, payors provide coverage and reimbursement for CABG procedures only when they are medically necessary. Our technology will be used concomitantly in CABG procedures. We realize though that Cardica technologies will bring added costs to medical providers and may not be reimbursed separately by third-party payors at rates sufficient to allow us to sell our products on a competitive and profitable basis.

We believe the majority of bypass graft patients in the United States will be Medicare beneficiaries. Further, private payors often consider Medicare's coverage and payment decisions when developing their own policies. The Centers for Medicare & Medicaid Services, referred to as CMS, is the agency within the Department of Health and Human Services that administers Medicare and will be responsible for reimbursement decisions for the Cardica devices when used to treat Medicare beneficiaries during CABG surgery.

Once a device has received approval or clearance for marketing by the FDA, there is no assurance that Medicare will cover the device and related services. In some cases, CMS may place certain restrictions on the circumstances in which coverage will be available. In making such coverage determinations, CMS considers, among other things, peer-reviewed publications concerning the effectiveness of the technology, the opinions of medical specialty societies, input from the FDA, the National Institutes of Health, and other government agencies.

In general, Medicare makes a predetermined, fixed payment amount for its beneficiaries receiving covered inpatient services in acute care hospitals. This payment methodology is part of the inpatient prospective payment system, or IPPS. For acute care hospitals, under IPPS, payment for an inpatient stay is based on diagnosis-related groups, or DRGs, which include reimbursement for all covered medical services and medical products that are provided during a hospital stay. Additionally, a relative weight is calculated for each individual DRG which represents the average resources required to care for cases in that particular DRG relative to the average resources required to treat cases in all DRGs. Generally, DRG relative weights are adjusted annually to reflect changes in medical practice in a budget neutral manner.

CMS has made no decisions with respect to DRG assignment when patients undergo CABG procedures in which our products would be used, and there can be no assurance that the DRG to which such patients will be assigned will result in Medicare payment levels that are considered by hospitals to be adequate to support purchase of our products.

Under current CMS reimbursement policies, CMS offers a process to obtain add-on payment for a new medical technology when the existing DRG prospective payment rate is inadequate. To obtain add-on payment, a technology must be considered "new," demonstrate substantial improvement in care and exceed certain payment thresholds. Add-on payments are made for no less than two years and no more than three years. We must demonstrate the safety and effectiveness of our technology to the FDA in addition to CMS requirements before add-on payments can be made. Further, Medicare coverage is based on our ability to demonstrate the treatment is "reasonable and necessary" for Medicare beneficiaries. The process involved in applying for additional reimbursement for new medical technologies from CMS is lengthy and expensive. Our products may not be awarded additional or separate reimbursement in the foreseeable future, if at all. Moreover, many private payors look to CMS in setting their reimbursement policies and payment amounts. If CMS or other agencies limit coverage and decrease or limit reimbursement payments for hospitals and physicians, this may affect coverage and reimbursement determinations by many private payors.

Medicare policies allow Medicare contractors discretion to cover items involving Category B investigational devices. However, even with items or services involving Category B devices, Medicare coverage may be denied if any other coverage requirements are not met, for example if the treatment is not medically necessary for the specific Medicare beneficiary. In our conditionally approved IDE, the PAS-Port system has been classified by the FDA as a Category B1 device. To that end, the five planned U.S. investigational sites for our upcoming trial may be able to seek specific CMS reimbursement for use of the PAS-Port.

For classification of physician services, the American Medical Association, referred to as the AMA, has developed a coding system known as the Current Procedural Terminology, or CPT. CPT codes are established by the AMA and adopted by the Medicare program in the Healthcare Common Procedure Coding System, to describe and develop payment amounts for physician services. Physician services are reimbursed by Medicare based on a physician fee schedule whereby payment is based generally on the number of "relative value units" assigned by CMS to the service furnished by the physician. No decision has been made concerning whether existing CPT codes would be appropriate for use in coding anastomosis procedures when our products are used or if new CPT codes and payment are required. We cannot assure you that codes used for submitting claims for anastomosis procedures using our products will result in incremental payment to physicians. CPT codes are used by many other third-party payors in addition to Medicare. Failure by physicians to receive what they consider to be adequate reimbursement for

anastomosis procedures in which our products are used could have a material adverse effect on our business, financial condition and results of operations.

Research and Development

As of June 30, 2006, we had 18 employees in our research and development department. We currently have a preclinical program to develop smaller devices designed for endoscopic use and for use with automated surgical robotic systems. Future research and development efforts will involve continued enhancements to and cost reductions for our current C-Port and PAS-Port systems. We are also exploring the development of other products that can be derived from our core technology platform and intellectual property. Research and development expenses for fiscal years ended June 30, 2006, 2005 and 2004 were \$6.5 million, \$6.3 million and \$5.8 million, respectively. We expect research and development efforts and expenses to increase in absolute dollar terms as we enhance the capabilities of our current products and explore new applications and indications for our automated anastomosis technology platform.

Patents and Intellectual Property

We believe our competitive position will depend significantly upon our ability to protect our intellectual property. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our technology, inventions and improvements that are important to the development of our business. As of June 30, 2006, we have 43 issued U.S. patents, 61 additional U.S. patent applications and another six patent applications filed in select international markets. Our issued patents expire between 2018 and 2023.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We typically require our employees, consultants and advisors to execute confidentiality and assignment of inventions agreements in connection with their employment, consulting or advisory relationships with us. There can be no assurance, however, that these agreements will not be breached or that we will have adequate remedies for any breach. Furthermore, no assurance can be given that competitors will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our proprietary technology, or that we can meaningfully protect our rights in unpatented proprietary technology.

Patent applications in the United States and in foreign countries are maintained in secrecy for a period of time after filing, which results in a delay between the actual discoveries and the filing of related patent applications and the time when discoveries are published in scientific and patent literature. Patents issued and patent applications filed relating to medical devices are numerous, and there can be no assurance that current and potential competitors and other third parties have not filed or in the future will not file applications for, or have not received or in the future will not receive, patents or obtain additional proprietary rights relating to products, devices or processes used or proposed to be used by us. We are aware of patents issued to third parties that contain subject matter related to our technology. We believe that the technologies we employ in our products and systems do not infringe the valid claims of any such patents. There can be no assurance, however, that third parties will not seek to assert that our devices and systems infringe their patents or seek to expand their patent claims to cover aspects of our products and systems.

The medical device industry in general, and the industry segment that includes products for the treatment of cardiovascular disease in particular, has been characterized by substantial litigation regarding patents and other intellectual property rights. Any such claims, regardless of their merit, could be time-consuming and expensive to respond to and could divert our technical and management personnel. We may be involved in litigation to defend against claims of infringement by other patent holders, to enforce patents issued to us, or to protect our trade secrets. If any relevant claims of third-party patents are upheld as valid and enforceable in any litigation or administrative proceeding, we could be prevented from practicing the subject matter claimed in such patents, or would be required to obtain licenses from the patent owners of each such patent, or to redesign its products, devices or processes to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be available on terms acceptable to us or that we would be successful in any attempt to redesign our products or processes to avoid infringement. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products, which would have a material adverse effect on our business, financial condition and results of operations. We intend to vigorously protect and defend our intellectual property. Costly and time-consuming litigation brought by us may be necessary

to enforce patents issued to us, to protect trade secrets or know-how owned by us or to determine the enforceability, scope and validity of the proprietary rights of others. See “Risk Factors.”

On October 28, 2005, we received a letter from Integrated Vascular Interventional Technologies, Inc., referred to as IVIT, advising us for the first time of IVIT’s effort to provoke an interference in the U.S. Patent and Trademark Office between one of IVIT’s patent applications (serial no. 10/243,543) and a patent currently held by us (U.S. patent no. 6,391,038) and relating to the C-Port system. We also learned on that date that IVIT is attempting to provoke an interference in the U.S. Patent and Trademark Office between another of its U.S. patent applications (serial no. 10/706,245) and another of our issued patents (U.S. Patent No. 6,478,804). IVIT makes no specific demands in the letter, but alleges that it has an indication of an allowed claim and that it expects to receive a declaration of interference regarding that claim, and states that it would be “strategically beneficial” for us to discuss this matter prior to receiving a declaration of interference.

On March 16, 2006, we received notice that the Board of Patent Appeals and Interferences of the U.S. Patent and Trademark Office, referred to as the Patent Appeals Board, declared an interference between our U.S. Patent No 6,391,038 (which relates to our C-Port system) and a pending U.S. Patent Application 10/243,543, which patent application has been assigned to Integrated Vascular Interventional Technologies, LLC, or IVIT. An interference is a proceeding within the U.S. Patent and Trademark Office to determine priority of invention of the subject matter of patent claims. The declaration of interference is made by the Patent Appeals Board only after claims in a patent application are deemed allowable but for the interfering subject matter (in this case our issued patent) and a determination that interfering subject matter exists. The declaration of interference initiates an adversarial proceeding in the U.S. Patent and Trademark Office before the Patent Appeals Board. The proceeding will involve issues including but not limited to whether an interference proceeding is appropriate, whether the involved claims of the parties are patentable and which party was first to invent the interfering subject matter. We will vigorously defend our patents against such claim of interference, although there can be no assurance that we will succeed in doing so. There can be no assurance that IVIT’s patent claims, if allowed, will be in their present form, or that our products would not be found to infringe such claims or any other claims that are issued.

Government Regulation

The FDA and other regulatory bodies extensively regulate the research, development, manufacture, labeling, distribution and marketing of our products. Our current products are regulated by the FDA as medical devices, and we are required to obtain review and clearance or approval from the FDA prior to commercializing our devices in the United States.

FDA regulations govern nearly all of the activities that we perform, or that are performed on our behalf, to ensure that medical products distributed domestically or exported internationally are safe and effective for their intended uses. The activities that the FDA regulates include the following:

- product design, development and manufacture;
- product safety, testing, labeling and storage;
- pre-clinical testing in animals and in the laboratory;
- clinical investigations in humans;
- marketing applications, such as 510(k) notifications and PMA applications;
- record keeping and document retention procedures;
- advertising and promotion;
- product marketing, distribution and recalls; and
- post-marketing surveillance and medical device reporting, including reporting of deaths, serious injuries, device malfunctions or other adverse events.

FDA’s Premarket Clearance and Approval Requirements. Unless an exemption applies, each medical device distributed commercially in the United States will require either prior 510(k) clearance or premarket approval,

referred to as a PMA, from the FDA. The FDA classifies medical devices into one of three classes. Class I devices are subject to only general controls, such as establishment registration and device listing, labeling, medical devices reporting, and prohibitions against adulteration and misbranding. Class II medical devices generally require prior 510(k) clearance before they may be commercially marketed in the United States. The FDA will clear marketing of a medical device through the 510(k) process if the FDA is satisfied that the new product has been demonstrated to be substantially equivalent to another legally marketed device, or predicate, device, and otherwise meets the FDA's requirements. Class II devices are also subject to general controls and may be subject to performance standards and other special controls. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, are placed in Class III, generally requiring submission of a PMA supported by clinical trial data.

510(k) Clearance Pathway. To obtain 510(k) clearance, we must submit a notification to the FDA demonstrating that our proposed device is substantially equivalent to a predicate device, i.e., a device that was in commercial distribution before May 28, 1976, a device that has been reclassified from Class III to Class I or Class II, or a 510(k)-cleared device. The FDA's 510(k) clearance process generally takes from three to 12 months from the date the application is submitted, but can take significantly longer. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously-cleared device or use, the device is automatically placed into Class III, requiring the submission of a PMA. Any modification to a 510(k)-cleared device that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the device until 510(k) clearance or PMA is obtained. If the FDA requires us to seek 510(k) clearance or PMAs for any modifications, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance or PMA is obtained and we could be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to voluntary recall if we or the FDA determines, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death. Delays in receipt or failure to receive clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

Premarket Approval Pathway. A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process. The PMA process is much more demanding than the 510(k) notification process. A PMA must be supported by extensive data, including but not limited to data obtained from preclinical or clinical studies or relating to manufacturing and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

After a PMA is complete, the FDA begins an in-depth review of the submitted information, which generally takes between one and three years, but may take significantly longer. During this review period, the FDA will typically request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with Quality System Regulation, or QSR. New PMA applications or PMA supplements are required for significant modifications to the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. PMA supplements often require submission of the same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials. Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. To perform a clinical trial in the United States for a significant risk device, prior submission of an application for an IDE to the FDA is required. An IDE amendment must also be submitted before initiating a new clinical study under an existing IDE, such as initiating a pivotal trial following the conclusion of a

feasibility trial. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, and any available data on human clinical experience, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The animal and laboratory testing must meet the FDA's good laboratory practice requirements.

The IDE and any IDE supplement for a new trial must be approved in advance by the FDA for a specific number of patients. Clinical trials conducted in the United States for significant risk devices may not begin until the IDE application or IDE supplement is approved by the FDA and the appropriate institutional review boards, or IRBs, overseeing the welfare of the research subjects and responsible for that particular clinical trial. If the product is considered a non-significant risk device under FDA regulations, only the patients' informed consent and IRB approval are required. Under its regulations, the agency responds to an IDE or an IDE amendment for a new trial within 30 days. The FDA may approve the IDE or amendment, grant an approval with certain conditions, or identify deficiencies and request additional information. It is common for the FDA to require additional information before approving an IDE or amendment for a new trial, and thus final FDA approval on a submission may require more than the initial 30 days. The FDA may also require that a small-scale feasibility study be conducted before a pivotal trial may commence. In a feasibility trial, the FDA limits the number of patients, sites and investigators that may participate. Feasibility trials are typically structured to obtain information on safety and to help determine how large a pivotal trial should be to obtain statistically significant results.

Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an IRB for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices. We are also required to obtain the patients' informed consent in form and substance that complies with both FDA requirements and state and federal privacy and human subject protection regulations. We, the FDA or the IRB may suspend a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA approval to market the product in the United States. Similarly, in Europe the clinical study must be approved by a local ethics committee and in some cases, including studies with high-risk devices, by the ministry of health in the applicable country.

Pervasive and Continuing Regulation. There are numerous regulatory requirements governing the approval and marketing of a product. These include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance or approval of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to an adverse event, a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- notices of correction or removal and recall regulations.

Advertising and promotion of medical devices are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, some promotional activities for FDA–regulated products have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims.

We have registered with the FDA as a medical device manufacturer. The FDA has broad post–market and regulatory enforcement powers. We are subject to unannounced inspections by the FDA to determine our compliance with the QSR, and other regulations, and these inspections may include the manufacturing facilities of our suppliers.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or state authorities, which may include any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delay in processing marketing applications for new products or modifications to existing products;
- mandatory product recalls;
- withdrawing approvals that have already been granted; and
- criminal prosecution.

Fraud and Abuse and False Claims. We are directly and indirectly subject to various federal and state laws governing our relationship with healthcare providers and pertaining to healthcare fraud and abuse, including anti–kickback laws. In particular, the federal healthcare program Anti–Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service, for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. The Anti–Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. In implementing the statute, the Office of Inspector General of the U.S. Department of Health and Services, or OIG, has issued a series of regulations, known as the “safe harbors.” These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti–Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable element of a safe harbor may result in increased scrutiny by government enforcement authorities, such as the OIG.

The Federal False Claims Act imposes civil liability on any person or entity who submits, or causes the submission of a false or fraudulent claim to the United States Government. Damages under the Federal False Claims Act can be significant and consist of the imposition of fines and penalties. The Federal False Claims Act also allows a private individual or entity with knowledge of past or present fraud on the federal government to sue on behalf of the government to recover the civil penalties and treble damages. The U.S. Department of Justice on behalf of the government has successfully enforced the Federal False Claims Act against pharmaceutical manufacturers. Federal suits have alleged that pharmaceutical manufacturers whose marketing and promotional practices were found to have included the off–label promotion of drugs or the payment of prohibited kickbacks to doctors violated the Federal False Claims Act on the grounds that these prohibited activities resulted in the submission of claims to federal and state healthcare entitlement programs such as Medicaid, resulting in the payment of claims by Medicaid for the off–label use of the drug that was not a use of the drug otherwise covered by Medicaid. Such manufacturers have entered into settlements with the federal government under which they paid amounts and entered into corporate integrity agreements that require, among other things, substantial reporting and remedial actions.

The Federal authorities, and state equivalents, may likewise seek to enforce the False Claims Act against medical device manufacturers. We believe that our marketing practices are not in violation of the Federal False Claims Act or state equivalents, but we cannot assure you that the federal authorities will not take action against us and, if such action were successful, we could be required to pay significant fines and penalties and change our marketing practices. Such enforcement could have a significant adverse effect on our ability to operate.

We engage in a variety of activities that are subject to these laws and that have come under particular scrutiny in recent years by federal and state regulators and law enforcement entities. These activities have included, consulting arrangements with cardiothoracic surgeons, grants for training and other education, grants for research, and other interactions with doctors.

International Regulation. International sales of medical devices are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain certification or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ.

The primary regulatory body in Europe is the European Union, which has adopted numerous directives and has promulgated voluntary standards regulating the design, manufacture and labeling of and clinical trials and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout the member states of the European Union and other countries that comply with or mirror these directives. The method for assessing conformity varies depending upon the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a notified body, which is an independent and neutral institution appointed by a country to conduct the conformity assessment. This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's device. Such an assessment is required for a manufacturer to commercially distribute the product throughout these countries. International Standards Organization, or ISO, 9001 and ISO 13845 certifications are voluntary standards. Compliance establishes the presumption of conformity with the essential requirements for the CE Mark. We have the authorization to affix the CE Mark to the PAS-Port and C-Port devices and to commercialize the devices in the European Union for coronary artery bypass grafting.

In Japan, medical devices must be approved prior to importation and commercial sale by the Ministry of Health, Labor and Welfare, or MHLW. Manufacturers of medical devices outside of Japan must utilize a contractually bound In-Country Caretaker, or ICC, to submit an application for device approval to the MHLW. The MHLW evaluates each device for safety and efficacy. As part of its approval process, the MHLW may require that the product be tested in Japanese laboratories. The approval process for products such as our existing anastomotic products is typically 13 to 14 months. Other medical devices may require a longer review period for approval. Once approved, the manufacturer may import the device into Japan for sale by the manufacturer's contractually bound importer or distributor.

After a device is approved for importation and commercial sale in Japan, the MHLW continues to monitor sales of approved products for compliance with labeling regulations, which prohibit promotion of devices for unapproved uses and reporting regulations, which require reporting of product malfunctions, including serious injury or death caused by any approved device. Failure to comply with applicable regulatory requirements can result in enforcement action by the MHLW, which may include fines, injunctions, and civil penalties, recall or seizure of our products, operating restrictions, partial suspension or total shutdown of sales in Japan, or criminal prosecution.

We have received approval from the MHLW to distribute our PAS-Port system in Japan. We will be required to submit applications with respect to all new products and product enhancements for review and approval by the MHLW. Our contract with Century, our distributor in Japan, has a multi-year term and is renewable for additional multi-year terms upon mutual agreement of the parties.

In addition to MHLW oversight, the regulation of medical devices in Japan is also governed by the Japanese Pharmaceutical Affairs Law, or PAL. PAL was substantially revised in July 2002, and the new provisions were implemented in stages through April 2005. Revised provisions of the approval and licensing system of medical

devices in Japan, which constitutes the core of import regulations, came into effect on April 1, 2005. The revised law changes class categorizations of medical devices in relation to risk, introduces a third-party certification system, strengthens safety countermeasures for biologically derived products, and reinforces safety countermeasures at the time of resale or rental. The revised law also abolishes the ICC system and replaces it with the “primary distributor” system. Under the PAL in effect prior to April 1, 2005, manufacturers of medical devices outside of Japan were required to utilize an ICC to obtain on their behalf approval of each product by the MHLW prior to the sale or distribution of their products in Japan. Under the revised PAL, manufacturers outside of Japan must now appoint a “primary distributor” located in Japan that holds a primary distributor license for medical devices to provide primary distribution services, including conducting quality assurance and safety control tasks, for each product at the time an application for the approval of each such product is submitted to the MHLW. Century Medical serves as the “primary distributor” for Cardica. As an interim measure, an ICC licensed under the PAL in effect prior to April 1, 2005 will be deemed to be the primary distributor under the revised PAL if that ICC had a license to import and distribute the relevant medical devices that was applied for and obtained under the old PAL. We are unable at this time to determine the impact of such changes on our approved products or future products. We do not anticipate that these changes will have a material impact on our existing level of third-party reimbursement for sales of our products in Japan.

Strategic Agreements

Under a distribution agreement dated May 2003 and amended in January 2004 with Guidant Corporation, or Guidant, Guidant distributed our C-Port and PAS-Port products in Europe. This agreement was terminated by Guidant in September 2004. Revenue from Guidant under this agreement was \$7,000, \$1.0 million and \$401,000 in fiscal 2006, 2005 and 2004, respectively.

In addition, on December 4, 2003, we entered into a development and supply agreement with Guidant to develop and manufacture an aortic cutter for Guidant’s Heartstring product. Future production of the aortic cutter has been outsourced by Guidant to a third-party manufacturer, and we will receive a modest royalty for each unit sold in the future, but will no longer manufacture the aortic cutter for Guidant. Revenue from Guidant under this agreement was \$310,000 and \$223,000 in fiscal 2005 and 2004, respectively. Royalty revenue received in fiscal 2006 was \$24,000.

Employees

As of June 30, 2006, we had 56 employees, including 16 employees in manufacturing, 6 employees in sales and marketing, 9 employees in clinical, regulatory and quality assurance, 7 employees in general and administrative and 18 employees in research and development. We believe that our future success will depend upon our continued ability to attract, hire and retain qualified personnel. None of our employees is represented by a labor union or party to a collective bargaining agreement, and we believe our employee relations are good.

Corporate Information

We were incorporated in Delaware in October 1997 as Vascular Innovations, Inc. and changed our name to Cardica, Inc. in November 2001. Our principal executive offices are located at 900 Saginaw Drive, Redwood City, California 94063 and our telephone number is (650) 364-9975. We are located on the world wide web at www.cardica.com.

MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information concerning our executive officers and directors as of August 31, 2006:

Name	Age	Position
Bernard A. Hausen, M.D., Ph.D.	46	President, Chief Executive Officer, Chief Medical Officer and Director
Robert Y. Newell	58	Vice President, Finance & Operations, Chief Financial Officer
Douglas T. Ellison	43	Vice President, Sales and Marketing
Bryan D. Knodel, Ph.D.	46	Vice President, Research and Development
J. Michael Egan(1)(2)	52	Chairman of the Board
Kevin T. Larkin(3)	56	Director
Richard P. Powers(1)(2)(3)	61	Director
Robert C. Robbins, M.D.(2)	48	Director
Jeffrey L. Purvin	54	Director
John Simon, Ph.D.	62	Director
Stephen A. Yenko, Ph.D.	44	Director
William H. Younger, Jr.(1)(3)	56	Director

- (1) Member of the Audit Committee
- (2) Member of the Compensation Committee
- (3) Member of the Nominating Committee

Executive Officers and Directors

Bernard A. Hausen, M.D., Ph.D. has been our President and Chief Executive Officer since December 2000. Dr. Hausen co-founded the Company in October 1997 and has served as a director and our Chief Medical Officer since inception. Dr. Hausen received a medical degree from Hannover Medical School in Germany in 1988 and was trained there as a general and cardiothoracic surgeon. Upon completion of his training, he received a Ph.D. degree in Medical Physiology in 1999. From 1996 to 2000, he was employed as a Senior Research Scientist in the Laboratory for Transplantation Immunology of the Department of Cardiothoracic Surgery at Stanford University. Until Dr. Hausen became our full-time employee in October of 2000, he remained responsible for all surgery-related research in that laboratory.

Robert Y. Newell has been our Vice President, Finance, and Chief Financial Officer since March 2003 and was appointed Vice President, Finance and Operations, in July 2005. From January 2000 to February 2003 he was Vice President, Finance and Chief Financial Officer for Omnicell, Inc., a hospital supply and medication management company. Mr. Newell holds a B.A. degree in Mathematics from the College of William & Mary and an M.B.A. degree from the Harvard Business School.

Douglas T. Ellison joined us in December 2004 as our Vice President of Sales and Marketing. From June 2004 to December 2004, Mr. Ellison consulted for medical device companies. From June 2001 until June 2004, Mr. Ellison was Vice President of Sales of Artemis Medical, Inc., a medical device company. From December 1997 until June 2001, Mr. Ellison held sales and sales management positions with Heartport, Inc., a medical device company focused on minimally-invasive cardiac surgery. Mr. Ellison holds a B.S.C.E. degree from Purdue University.

Bryan D. Knodel joined Cardica as our Vice President of Research and Development in July 2005. Since January 1998, he has been president of Bryan D. Knodel, Inc., a consulting firm specializing in medical device design and product development. From April 2001 until June 2005, Mr. Knodel consulted for us in product development. From 1992 to 1997, he was a principal engineer with Ethicon Endo-Surgery, a Johnson & Johnson

company developing medical devices for less invasive surgery. Mr. Knodel holds B.S., M.S. and Ph.D. degrees in Mechanical Engineering from the University of Illinois.

J. Michael Egan has served as the Chairman of the Board and a director since August 2000. From April 1996 through May 2004, Mr. Egan was President and CEO of Bluebird Development, LLC, a financial partnership with Kobayashi Pharmaceutical Company, an Osaka, Japan-based major distributor of medical devices in Asia. Mr. Egan is a director of several privately held companies and of Western Technology Investment, a registered investment company. Mr. Egan holds a B.A. degree in Business Administration from Colorado College.

Kevin T. Larkin joined our board in December 2005. Mr. Larkin has been President, Chief Executive Officer and a director of TherOx, a medical device company, since May 2001. From July 1998 until April 2001, Mr. Larkin was President and Chief Executive Officer of CardioVasc, a medical device company. Mr. Larkin also has held senior sales and marketing management positions with Ventritex, Medtronic and Cordis.

Richard P. Powers has been a director and chairman of our Audit Committee since October 2005. From October 2001 to the present, Mr. Powers has been Vice President and Chief Financial Officer of Anesiva, Inc. (formerly Corgentech Inc.), a biotechnology company. From March 1999 to August 2000, Mr. Powers served as Executive Vice President and Chief Financial Officer of Eclipse Surgical Technologies, Inc., a medical device company. From February 1996 to March 1999, Mr. Powers served as Executive Vice President and Chief Financial Officer of CardioGenesis Corporation, a medical device company. From January 1981 to August 1995, Mr. Powers held a number of senior management positions at Syntex Corporation, a biopharmaceutical company, including Senior Vice President and Chief Financial Officer. Mr. Powers also currently serves on the board of directors of HemoSense Inc., a manufacturer of blood monitoring equipment. Mr. Powers holds a B.S. degree in Accounting from Canisius College and an M.B.A. degree from the University of Rochester, New York.

Robert C. Robbins, M.D. has been a director since January 2001 and has been one of our scientific advisors since October 1997. Dr. Robbins is the Chairman of the Department of Cardiothoracic Surgery at the Stanford University School of Medicine, where he has been a member of the faculty since 1993. Dr. Robbins is also the director of the Stanford Cardiovascular Institute. Previously, Dr. Robbins was a Pediatric Fellow of Cardiothoracic Surgery at Emory University, and Royal Children's Hospital in Melbourne, Australia. Dr. Robbins is a former guest editor for the Surgical Supplement of Circulation and is a manuscript reviewer for a number of periodicals, including the New England Journal of Medicine and the Annals of Thoracic Surgery. He is also on the editorial board for the Journal of Thoracic and Cardiovascular Surgery. Dr. Robbins is certified by the American Board of Surgery and American Board of Thoracic Surgery. Dr. Robbins holds a B.S. degree from Millsaps College and an M.D. degree from the University of Mississippi Medical Center. Dr. Robbins completed his residency in Cardiothoracic Surgery at Stanford.

Jeffrey L. Purvin has been a director since August 2006. Mr. Purvin was most recently the chairman and chief executive officer of Metrika, Inc., a privately held manufacturer and marketer of multi-use disposable diabetes monitoring products, from November 2004 until July 2006, when the company was sold to the Bayer Group. Prior to Metrika, Mr. Purvin was president of the Interventional Products Division of Datascope Corporation, a diversified medical device company, from April 2001 until October 2004. Before Datascope, Mr. Purvin spent more than 20 years at GlaxoSmithKline, where he concluded his service as vice president, general manager. Mr. Purvin holds an M.B.A. in marketing from The Wharton School, University of Pennsylvania and a B.A. degree in psychology from Brown University.

John Simon, Ph.D. has been a director since June 2001. Mr. Simon is a Managing Director of the investment banking firm, Allen & Company LLC, where he has been employed for over 25 years. He currently serves on the board of directors for Neurogen Corporation, as well as on the boards of several privately held companies. Mr. Simon holds a B.S. degree in Chemistry from The College of William & Mary, a Ph.D. degree in Chemical Engineering from Rice University, and both an M.B.A. degree in finance and a J.D. degree from Columbia University.

Stephen A. Yencho, Ph.D. has been a director since inception. Dr. Yencho co-founded Cardica in October 1997 with Dr. Hausen. From October 1997 through December 2000, Dr. Yencho was our chief executive officer. From December 2000 through July 2003, Dr. Yencho was our Chief Technology Officer, and Dr. Yencho provided consulting services to us until February 2004. Since February 2004, Dr. Yencho has been engaged in the development of early stage ventures

separate from us. Dr. Yencho holds a B.S. degree in Mechanical Engineering from the University of Illinois and an M.S. degree in Manufacturing Systems Engineering from Stanford University. In addition, Dr. Yencho was sponsored by a Hewlett Packard Fellowship in the Ph.D. program in Precision Machinery Engineering at the University of Tokyo. He holds a Ph.D. degree in Materials Science and Engineering from Stanford University.

William H. Younger, Jr. has been a director since August 2000. Mr. Younger is a managing director of the general partner of Sutter Hill Ventures, a venture capital firm, where he has been employed since 1981. Mr. Younger holds a B.S. degree in Electrical Engineering from the University of Michigan and an M.B.A. degree from Stanford University. Mr. Younger is also a director of Omnicell, Inc., as well as of several privately held companies.

Availability of Reports filed with the SEC

A copy of our annual report on Form 10–K, quarterly reports on Form 10–Q, current reports on Form 8–K and amendments to those reports filed or furnished to the SEC can be obtained free of charge at our website www.cardica.com, or without exhibits by sending a request to our Corporate Secretary at 900 Saginaw Drive, Redwood City, CA 94063. Information on our website is not incorporated by reference to any of our filings with the SEC.

ITEM 1A. Risk Factors

Our business is subject to the risks set forth below.

Risks Related to Our Business

We are dependent upon the success of our current products, and we have U.S. regulatory clearance for our C–Port system only. We cannot be certain that any of our other products will receive regulatory clearance or approval or that any of our products, including the C–Port system, will be commercialized in the United States. If we are unable to commercialize our products in the United States, or experience significant delays in doing so, our ability to generate revenue will be significantly delayed or halted, and our business will be harmed.

We have expended significant time, money and effort in the development of our current products, the C–Port System, and the PAS–Port System. While we have regulatory approval for commercial sale of our C–Port system in the United States and in the European Union and our PAS–Port system in the European Union and Japan, we do not have clearance or approval in the United States for the PAS–Port system, later iterations of the C–Port system or any other product. While we believe most of our revenue in the near future will be derived from the sales and distribution of the C–Port system, we anticipate that our ability to increase our revenue in the longer term will depend on the regulatory clearance or approval and commercialization of the PAS–Port system and later iterations of the C–Port system in the United States.

If we are not successful in commercializing our C–Port system or obtaining U.S. Food and Drug Administration, or FDA, clearance or approval of either our later iterations of the C–Port system or the current iteration of the PAS–Port system, or if FDA clearance or approval of any of our products is significantly delayed, we may never generate substantial revenue, our business, financial condition and results of operations would be materially and adversely affected, and we may be forced to cease operations. We commenced sales of our C–Port system in the United States in January 2006, but sales may not meet our expectations. Although we have other products under development, we may never obtain regulatory clearance or approval of those devices. We may be required to spend significant amounts of capital or time to respond to requests for additional information by the FDA or foreign regulatory bodies or may otherwise be required to spend significant amounts of time and money to obtain FDA clearance or approval and foreign regulatory approval. Imposition of any of these requirements could substantially delay or preclude us from marketing our products in the United States or foreign countries.

A prior automated cardiac proximal anastomosis system was introduced by another manufacturer but was withdrawn from the market, and, as a result, we may experience difficulty in commercializing our C–Port and PAS–Port systems.

A prior automated proximal anastomosis device was introduced by another manufacturer in the United States in 2002. The FDA received reports of apparently device–related adverse events, and in 2004, the device was

voluntarily withdrawn from the market by the manufacturer. Because of the FDA's experience with this prior device, the FDA has identified new criteria for the clinical data required to obtain clearance for a proximal anastomosis device like the PAS-Port. We may not be able to show that the PAS-Port satisfies these criteria, and we may therefore be unable to obtain FDA clearance or approval to market the device in the United States, which would substantially harm our business and prospects. Moreover, physicians who have experience with or knowledge of prior anastomosis devices may be predisposed against using our C-Port or PAS-Port products, which could limit our ability to commercialize them if they are approved by the FDA. If we fail to achieve market adoption, our business, financial condition and results of operations would be materially harmed.

Lack of third-party coverage and reimbursement for our products could delay or limit their adoption.

We may experience limited sales growth resulting from limitations on reimbursements made to purchasers of our products by third-party payors, and we cannot assure you that our sales will not be impeded and our business harmed if third-party payors fail to provide reimbursement that hospitals view as adequate.

In the United States, our products will be purchased primarily by medical institutions, which then bill various third-party payors, such as the Centers for Medicare & Medicaid Services, or CMS, which administer the Medicare program, and other government programs and private insurance plans, for the health care services provided to their patients. The process involved in applying for coverage and incremental reimbursement from CMS is lengthy and expensive. Even if our products receive FDA and other regulatory clearance or approval, they may not be granted coverage and reimbursement in the foreseeable future, if at all. Moreover, many private payors look to CMS in setting their reimbursement policies and amounts. If CMS or other agencies limit coverage or decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors.

We cannot assure you that CMS will provide coverage and reimbursement for our products. If a medical device does not receive incremental reimbursement from CMS, then a medical institution would have to absorb the cost of our products as part of the cost of the procedure in which the products are used. Acute care hospitals are now generally reimbursed by CMS for inpatient operating costs under a Medicare hospital inpatient prospective payment system. Under the Medicare hospital inpatient prospective payment system, acute care hospitals receive a fixed payment amount for each covered hospitalized patient based upon the Diagnosis-Related Group, or DRG, to which the inpatient stay is assigned, regardless of the actual cost of the services provided. At this time, we do not know the extent to which medical institutions would consider insurers' payment levels adequate to cover the cost of our products. Failure by hospitals and physicians to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used could deter them from purchasing our products and limit our revenue growth. In addition, pre-determined DRG payments may decline over time, which could deter medical institutions from purchasing our products. If medical institutions are unable to justify the costs of our products, they may refuse to purchase them, which would significantly harm our business.

We have limited data regarding the safety and efficacy of the PAS-Port and C-Port and have only recently begun training physicians in the United States to use the C-Port system. Any data that is generated in the future may not be positive or consistent with our existing data, which would affect market acceptance and the rate at which our devices are adopted.

The C-Port and PAS-Port systems are innovative products, and our success depends upon their acceptance by the medical community as safe and effective. An important factor upon which the efficacy of the C-Port and PAS-Port will be measured is long-term data regarding the duration of patency, or openness, of the artery or the graft vessel. Equally important will be physicians' perceptions of the safety of our products. Our technology is relatively new in cardiac bypass surgery, and the results of short-term clinical experience of the C-Port and PAS-Port systems do not necessarily predict long-term clinical benefit. We believe that physicians will compare long-term patency for the C-Port and PAS-Port devices against alternative procedures, such as hand-sewn anastomoses. If the long-term rates of patency do not meet physicians' expectations, or if physicians find our devices unsafe, the C-Port and PAS-Port systems may not become widely adopted and physicians may recommend alternative treatments for their patients. In addition, we have recently begun training physicians in the United States to use our C-Port system. Any adverse experiences of physicians using the C-Port system, or adverse outcomes to patients, may deter physicians from using our products and negatively impact product adoption.

Our C–Port and PAS–Port systems were designed for use with venous grafts. Additionally, while our indications for use of the C–Port system cleared by the FDA refer broadly to grafts, we have studied the use of the C–Port system only with venous grafts and not with arterial grafts. Using the C–Port system with arterial grafts may not yield patency rates or material adverse cardiac event rates comparable to those found in our clinical trials using venous grafts, which could negatively affect market acceptance of our C–Port system. In addition, the clips and staples deployed by our products are made of 316L medical–grade stainless steel, to which some patients are allergic. These allergies may result in adverse reactions that negatively affect the patency of the anastomoses or the healing of the implants and may therefore adversely affect outcomes, particularly when compared to anastomoses performed with other materials, such as sutures. Additionally, in the event a surgeon, during the course of surgery, determines that it is necessary to convert to a hand–sewn anastomosis and to remove an anastomosis created by one of our products, the removal of the implants may result in more damage to the target vessel (such as the aorta or coronary artery) than would typically be encountered during removal of a hand–sewn anastomosis. Moreover, the removal may damage the target vessel to an extent that could further complicate construction of a replacement hand–sewn or automated anastomosis, which could be detrimental to patient outcome. These or other issues, if experienced, could limit physician adoption of our products.

Even if the data collected from future clinical studies or clinical experience indicates positive results, each physician’s actual experience with our device outside the clinical study setting may vary. Clinical studies conducted with the C–Port and PAS–Port systems have involved procedures performed by physicians who are technically proficient, high–volume users of the C–Port and PAS–Port systems. Consequently, both short– and long–term results reported in these studies may be significantly more favorable than typical results of practicing physicians, which could negatively impact rates of adoption of the C–Port and PAS–Port systems.

Even though our C–Port product has received U.S. regulatory clearance, our PAS–Port system, as well as our future products, may still face future development and regulatory difficulties.

Even though the current iteration of the C–Port system has received U.S. regulatory clearance, the FDA may still impose significant restrictions on the indicated uses or marketing of this product or ongoing requirements for potentially costly post–clearance studies. Any of our other products, including the PAS–Port system and future iterations of the C–Port system, may also face these types of restrictions or requirements. In addition, regulatory agencies subject a product, its manufacturer and the manufacturer’s facilities to continual review, regulation and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, our collaborators or us, including requiring withdrawal of the product from the market. Our products will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record–keeping and submission of safety and other post–market information on the product. If our products fail to comply with applicable regulatory requirements, a regulatory agency may impose any of the following sanctions:

- warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications, repair, replacement, refunds, recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- delay in processing marketing applications for new products or modifications to existing products;
- withdrawing approvals that have already been granted; and
- criminal prosecution.

To market any products internationally, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA clearance or approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA clearance or approval in the United States. Regulatory approval in one country does not ensure regulatory approval in another, but a failure

or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA clearance or approval in the United States, including the risk that our products may not be approved for use under all of the circumstances requested, which could limit the uses of our products and adversely impact potential product sales, and that such clearance or approval may require costly, post-marketing follow-up studies. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

If we do not achieve our projected development goals in the time frames we announce or expect, the commercialization of our product candidates may be delayed and, as a result, our stock price may decline.

From time to time, we may estimate and publicly announce the timing anticipated for the accomplishment of various clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include an Investigational Device Exemption application to commence our enrollment of patients in our clinical trials, the release of data from our clinical trials, receipt of clearances or approvals from regulatory authorities or other clinical and regulatory events. These estimates are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, the commercialization of our products may be delayed and, as a result, our stock price may decline.

Our products may never gain any significant degree of market acceptance, and a lack of market acceptance would have a material adverse effect on our business.

We cannot assure you that our products will gain any significant degree of market acceptance among physicians or patients, even if necessary regulatory and reimbursement approvals are obtained. We believe that recommendations by physicians will be essential for market acceptance of our products; however, we cannot assure you that any recommendations will be obtained. Physicians will not recommend the products unless they conclude, based on clinical data and other factors, that the products represent a safe and acceptable alternative to other available options. In particular, physicians may elect not to recommend using our products in surgical procedures until such time, if ever, as we successfully demonstrate with long-term data that our products result in patency rates comparable to or better than those achieved with hand-sewn anastomoses, and we resolve any technical limitations that may arise.

We believe graft patency will be a significant factor for physician recommendation of our products. Although we have not experienced low patency rates in our clinical trials, graft patency determined during the clinical trials conducted by us or other investigators may not be representative of the graft patency actually encountered during commercial use of our products. The surgical skill sets of investigators in our clinical trials may not be representative of the skills of future product users, which could negatively affect graft patency. In addition there may have been a selection bias in the patients, grafts and target vessels used during the clinical trials that positively affected graft patency. The patients included in the clinical trials may not be representative of the general patient population in the United States, which may have resulted in improved graft patency in patients enrolled in the clinical trials. Finally, patient compliance in terms of use of prescribed anticoagulating medicines may have been higher in clinical trials than may occur during commercial use, thereby negatively affecting graft patency during commercial use.

Widespread use of our products will require the training of numerous physicians, and the time required to complete training could result in a delay or dampening of market acceptance. Even if the safety and efficacy of our products is established, physicians may elect not to use our products for a number of reasons beyond our control, including inadequate or no reimbursement from health care payors, physicians' reluctance to perform anastomoses with an automated device, the introduction of competing devices by our competitors and pricing for our products. Failure of our products to achieve any significant market acceptance would have a material adverse effect on our business, financial condition and results of operations.

Because one customer accounts for substantially all of our product revenue, the loss of this significant customer could cause a substantial decline in our revenue.

We derive a significant portion of our product revenue from sales to Century Medical, Inc., or Century, our distributor in Japan. The loss of Century as a customer would cause a decrease in revenue and, consequently, an increase in our net loss. For fiscal 2006 and 2005, sales to Century accounted for approximately 64% and 94%, respectively, of our total product revenue excluding related party product revenue. We expect that Century will continue to account for a substantial portion of our revenue in the near term. As a result, if we lose Century as a customer, our revenue and net loss would be adversely affected. In addition, customers that have accounted for significant revenue in the past may not generate revenue in any future period. The failure to obtain new significant customers or additional orders from existing customers will materially affect our operating results.

If our competitors have products that are approved in advance of ours, marketed more effectively or demonstrated to be more effective than ours, our commercial opportunity will be reduced or eliminated and our business will be harmed.

The market for anastomotic solutions and cardiac bypass products is competitive. Competitors include a variety of public and private companies that currently offer or are developing cardiac surgery products generally and automated anastomotic systems specifically that would compete directly with ours.

We believe that the primary competitive factors in the market for medical devices used in the treatment of coronary artery disease include:

- improved patient outcomes;
- access to and acceptance by leading physicians;
- product quality and reliability;
- ease of use;
- device cost–effectiveness;
- training and support;
- novelty;
- physician relationships; and
- sales and marketing capabilities.

We may be unable to compete successfully on the basis of any one or more of these factors, which could have a material adverse affect on our business, financial condition and results of operations.

A number of different technologies exist or are under development for performing anastomoses, including sutures, mechanical anastomotic devices, suture–based anastomotic devices and shunting devices. Currently, substantially all anastomoses are performed with sutures and, for the foreseeable future, we believe that sutures will continue to be the principal alternative to our anastomotic products. Sutures are far less expensive than our automated anastomotic products, and other anastomotic devices may be less expensive than our own. Surgeons, who have been using sutures for their entire careers, may be reluctant to consider alternative technologies, despite potential advantages. Any resistance to change among practitioners could delay or hinder market acceptance of our products, which would have a material adverse effect on our business.

Cardiovascular diseases may also be treated by other methods that do not require anastomoses, including, interventional techniques such as balloon angioplasty with or without the use of stents, pharmaceuticals, atherectomy catheters and lasers. Several of these alternative treatments are widely accepted in the medical community and have a long history of use. In addition, technological advances with other therapies for cardiovascular disease, such as drugs, or future innovations in cardiac surgery techniques could make other methods of treating this disease more effective or lower cost than bypass procedures. For example, the number of bypass procedures in the United States and other major markets has declined in recent years and is expected to decline in

the years ahead because competing treatments are, in many cases, far less invasive and provide acceptable clinical outcomes. Many companies working on treatments that do not require anastomoses may have significantly greater financial, manufacturing, marketing, distribution, and technical resources and experience than we have. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical testing, clinical trials, obtaining regulatory clearance or approval and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Our competitors may succeed in developing technologies and therapies that are more effective, better tolerated or less costly than any that we are developing or that would render our product candidates obsolete and noncompetitive. Our competitors may succeed in obtaining clearance or approval from the FDA and foreign regulatory authorities for their products sooner than we do for ours. We will also face competition from these third parties in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient enrollment for clinical trials and in acquiring and in-licensing technologies and products complementary to our programs or advantageous to our business.

We have limited manufacturing experience and may encounter difficulties in increasing production to provide an adequate supply to customers.

To date, our manufacturing activities have consisted primarily of producing limited quantities of our products for use in clinical studies and for sales in Japan and Europe. We do not have experience in manufacturing our products in the commercial quantities that might be required to market our products in the United States. Production in commercial quantities will require us to expand our manufacturing capabilities and to hire and train additional personnel. We may encounter difficulties in increasing our manufacturing capacity and in manufacturing commercial quantities, including:

- maintaining product yields;
- maintaining quality control and assurance;
- providing component and service availability;
- maintaining adequate control policies and procedures; and
- hiring and retaining qualified personnel.

Difficulties encountered in increasing our manufacturing could have a material adverse effect on our business, financial condition and results of operations.

The manufacture of our products is a complex and costly operation involving a number of separate processes and components. In addition, the current unit costs for our products, based on limited manufacturing volumes, are very high, and it will be necessary to achieve economies of scale to become profitable. Certain of our manufacturing processes are labor intensive, and achieving significant cost reductions will depend in part upon reducing the time required to complete these processes. We cannot assure you that we will be able to achieve cost reductions in the manufacture of our products and, without these cost reductions, our business may never achieve profitability.

We have considered, and will continue to consider as appropriate, manufacturing in-house certain components currently provided by third parties, as well as implementing new production processes. Manufacturing yields or costs may be adversely affected by the transition to in-house production or to new production processes, when and if these efforts are undertaken, which would materially and adversely affect our business, financial condition and results of operations.

Our manufacturing facilities, and those of our suppliers, must comply with applicable regulatory requirements. Failure to obtain regulatory approval of our manufacturing facilities would harm our business and our results of operations.

Our manufacturing facilities and processes are subject to periodic inspections and audits by various U.S. federal, U.S. state and foreign regulatory agencies. For example, our facilities have been inspected by State of California regulatory authorities pursuant to granting a California Device Manufacturing License, but not, to

date, by the FDA. Additionally, to market products in Europe, we are required to maintain ISO 13485:2003 certification and are subject to periodic surveillance audits. We are currently ISO 13485:2003 certified; however, our failure to maintain necessary regulatory approvals for our manufacturing facilities could prevent us from manufacturing and selling our products.

Additionally, our manufacturing processes and, in some cases, those of our suppliers are required to comply with FDA's Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products, including the PAS-Port and C-Port. We are also subject to similar state requirements and licenses. In addition, we must engage in extensive record keeping and reporting and must make available our manufacturing facilities and records for periodic inspections by governmental agencies, including FDA, state authorities and comparable agencies in other countries. If we fail a QSR inspection, our operations could be disrupted and our manufacturing interrupted. Failure to take adequate corrective action in response to an adverse QSR inspection could result in, among other things, a shut-down of our manufacturing operations, significant fines, suspension of product distribution or other operating restrictions, seizures or recalls of our device and criminal prosecutions, any of which would cause our business to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements, which may result in manufacturing delays for our products and cause our revenue to decline.

If we are unable to establish sales and marketing capabilities or enter into and maintain arrangements with third parties to market and sell our products, our business may be harmed.

We are in the beginning stages of building a sales and marketing organization, and we have limited experience as a company in the sales, marketing and distribution of our products. Century is responsible for marketing and commercialization of the PAS-Port system in Japan. To promote our current and future products in the United States and Europe, we must develop our sales, marketing and distribution capabilities or make arrangements with third parties to perform these services. Competition for qualified sales personnel is intense. Developing a sales force is expensive and time consuming and could delay any product launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our products. To the extent that we enter into arrangements with third parties to perform sales and marketing services, our product revenue may be lower than if we directly marketed and sold our products. We expect to rely on third-party distributors for substantially all of our international sales. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenue and may not become profitable.

We will need to increase the size of our organization, and we may experience difficulties in managing this growth.

As of June 30, 2006, we had 56 employees. We will need to continue to expand our managerial, operational, financial and other resources to manage and fund our operations and clinical trials, continue our research and development activities and commercialize our products. It is possible that our management and scientific personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and programs requires that we continue to improve our operational, financial and management controls, reporting systems and procedures and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and commercialization goals.

We are dependent upon a number of key suppliers, including single source suppliers, the loss of which would materially harm our business.

We use or rely upon sole source suppliers for certain components and services used in manufacturing our products, and we utilize materials and components supplied by third parties with which we do not have any long-term contracts. In recent years, many suppliers have ceased supplying raw materials for use in implantable medical devices. We cannot assure you that materials required by us will not be restricted or that we will be able to obtain sufficient quantities of such materials or services in the future. Moreover, the continued use by us of materials

manufactured by third parties could subject us to liability exposure. Because we do not have long-term contracts, none of our suppliers is required to provide us with any guaranteed minimum production levels.

We cannot quickly replace suppliers or establish additional new suppliers for some of these components, particularly due to both the complex nature of the manufacturing process used by our suppliers and the time and effort that may be required to obtain FDA clearance or approval or other regulatory approval to use materials from alternative suppliers. Any significant supply interruption or capacity constraints affecting our facilities or those of our suppliers would have a material adverse effect on our ability to manufacture our products and, therefore, a material adverse effect on our business, financial condition and results of operations.

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 products.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. We may become a party to patent infringement claims and litigation or interference proceedings declared by the U.S. Patent and Trademark Office to determine the priority of inventions. The defense and prosecution of these matters are both costly and time consuming. Additionally, we may need to commence proceedings against others to enforce our patents, to protect our trade secrets or know-how or to determine the enforceability, scope and validity of the proprietary rights of others. These proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel.

We are aware of patents issued to third parties that contain subject matter related to our technology. We cannot assure you that these or other third parties will not assert that our products and systems infringe the claims in their patents or seek to expand their patent claims to cover aspects of our products and systems. An adverse determination in litigation or interference proceedings to which we may become a party could subject us to significant liabilities or require us to seek licenses. In addition, if we are found to willfully infringe third-party patents, we could be required to pay treble damages in addition to other penalties. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with these arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. If we do not obtain necessary licenses, we may be required to redesign our products to avoid infringement, and it may not be possible to do so effectively. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling the C-Port system, PAS-Port system or any other product we may develop, which would have a significant adverse impact on our business.

On March 16, 2006, we received notice that the Board of Patent Appeals and Interferences of the U.S. Patent and Trademark Office, referred to as the Patent Appeals Board, declared an interference between our U.S. Patent No 6,391,038 (which relates to our C-Port system) and a pending U.S. Patent Application 10/243,543, which patent application has been assigned to Integrated Vascular Interventional Technologies, LLC, or IVIT. An interference is a proceeding within the U.S. Patent and Trademark Office to determine priority of invention of the subject matter of patent claims. The declaration of interference is made by the Patent Appeals Board only after claims in a patent application are deemed allowable but for the interfering subject matter (in this case our issued patent) and a determination that interfering subject matter exists. The declaration of interference initiates an adversarial proceeding in the U.S. Patent and Trademark Office before the Patent Appeals Board. The proceeding will involve issues including but not limited to whether an interference proceeding is appropriate, whether the involved claims of the parties are patentable and which party was first to invent the interfering subject matter. We will vigorously defend our patents against such claim of interference, although there can be no assurance that we will succeed in doing so. There can be no assurance that IVIT's patent claims, if allowed, will be in their present form, or that our products would not be found to infringe such claims or any other claims that are issued.

Intellectual property rights may not provide adequate protection, which may permit third parties to compete against us more effectively.

We rely upon patents, trade secret laws and confidentiality agreements to protect our technology and products. Our pending patent applications may not issue as patents or, if issued, may not issue in a form that will be advantageous to us. Any patents we have obtained or will obtain in the future might be invalidated or circumvented by third parties. If any challenges are successful, competitors might be able to market products and use manufacturing processes that are substantially similar to ours. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors or former or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be adequate. In addition, the laws of many foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. To the extent that our intellectual property protection is inadequate, we are exposed to a greater risk of direct competition. In addition, competitors could purchase any of our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. If our intellectual property is not adequately protected against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We also rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We require our employees, consultants and advisors to execute appropriate confidentiality and assignment-of-inventions agreements with us. These agreements typically provide that all materials and confidential information developed or made known to the individual during the course of the individual's relationship with us be kept confidential and not disclosed to third parties except in specific circumstances and that all inventions arising out of the individual's relationship with us shall be our exclusive property. These agreements may be breached, and in some instances, we may not have an appropriate remedy available for breach of the agreements. Furthermore, our competitors may independently develop substantially equivalent proprietary information and techniques, reverse engineer our information and techniques, or otherwise gain access to our proprietary technology.

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 our products. Accordingly, our success will depend in part upon our ability to respond quickly to medical and technological changes through the development and introduction of new products. The relative speed with which we can develop products, complete clinical testing and regulatory clearance or approval processes, train physicians in the use of our products, gain reimbursement acceptance, and supply commercial quantities of the products to the market are expected to be important competitive factors. 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 have experienced delays in completing the development and commercialization of our planned products, and there can be no assurance that these delays will not continue or recur in the future. Any delays could result in a loss of market acceptance and market share.

We may not be successful in our efforts to expand our product portfolio, and our failure to do so could cause our business and prospects to suffer.

We intend to use our knowledge and expertise in anastomotic technologies to discover, develop and commercialize new applications in endoscopic surgery, general vascular surgery or other markets. However, the process of researching and developing anastomotic devices is expensive, time-consuming and unpredictable. Our efforts to create products for these new markets are at a very early stage, and we may never be successful in developing viable products for these markets. Even if our development efforts are successful and we obtain the

necessary regulatory and reimbursement approvals, we cannot assure you that these or our other products will gain any significant degree of market acceptance among physicians, patients or health care payors. Accordingly, we anticipate that, for the foreseeable future, we will be substantially dependent upon the successful development and commercialization of anastomotic systems and instruments for cardiac surgery, mainly the PAS–Port system and the C–Port system. Failure by us to successfully develop and commercialize these systems for any reason, including failure to overcome regulatory hurdles or inability to gain any significant degree of market acceptance, would have a material adverse effect on our business, financial condition and results of operations.

We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and, if we are unable to fully comply with such laws, could face substantial penalties.

Our operations may be directly or indirectly affected by various broad state and federal healthcare fraud and abuse laws, including the federal healthcare program Anti–Kickback Statute, which prohibit any person from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce or reward either the referral of an individual, or the furnishing or arranging for an item or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. Foreign sales of our products are also subject to similar fraud and abuse laws, including application of the U.S. Foreign Corrupt Practices Act. If our operations, including any consulting arrangements we may enter into with physicians who use our products, are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation. If enforcement action were to occur, our business and financial condition would be harmed.

We could be exposed to significant product liability claims, which could be time consuming and costly to defend, divert management attention, and adversely impact our ability to obtain and maintain insurance coverage. The expense and potential unavailability of insurance coverage for our company or our customers could adversely affect our ability to sell our products, which would adversely affect our business.

The testing, manufacture, marketing, and sale of our products involve an inherent risk that product liability claims will be asserted against us. Additionally, we are currently training physicians in the United States on the use of our C–Port system. During training, patients may be harmed, which could also lead to product liability claims. Product liability claims or other claims related to our products, or their off–label use, regardless of their merits or outcomes, could harm our reputation in the industry, reduce our product sales, lead to significant legal fees, and result in the diversion of management’s attention from managing our business. As of August 2006, we were not aware of any existing product liability claims.

Although we maintain product liability insurance in the amount of \$5,000,000, we may not have sufficient insurance coverage to fully cover the costs of any claim or any ultimate damages we might be required to pay. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage. Product liability claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and adversely affecting our financial condition and operating results.

Some of our customers and prospective customers may have difficulty in procuring or maintaining liability insurance to cover their operations and use of the C–Port or PAS–Port systems. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using the C–Port or PAS–Port systems and potential customers may opt against purchasing the C–Port or PAS–Port systems due to the cost or inability to procure insurance coverage.

We sell our systems internationally and are subject to various risks relating to these international activities, which could adversely affect our revenue.

The majority of our product revenue in fiscal 2006 and 2005 was attributable to sales in international markets. By doing business in international markets, we are exposed to risks separate and distinct from those we face in our domestic operations. Our international business may be adversely affected by changing economic conditions in foreign countries. Because most of our sales are currently denominated in U.S. dollars, if the value of the U.S. dollar increases relative to foreign currencies, our products could become more costly to the international customer and, therefore, less competitive in international markets, which could affect our results of operations. Engaging in international business inherently involves a number of other difficulties and risks, including:

- export restrictions and controls relating to technology;
- the availability and level of reimbursement within prevailing foreign healthcare payment systems;
- pricing pressure that we may experience internationally;
- required compliance with existing and changing foreign regulatory requirements and laws;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs and other trade barriers;
- international terrorism and anti-American sentiment;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties in enforcing intellectual property rights.

Our exposure to each of these risks may increase our costs, impair our ability to market and sell our products and require significant management attention. We cannot assure you that one or more of these factors will not harm our business.

We are dependent upon key personnel, loss of any of which could have a material adverse affect on our business.

Our future business and operating results depend significantly on the continued contributions of our key technical personnel and senior management, including those of our co-founder, CEO and President, Bernard Hausen, M.D., Ph.D. These services and individuals would be difficult or impossible to replace and none of these individuals is subject to a post-employment non-competition agreement. While we are subject to certain severance obligations to Dr. Hausen, either he or we may terminate his employment at any time and for any lawful reason or for no reason. Our business and future operating results also depend significantly on our ability to attract and retain qualified management, manufacturing, technical, marketing, sales and support personnel for our operations. Competition for such personnel is intense, and there can be no assurance that we will be successful in attracting or retaining such personnel. Additionally, although we have key-person life insurance in the amount of \$3.0 million on the life of Dr. Hausen, we cannot assure you that this amount would fully compensate us for the loss of Dr. Hausen's services. The loss of key employees, the failure of any key employee to perform or our inability to attract and retain skilled employees, as needed, could materially adversely affect our business, financial condition and results of operations.

Our operations are currently conducted at a single location that may be at risk from earthquakes, terror attacks or other disasters.

We currently conduct all of our manufacturing, development and management activities at a single location in Redwood City, California, near known earthquake fault zones. We have taken precautions to safeguard our

facilities, including insurance, health and safety protocols, and off-site storage of computer data. However, any future natural disaster, such as an earthquake, or a terrorist attack, could cause substantial delays in our operations, damage or destroy our equipment or inventory and cause us to incur additional expenses. A disaster could seriously harm our business and results of operations. Our insurance does not cover earthquakes and floods and may not be adequate to cover our losses in any particular case.

If we use hazardous materials in a manner that causes injury, we may be liable for damages.

Our research and development and manufacturing activities involve the use of hazardous materials. Although we believe that our safety procedures for handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot entirely eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of these materials. If one of our employees were accidentally injured from the use, storage, handling or disposal of these materials, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific hazardous waste insurance coverage, and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory clearances or approvals could be suspended.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.

If our products receive FDA clearance or approval, our promotional materials and training methods regarding physicians will need to comply with FDA and other applicable laws and regulations. If the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

Risks Related to Our Finances and Capital Requirements

We have a history of net losses, which we expect to continue for the foreseeable future, and we are unable to predict the extent of future losses or when we will become profitable, if at all.

We have incurred net losses since our inception in October 1997. As of June 30, 2006, our accumulated deficit was approximately \$60.4 million. We expect to incur substantial additional losses until we can achieve significant commercial sales of our products, which depend upon a number of factors, including the successful commercial launch of our C-Port system in the United States and receipt of regulatory clearance or approval and market adoption of our additional products in the United States. We commenced commercial sales of the C-Port system in Europe in 2004 and in the United States in 2006 and the PAS-Port system in Japan in 2004, and our short commercialization experience makes it difficult for us to predict future performance. Our failure to accurately predict financial performance may lead to volatility in our stock price.

Our cost of product revenue was 203% and 142% of our net product revenue for fiscal 2006 and 2005, respectively. We expect to continue to have high costs of product revenue for the foreseeable future. In addition, we expect that our operating expenses will increase as we expand our commercialization efforts and devote resources to our sales and marketing, as well as conduct other research and development activities. If, over the long term, we are unable to reduce our cost of producing goods and expenses relative to our net revenue, we may not achieve profitability even if we are able to generate significant revenue from sales of the C-Port and PAS-Port systems. Our failure to achieve and sustain profitability would negatively impact the market price of our common stock.

We currently lack a significant source of product revenue, and prior agreements with Guidant, which represented 75% of our revenue in fiscal year 2004 and 65% of our revenue in fiscal year 2005, have been terminated. We may not become or remain profitable.

Our ability to become and remain profitable depends upon our ability to generate product revenue. Our ability to generate significant continuing revenue depends upon a number of factors, including:

- achievement of U.S. regulatory clearance or approval for our additional products;
- successful completion of ongoing clinical trials for our products; and
- successful sales, manufacturing, marketing and distribution of our products.

For the fiscal year ended June 30, 2005, sales of our products and development activities generated only \$2.1 million of revenue, 65% of which was from Guidant. For the fiscal year ended June 30, 2004, sales of our products and development activities generated only \$0.8 million of revenue, 75% of which was from Guidant. Our distribution and development agreements with Guidant have terminated. We do not expect to enter into future development contracts with Guidant. Accordingly, we do not anticipate any future revenue from development contracts with Guidant. As Guidant outsourced the manufacture of the aortic cutter to a contract manufacturing company, we ceased manufacturing the aortic cutter. While we receive a modest royalty from Guidant's sales of the aortic cutter, we do not anticipate any significant future revenue from this royalty. We received \$24,000 in royalty revenue from Guidant in fiscal 2006.

We do not anticipate that we will generate significant product revenue for the foreseeable future. If we are unable to generate significant product revenue, we will not become or remain profitable, and we may be unable to continue our operations.

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

Our development efforts have consumed substantial capital to date. We believe that our existing cash, cash equivalents and short-term investments, along with cash that we expect to generate from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures through at least the next 18 months. Because we do not anticipate that we will generate significant product revenue for the foreseeable future, if at all, we will need to raise substantial additional capital to finance our operations in the future. Our future liquidity and capital requirements will depend upon, and could increase significantly as a result of, numerous factors, including:

- market acceptance and adoption of our products;
- our revenue growth;
- costs associated with our sales and marketing initiatives and manufacturing activities;
- costs of obtaining and maintaining FDA and other regulatory clearances and approvals for our products;
- securing, maintaining and enforcing intellectual property rights;
- the costs of developing marketing and distribution capabilities;
- the extent of our ongoing research and development programs;
- the progress of clinical trials; and
- effects of competing technological and market developments.

Until we can generate significant continuing revenue, if ever, we expect to satisfy our future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any corporate collaboration and licensing arrangements may require us to

relinquish valuable rights. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our commercialization efforts or one or more of our research and development programs.

If we do not generate sufficient cash flow through increased revenue or raising additional capital, then we may not be able to meet our substantial debt obligations that become due in 2008.

As of June 30, 2006, we had an aggregate principal amount of approximately \$13.3 million in long-term notes payable to Century and Guidant Investment Corporation that mature in 2008. The accrued interest under the Guidant note due at maturity in 2008 will be \$4.2 million, of which \$2.3 million was recorded as of June 30, 2006. This substantial indebtedness has and will continue to impact us by:

- making it more difficult to obtain additional financing; and
- constraining our ability to react quickly in an unfavorable economic climate.

Currently we are not generating positive cash flow. Adverse occurrences related to our product commercialization, development and regulatory efforts would adversely impact our ability to meet our obligations to repay the principal amounts on our notes when due in 2008. If we are unable to satisfy our debt service requirements, we may not be able to continue our operations. We may not generate sufficient cash from operations to repay our notes or satisfy any additional debt obligations when they become due and may have to raise additional financing from the sale of equity or debt securities, enter into commercial transactions or otherwise restructure our debt obligations. There can be no assurance that any such financing or restructuring will be available to us on commercially acceptable terms, if at all. If we are unable to restructure our obligations, we may be forced to seek protection under applicable bankruptcy laws. Any restructuring or bankruptcy could materially impair the value of our common stock.

Existing creditors have rights to our assets that are senior to our stockholders.

Existing arrangements with our current lenders, Century and Guidant Investment Corporation, as well as future arrangements with other creditors, allow or may allow these creditors to liquidate our assets, which may include our intellectual property rights, if we are in default or breach of our debt obligations for a continued period of time. The proceeds of any sale or liquidation of our assets under these circumstances would be applied first to any of our debt obligations and would have priority over any of our capital stock, including any liquidation preference of the preferred stock. After satisfaction of our debt obligations, we may have little or no proceeds left under these circumstances to distribute to the holders of our capital stock.

Our quarterly operating results and stock price may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. The revenue we generate, if any, and our operating results will be affected by numerous factors, many of which are beyond our control, including:

- the rate of physician adoption of our products;
- the results of clinical trials related to our products;
- the introduction by us or our competitors, and market acceptance of, new products;
- the results of regulatory and reimbursement actions;
- the timing of orders by distributors or customers;
- the expenditures incurred in the research and development of new products; and
- competitive pricing.

Quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

Risks Related to Our Common Stock

The price of our common stock may continue to be volatile, and the value of an investment in our common stock may decline.

We sold shares of common stock in our IPO in February 2006 at a price of \$10.00 per share, and our stock has subsequently traded at per share prices as low as \$4.50 per share as of August 31, 2006. An active and liquid trading market for our common stock may not develop or be sustained. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- market acceptance and adoption of our products;
- regulatory clearance or approvals of our products;
- volume and timing of orders for our products;
- changes in earnings estimates, investors' perceptions, recommendations by securities analysts or our failure to achieve analysts' earning estimates;
- quarterly variations in our or our competitors' results of operations;
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors;
- the announcement of new products or product enhancements by us or our competitors;
- announcements related to patents issued to us or our competitors and to litigation; and
- developments in our industry.

In addition, the stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of those companies. These factors may materially and adversely affect the market price of our common stock.

The ownership of our common stock is highly concentrated, and your interests may conflict with the interests of our existing stockholders.

Our executive officers and directors and their affiliates, together with our current significant stockholders, beneficially owned approximately 41.2% of our outstanding common stock as of June 30, 2006. Accordingly, these stockholders, acting as a group, have significant influence over the outcome of corporate actions requiring stockholder approval and continue to have significant influence over our operations. The interests of these stockholders may be different than the interests of other stockholders on these matters. This concentration of ownership could also have the effect of delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could reduce the price of our common stock.

Evolving regulation of corporate governance and public disclosure will result in additional expenses and continuing uncertainty.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes–Oxley Act of 2002, new SEC regulations and Nasdaq National Market rules are creating uncertainty for public companies. We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional compliance costs we may incur or the timing of such costs. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by courts and regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Maintaining appropriate standards of corporate governance and public disclosure will result in increased general and administrative expenses and a diversion of management time and attention from revenue–generating activities to compliance activities. In addition, if we fail to comply with new or changed laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business and reputation may be harmed.

If we sell shares of our common stock in future financings, common stockholders may experience immediate dilution and, as a result, our stock price may decrease.

We may from time to time issue additional shares of capital stock at a discount from the current trading price of our common stock. As a result, our common stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders could experience dilution and our stock price may decline.

A significant portion of our total outstanding shares have been restricted from immediate resale subsequent to our initial public offering in February 2006, but these shares are now tradable subject to Rule 144. If there are substantial sales of our common stock, the price of our common stock could decline

Sales of substantial amounts of our common stock in the public market could adversely affect the price of our common stock. As of September 1, 2006, a total of 9,815,693 shares of common stock were outstanding. Up to 4,033,492 of those shares are held by affiliates and may only be sold in compliance with the volume limitations of Rule 144. These volume limitations restrict the number of shares that may be sold by an affiliate in any three-month period to the greater of 1% of the number of shares then outstanding, which equals approximately 981,569, or the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Our future operating results may be below securities analysts' or investors' expectations, which could cause our stock price to decline.

The revenue and income potential of our products and our business model are unproven, and we may be unable to generate significant revenue or grow at the rate expected by securities analysts or investors. In addition, our costs may be higher than we, securities analysts or investors expect. If we fail to generate sufficient revenue or our costs are higher than we expect, our results of operations will suffer, which in turn could cause our stock price to decline. Our results of operations will depend upon numerous factors, including:

- FDA or other regulatory clearance or approval of our PAS-Port system, future iterations of our C-Port system or our other products;
- demand for our products;
- the performance of third-party contract manufacturers and component suppliers;
- our ability to develop sales and marketing capabilities;
- our ability to develop, introduce and market new or enhanced versions of our products on a timely basis; and
- our ability to obtain and protect proprietary rights.

Our operating results in any particular period may not be a reliable indication of our future performance. In some future quarters, our operating results may be below the expectations of securities analysts or investors. If this occurs, the price of our common stock will likely decline.

Anti-takeover defenses that we have in place could prevent or frustrate attempts to change our direction or management.

Provisions of our certificate of incorporation and bylaws and applicable provisions of Delaware law may make it more difficult for or prevent a third party from acquiring control of us without the approval of our board of directors. These provisions:

- limit who may call a special meeting of stockholders;

- establish advance notice requirements for nominations for election to our board of directors or for proposing matters that can be acted upon at stockholder meetings;
- prohibit cumulative voting in the election of our directors, which would otherwise permit less than a majority of stockholders to elect directors;
- prohibit stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; and
- provide our board of directors with the ability to designate the terms of and issue a new series of preferred stock without stockholder approval.

In addition, Section 203 of the Delaware General Corporation Law generally prohibits us from engaging in any business combination with certain persons who own 15% or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15% or more of our outstanding voting stock. These provisions may have the effect of entrenching our management team and may deprive you of the opportunity to sell your shares to potential acquirors at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock.

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

The stock market in general, the Nasdaq National Market and the market for medical device companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, the market prices of securities of medical device companies have been particularly volatile. 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.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date, and we currently intend to return our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 29,000 square feet in Redwood City, California. We believe that our existing facility should meet our needs for at least the next 24 months. Our facility is subject to periodic inspections by state and federal regulatory authorities.

Item 3. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations. Other than the interference proceedings described below, we are not currently involved in any material legal proceedings.

On March 16, 2006, we received notice that the Board of Patent Appeals and Interferences of the U.S. Patent and Trademark Office (the "Patent Appeals Board") declared an interference between our U.S. Patent No 6,391,038 (which relates to our C-Port system) and a pending U.S. Patent Application 10/243,543, which patent application has been assigned to Integrated Vascular Interventional Technologies, LLC ("IVIT").

An interference is a proceeding within the U.S. Patent and Trademark Office to determine priority of invention of the subject matter of patent claims. The declaration of interference is made by the Patent Appeals Board only after claims in a patent application are deemed allowable but for the interfering subject matter (in this case our issued patent) and a determination that interfering subject matter exists. The declaration of interference initiates an adversarial proceeding in the U.S. Patent and Trademark Office before the Patent Appeals Board. The proceeding will involve issues including but not limited to whether an interference proceeding is appropriate, whether the involved claims of the parties are patentable and which party was first to invent the interfering subject matter.

We will vigorously defend our patents against such claim of interference, although there can be no assurance that we will succeed in doing so. We continue to believe that if IVIT's patent claims are allowed in their present form, our products would not infringe such claims. There can be no assurance that IVIT's patent claims, if allowed, will be in their present form, or that our products would not be found to infringe such claims or any other claims that are issued.

Item 4. *Submission of Matters to a Vote of Security Holders*

No matters were submitted to a vote of Cardica's stockholders, through the solicitation of proxies or otherwise, during the fiscal quarter ended June 30, 2006.

PART II

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

Market for Common Equity

Our common stock began trading on the NASDAQ Global Market on February 3, 2006, under the symbol "CRDC." The table below sets forth the high and low closing prices for our common stock for the periods indicated:

	<u>High</u>	<u>Low</u>
Third Quarter ended March 31, 2006 (From February 3, 2006)	\$ 10.35	\$ 7.87
Fourth Quarter ended June 30, 2006	\$ 8.10	\$ 5.80

As of July 31, 2006, there were 199 holders of record of common stock. This number does not include the number of persons whose shares are in nominee or in "street name" accounts through brokers.

Dividend Policy

We have never declared or paid any dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance our operations and do not anticipate paying any cash dividends on our capital stock in the foreseeable future.

Equity Compensation Plan Information

The information required by this Item 5 concerning the Company's equity compensation plans will be contained in our definitive Proxy Statement with respect to our Annual Meeting of Stockholders, to be held on November 8, 2006, under the caption "Equity Compensation Plan Information" and is incorporated herein by reference.

Recent Sales of Unregistered Securities

During the fiscal year ended June 30, 2006, we sold and issued the following securities which were not registered under the Securities Act of 1933. The following share numbers have been adjusted to reflect a 1-for-3 reverse stock split of preferred stock and common stock and the conversion of our preferred stock into common stock effected immediately prior to the completion of the our initial public offering.

1. We granted stock options to employees and directors under our 1997 Equity Incentive Plan exercisable for an aggregate of 318,543 shares of common stock, with exercise prices ranging from \$2.85 to \$9.75 and a weighted average exercise price of \$5.42. During this period, options to purchase an aggregate 80,790 shares of our common stock were cancelled without being exercised. Also, during this period, options to purchase an aggregate of 24,138 shares of our common stock, with a weighted-average exercise price of \$1.83, were exercised.

2. We issued 3,333 shares of common stock to a director for services rendered. For accounting purposes, we valued the consideration received for these shares at \$30,000.

The sales and issuances of securities in the transactions described in paragraphs (1) and (2) above were deemed exempt from registration under the Securities Act of 1933, as amended (the "Securities Act") under Section 4(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

Use of Proceeds From Registered Securities

The initial public offering of 3,700,000 shares of our common stock was effected through a Registration Statement on Form S-1 (Reg. No. 333-129497) which was declared effective by the Securities and Exchange Commission on February 7, 2006. We issued 3,500,000 shares on February 8, 2006 for gross proceeds of \$35.0 million. On February 27, 2006, we sold an additional 200,000 shares of our common stock to the underwriters pursuant to the exercise of the over-allotment option in part for gross proceeds of \$2.0 million. After deducting the underwriters' commission and the offering expenses, we received net proceeds of approximately \$32.6 million.

Allen & Company, LLC received an underwriting commission of \$1,041,250 in connection with our initial public offering. John Simon, a member of our Board of Directors, is affiliated with Allen & Company, LLC. No other payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

Of the net offering proceeds, through June 30, 2006, approximately \$0.5 million of the net proceeds have been used for sales and marketing activities. The remaining net proceeds have been invested into short-term investment grade securities and money market accounts. We have begun, and intend to continue to use, our net proceeds to continue funding the development of our products, including clinical trials and research programs, to build sales and marketing capabilities and for general corporate purposes, including capital expenditures and working capital.

Issuer Purchases of Equity Securities

During the fourth quarter of fiscal 2006, we did not repurchase any equity securities.

ITEM 6. Selected Financial Data

The following selected financial data should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and notes to those statements included elsewhere in this report.

The following selected balance sheet data as of June 30, 2006 and 2005 and the statements of operations data for each of the three years in the period ended June 30, 2006 have been derived from our audited financial statements, which are included elsewhere in this annual report. The selected balance sheet data as of June 30, 2004, 2003 and 2002 and the selected statements of operations data for the years ended June 30, 2004, 2003 and 2002 have been derived from our audited financial statements not included in this annual report. Historical results are not necessarily indicative of the results to be expected in future periods.

On December 12, 2005, our board of directors approved, and on January 6, 2006, our stockholders approved, an amendment to our Amended and Restated Certificate of Incorporation to effect a one-for-three reverse split of our common stock and preferred stock. All information related to common stock, preferred stock, options and warrants to purchase common or preferred stock and earnings per share included in these selected balance sheet data and selected statement of operations data has been retroactively adjusted to give effect to the reverse stock split.

	Fiscal Year Ended June 30,				
	2006	2005	2004	2003	2002
(In thousands, except per share data)					
Statements of Operation Data:					
Net revenue:					
Product revenue, net	\$ 1,028	\$ 719	\$ 212	\$ —	\$ —
Development revenue	1,000	—	—	—	—
Product and royalty revenue from related party, net	31	1,027	401	—	—
Development revenue from related party	—	310	223	—	—
Total net revenue	<u>2,059</u>	<u>2,056</u>	<u>836</u>	<u>—</u>	<u>—</u>
Operating costs and expenses:					
Cost of product revenue (includes related-party costs of \$1,180 and \$1,377 in fiscal 2005 and 2004, respectively)	2,102	2,478	2,105	—	—
Research and development	6,459	6,289	5,826	6,698	5,765
Selling, general and administrative	5,645	3,753	1,809	1,936	1,635
Total operating costs and expenses	<u>14,206</u>	<u>12,520</u>	<u>9,740</u>	<u>8,634</u>	<u>7,400</u>
Loss from operations	(12,147)	(10,464)	(8,904)	(8,634)	(7,400)
Interest income	782	305	209	294	210
Interest expense (includes related-party interest expense of \$897, \$897 and \$539 in fiscal 2006, 2005 and 2004, respectively)	(1,047)	(1,048)	(2,001)	(885)	(675)
Other income (expense), net (includes \$250 income from related-party in fiscal 2005)	(4)	257	(14)	—	—
Net loss	<u>\$ (12,416)</u>	<u>\$ (10,950)</u>	<u>\$ (10,710)</u>	<u>\$ (9,225)</u>	<u>\$ (7,865)</u>
Basic and diluted net loss per common share	<u>\$ (2.58)</u>	<u>\$ (7.82)</u>	<u>\$ (8.24)</u>	<u>\$ (7.84)</u>	<u>(7.53)</u>
Shares used in computing basic and diluted net loss per common share	<u>4,817</u>	<u>1,401</u>	<u>1,299</u>	<u>1,176</u>	<u>1,045</u>

	As of June 30,				
	2006	2005	2004	2003	2002
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 32,080	\$ 8,951	\$ 17,224	\$ 17,680	\$ 21,822
Working capital	31,602	9,032	16,402	13,396	18,730
Total assets	35,158	12,146	20,231	19,763	23,095
Long-term liabilities	15,836	15,156	14,359	5,129	1,984
Convertible preferred stock	—	39,683	39,683	35,038	35,038
Total stockholders’ equity (deficit)	17,677	(43,685)	(35,430)	(25,103)	(17,110)

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes to those statements included elsewhere in this report. In addition to historical financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results and timing of selected events may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this Report.

Overview

We design and manufacture proprietary automated anastomotic systems used by surgeons to perform coronary bypass surgery. In coronary artery bypass grafting, or CABG, procedures, veins or arteries are used to construct alternative conduits to restore blood flow beyond closed or narrowed portions of coronary arteries, "bypassing" the occluded portion of the coronary artery that is impairing blood flow to the heart muscle. Our products provide cardiovascular surgeons with easy-to-use automated systems to perform consistent, rapid and reliable connections, or anastomoses, of the vessels, which surgeons generally view as the most critical aspect of the bypass procedure. We currently sell our C-Port® Distal Anastomosis System, or C-Port system, in the United States and Europe. We submitted a 510(k) application for the C-Port xA, an iteration of the C-Port system, to the U.S. Food and Drug Administration, or FDA, in December 2005. The C-Port system is used to perform a distal anastomosis, which is the connection of a bypass graft vessel to a coronary artery downstream of the occluded portion of the coronary artery. We currently sell our PAS-Port® Proximal Anastomosis System, or the PAS-Port system, in Europe and Japan, and we initiated a clinical trial of this system in the United States and Europe in June 2006. The PAS-Port system is used to perform a proximal anastomosis, which is the connection of a bypass graft vessel to the aorta or other source of blood.

In December 2005, we entered into a license, development and commercialization agreement with Cook Incorporated, or Cook, relating to development of our X-Port™ Vascular Access Closure Device, or X-Port, a product candidate of ours that we are currently studying in preclinical animal model studies. Under the agreement, we will develop the X-Port with Cook, and Cook will have exclusive commercialization rights to market the product for medical procedures anywhere in the body. During fiscal 2006, we received payments aggregating \$1.0 million that we recorded as development revenue under the agreement. Cook will also pay us up to a total of an additional \$1.0 million in future payments if additional development milestones are achieved. We may potentially receive a royalty based on Cook's annual worldwide sales of the X-Port.

Guidant Corporation, referred to as Guidant, is our largest investor, having invested an aggregate of approximately \$14.0 million in our preferred stock in June 2002 and August 2003. Additionally, in August 2003, Guidant extended a line of credit to us for \$10.3 million. We have drawn down this line of credit and as of June 30, 2006, have a long-term loan of \$10.3 million and accrued interest payable of \$2.3 million outstanding to Guidant. The long-term loan and all accrued interest is due in August 2008. Interest of 8.75% per year accrues during the term of the loan. Guidant distributed our products in Europe under a distribution agreement that was signed in May 2003, amended in January 2004 and terminated in September 2004. Guidant terminated the distribution agreement prior to the expiration of its original term. In addition, we entered into a development and supply agreement with Guidant to develop an aortic cutter for Guidant's Heartstring product, and we manufactured the first 10,000 aortic cutters. Guidant outsourced future production of the aortic cutter to a third-party contract manufacturer, and we will receive a modest royalty for each unit sold, but we no longer manufacture the aortic cutter. During fiscal 2006 we recorded royalty revenue from Guidant of \$24,000.

We manufacture the C-Port and PAS-Port systems with parts we manufacture and components supplied by vendors, which we then assemble, test and package. For the fiscal year ended June 30, 2006, we generated net revenue of \$2.1 million, including \$1.0 million of development revenue from Cook, and incurred a net loss of \$12.4 million. We expect to continue to incur net losses for the foreseeable future.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of our financial statements requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates.

We believe that the following critical accounting policies to be the most critical to an understanding of our financial statements because they require us to make significant judgments and estimates that are used in the preparation of our financial statements.

Revenue Recognition. We recognize revenue in accordance with SEC Staff Accounting Bulletin, or SAB, No. 104, "*Revenue Recognition.*" SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) title has transferred; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. We generally use contracts and customer purchase orders to determine the existence of an arrangement. We assess whether the fee is fixed or determinable based upon the terms of the agreement associated with the transaction. To determine whether collection is probable, we assess a number of factors, including past transaction history with the customer and the creditworthiness of the customer. If we determine that collection is not reasonably assured, we would defer the recognition of revenue until collection becomes reasonably assured, which is generally upon receipt of payment.

Revenue generated from development contracts is recognized upon acceptance of non-refundable milestones payments by the customer in accordance with contractual terms, and when the earnings process is complete.

Inventory. We state our inventories at the lower of cost (computed on a standard cost basis, which approximates actual cost on a first-in, first-out basis) or market (which is determined as the lower of replacement cost or net realizable value). Standard costs are monitored on a quarterly basis and updated as necessary to reflect changes in raw material costs and labor and overhead rates. Inventory write-downs are established when conditions indicate that the selling price could be less than cost due to physical deterioration, usage, obsolescence, reductions in estimated future demand and reductions in selling prices. Inventory write-downs are measured as the difference between the cost of inventory and estimated market value. Inventory write-downs are charged to cost of product revenue and establish a lower cost basis for the inventory. We balance the need to maintain strategic inventory levels with the risk of obsolescence due to changing technology and customer demand levels. Unfavorable changes in market conditions may result in a need for additional inventory write-downs that could adversely impact our financial results.

Clinical Trial Accounting. Clinical trial costs are a component of research and development expenses and include fees paid to participating hospitals and other service providers that conduct clinical trial activities with patients on our behalf and the cost of clinical trial insurance. The various costs of the trial are contractually based on the nature of the services, and we accrue the costs as the services are provided. Accrued costs are based on estimates of the work completed under the service agreements, patient enrollment and past experience with similar contracts. Our estimate of the work completed and associated costs to be accrued includes our assessment of information received from our third-party service providers and the overall status of our clinical trial activities. If we have incomplete or inaccurate information, we may underestimate costs associated with various trials at a given point in time. Although our experience in estimating these costs is limited, the difference between accrued expenses based on our estimates and actual expenses have not been material to date.

Stock-Based Compensation. On November 4, 2005, upon filing of our initial Registration Statement on Form S-1, we adopted Statement of Financial Accounting Standards, or SFAS, 123R, "*Share-Based Payments*", which revises SFAS 123, "*Accounting for Stock-Based Compensation*". SFAS 123R establishes accounting for stock-based awards exchanged for employee services. Accordingly, stock-based compensation cost is measured on the grant date, based on the fair value of the award, and is recognized as an expense over the employee requisite service period. Prior to the adoption of SFAS 123R in the second quarter of fiscal 2006, we accounted for stock-based employee compensation arrangements using the intrinsic value method in accordance with the provisions of Accounting Principles Board Opinion, or APB, No. 25, "*Accounting for Stock Issued to Employees*" and Financial

Accounting Standard Board, or FASB, Interpretation, or FIN, No. 44, “*Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB No. 25*”. We adopted SFAS 123R applying the “prospective method” under which we will continue to account for nonvested equity awards outstanding at the date of adoption of SFAS 123R in the same manner as they had been accounted for prior to adoption, that is, we will continue to apply Opinion 25 in future periods to equity awards outstanding at the date it adopted SFAS 123R.

The expected term of options granted is determined using the “shortcut” method allowed by SAB No. 107. Under this approach, the expected term would be presumed to be the mid–point between the vesting date and the end of the contractual term. The shortcut approach is not permitted for options granted, modified or settled after December 31, 2007. The risk–free rate for periods within the contractual life of the option is based on a risk–free zero–coupon spot interest rate at the time of grant. We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. SFAS 123R also requires us to estimate forfeitures in calculating the expense related to stock–based compensation. In addition, SFAS 123R requires us to reflect the benefits of tax deductions in excess of recognized compensation cost to be reported as both a financing cash inflow and an operating cash outflow upon adoption. We recorded \$392,000, or \$0.08 per basic share, in stock–based compensation expense for fiscal 2006. Total compensation expense related to unvested awards not yet recognized is approximately \$1.4 million at June 30, 2006 and is expected to be recognized over the next 47 months.

Prior to the initial public offering, certain stock options were granted with exercise prices that were below the estimated fair value of the common stock at the date of grant. We recorded deferred stock compensation, net of cancellations due to terminated employees, of \$1.0 million for the period from July 1, 2005 through November 3, 2005 (until the adoption of SFAS 123R), and \$517,000 for fiscal 2005, in accordance with APB 25, and will amortize these amounts on a straight–line basis over the related vesting period of the options. We recorded employee stock compensation expense associated with the amortization of deferred stock compensation of \$442,000 and \$52,000 for fiscal 2006 and 2005, respectively.

The total unamortized deferred stock compensation recorded for all option grants through June 30, 2006 is expected to be amortized as follows: \$367,000 in fiscal 2007, \$341,000 in fiscal 2008, \$298,000 in fiscal 2009 and \$23,000 in fiscal 2010.

Stock compensation arrangements to non–employees are accounted for in accordance with Emerging Issues Task Force, or EITF, No. 96–18, “*Accounting for Equity Instruments that Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*”, using a fair value approach. The compensation costs of these options and warrants granted to non–employees, including lenders and consultants, are re–measured over the vesting terms as earned, and the resulting value is recognized as an expense over the period of services received or the term of the related financing.

Results of Operations

Fiscal Years ended June 30, 2006 and 2005

Net revenue. Net revenue was \$2.1 million in fiscal 2006 and fiscal 2005. Net product sales increased \$309,000, or 43%, to \$1.0 million in fiscal 2006 from \$719,000 in fiscal 2005. The net increase in product sales in fiscal 2006 compared to fiscal 2005 is primarily attributable to sales of the C–Port system in the United States beginning in January 2006. The C–Port system received FDA clearance in November 2005. Development revenue of \$1.0 million in fiscal 2006 reflect the successful completion of two development milestones related to the X–Port under the Cook development and collaboration agreement.

Related party revenue decreased 98%, or \$1.3 million, to \$31,000 in fiscal 2006 from \$1.3 million in fiscal 2005. The decrease in related party revenue in fiscal 2006 compared to fiscal 2005 reflects the completion in November 2004 of our development contract with Guidant, termination of the distribution agreement by Guidant in September 2004 and the corresponding absence of development revenue and product sales to Guidant in fiscal 2006. Related party royalty revenue in fiscal 2006 includes \$24,000 compared to no royalty revenue for fiscal 2005.

Cost of product revenue. Cost of product revenue consists primarily of material, labor and overhead costs. Cost of product revenue decreased \$376,000, or 15%, to \$2.1 million in fiscal 2006 from \$2.5 million in fiscal 2005.

The decrease in costs in fiscal 2006 compared to fiscal 2005 was primarily attributable to no costs incurred for the aortic cutter and higher production cost absorption due to a higher number of clinical and prototype units produced during the period charged to research and development expense, offset in part by higher product sales of the C-Port in the United States and higher charges taken in fiscal 2006 for obsolete PAS-Port and C-Port units.

Research and development expense. Research and development expenses consist primarily of personnel costs within our product development, regulatory and clinical groups and the costs of clinical trials. Research and development expenses increased \$170,000, or 3%, to \$6.5 million in fiscal 2006 from \$6.3 million in fiscal 2005.

The net increase in expenses in fiscal 2006 is attributable to increases in clinical trial costs for the C-Port xA system in Europe and clinical start-up costs for the PAS-Port system in the United States, increased prototype materials and tooling expenses for the X-Port program and C-Port xA program, offset in part by decreases in consulting as the result of hiring a full-time vice president of research and development in July 2006 and lower non-cash stock compensation charges.

We anticipate that research and development expenses will increase in absolute terms in future periods as we conduct new clinical studies for the C-Port xA and the PAS-Port systems, continue to enhance our existing product lines and begin to develop new applications of our technology. Research and development expenses fluctuate with the stage of development of, the timing of clinical trials related to, and the status of regulatory approval of our products.

Selling, general and administrative expense. Selling, general and administrative expenses consist primarily of stock-based compensation charges in fiscal 2005 and costs for administrative and sales and marketing personnel, intellectual property and marketing expenses. Selling, general and administrative expenses increased \$1.8 million, or 50%, to \$5.6 million in fiscal 2006 from \$3.8 million in fiscal 2005.

The net increase in expenses in fiscal 2006 is attributable to increase in salaries, benefits and travel as the result of hiring a field sales force in the United States to sell the C-Port system, higher legal costs for patent litigation, higher consulting for marketing and sales programs and higher professional expenses as the result of being a public company, offset in part by lower non-cash stock-based compensation expenses.

During fiscal 2005, we recorded a total of \$2.0 million in non-cash stock-based compensation expenses related to loans we previously made to three directors, each of whom is or was also an officer, to purchase shares of our common stock with promissory notes. This non-cash compensation expense was calculated by multiplying the difference between the option exercise price and the fair market value of our common stock at the end of each reporting period, by the number of vested shares purchased with promissory notes. These loans were repaid with common stock in October 2005, and there is no additional stock-based compensation expense for these loans after October 2005.

We expect selling, general and administrative expenses to increase as we expand our sales and marketing efforts and build our corporate infrastructure to support the requirements of being a public company, including costs associated with compliance with Section 404 of the Sarbanes-Oxley Act of 2002.

Interest income. Interest income increased \$477,000, or 156%, to \$782,000 for fiscal 2006, from \$305,000 for fiscal 2005. The increase in interest income in fiscal 2006 is primarily attributable to higher investment balances as a result of funds from the initial public offering completed in February 2006 and higher overall market interest rates for the period.

Interest expense. Interest expense of \$1.0 million in fiscal 2006 did not change from the \$1.0 million in fiscal 2005. Interest expenses in fiscal 2006 and 2005 is solely related to the \$13.3 million of long-term debt.

Other income (expense). Other expense in fiscal 2006 consisted of a small loss on the sale of obsolete capital equipment in the period. In fiscal 2005, other income of \$257,000 consisted primarily of a one-time payment of \$250,000 received from Guidant as a strategic agreement fee.

Fiscal Years ended June 30, 2005 and 2004

Net revenue. Net revenue increased \$1.2 million, or 146%, to \$2.1 million in fiscal 2005 from \$836,000 in fiscal 2004. A substantial majority of our product sales have been sales of our PAS–Port system. Revenue from Century, our distributor in Japan, accounted for 33%, and revenue from Guidant accounted for 65% of total net revenue during fiscal 2005. The increase in net revenue was attributable to increased product sales of the PAS–Port system to Century and to sales of approximately \$396,000 of the aortic cutter to Guidant. Sales to Century increased in fiscal 2005 relative to fiscal 2004 primarily because we sold the PAS–Port system to Century for only five months of fiscal 2004 compared to twelve months in fiscal 2005. Additionally, sales to Century have fluctuated in the past, and we cannot assure you that our sales to Century will remain constant or grow.

Product revenue from Guidant includes \$510,000 for fiscal 2005, recognized as the difference between the minimum contractual purchases due from Guidant and actual purchases through the date of the distribution agreement termination in September 2004. During fiscal 2005, we recognized development revenue from Guidant of \$310,000 compared to \$223,000 in fiscal 2004, based on the development and supply agreement that called for us to develop and manufacture the aortic cutter. We do not anticipate receiving any additional development revenue from Guidant. Future production of the aortic cutter has been outsourced by Guidant to a third–party manufacturer, and we will not receive any future revenue from Guidant for the manufacture of the aortic cutter. We will receive a modest royalty for each aortic cutter sold in the future but we do not expect these royalties to contribute significantly to our revenue for the foreseeable future.

Cost of product revenue. Cost of product revenue consists primarily of material, labor and overhead costs. Cost of product revenue increased \$373,000, or 18%, to \$2.5 million in fiscal 2005 from \$2.1 million in fiscal 2004. The increase in costs was primarily attributable to an increased number of PAS–Port systems and aortic cutters sold during the period. Future production of the aortic cutter has been outsourced by Guidant to a third party manufacturer.

Research and development expense. Research and development expenses consist primarily of personnel costs within our product development, regulatory and clinical groups and the costs of clinical trials. Research and development expenses increased \$463,000, or 8%, to \$6.3 million in fiscal 2005 from \$5.8 million in fiscal 2004. During fiscal 2005, increases in non–cash stock compensation expenses and product development expenses including personnel and prototype materials for the C–Port xA and X–Port programs were partially offset by a decrease in expenses for the PAS–Port program including personnel and tooling expenses.

Selling, general and administrative expense. Selling, general and administrative expenses consist primarily of stock–based compensation charges in fiscal 2005 and costs for administrative and sales and marketing personnel, intellectual property and marketing expenses. Selling, general and administrative expenses increased \$2.0 million, or 107%, to \$3.8 million in fiscal 2005 from \$1.8 million in fiscal 2004. During fiscal 2005, we recorded a total of \$2.0 million in non–cash stock–based compensation expenses related to loans we made to three directors, each of whom is or was also an officer, to purchase shares of our common stock with promissory notes. This non–cash compensation expense was calculated by multiplying the difference between the option exercise price and the fair value of our common stock at the end of each reporting period, by the number of vested shares purchased with promissory notes. These loans were repaid with common stock in October 2005, and there will be no additional stock–based compensation expense related to these loans after October 2005.

Interest income. Interest income increased \$96,000, or 46%, to \$305,000 for fiscal 2005, from \$209,000 for fiscal 2004. The increase in interest income is primarily attributable to higher interest income due to higher interest rates for the period.

Interest expense. Interest expense decreased \$953,000, to \$1.0 million in fiscal 2005 from \$2.0 million in fiscal 2004. Interest expenses in fiscal 2005 included only interest expense for the full fiscal year associated with the \$13.3 million of long–term debt. Interest expense in 2004 included interest expense for a partial year associated with the \$13.3 million of long–term debt and a \$1.1 million charge for the early extinguishment of debt in August 2003. The \$1.1 million charge consisted of issuing to the debt holder 45,745 shares of Series E preferred stock, valued at \$14.10 per share, for \$645,000 to pay for future interest due over the period from August 2003 to June 2005, and \$460,000 related to the acceleration of amortization of warrant expense accounted for as a discount of the debt.

Other income. In fiscal 2005, other income of \$257,000 consisted primarily of a one-time payment of \$250,000 received from Guidant as a strategic agreement fee.

Income Taxes

Due to uncertainty surrounding the realization of deferred tax assets through future taxable income, we have provided a full valuation allowance and no benefit has been recognized for the net operating loss and other deferred tax assets. Accordingly, deferred tax asset valuation allowances have been established as of June 30, 2006 and 2005 to reflect these uncertainties.

As of June 30, 2006, we had net operating loss carry-forwards to reduce future taxable income, if any, of approximately \$54.7 million for federal income tax purposes and \$48.7 million available to reduce future taxable income, if any, for California state income taxes. The net operating loss carry-forwards begin to expire in 2014 and 2009 for federal and California income taxes, respectively. We also had federal and state research and development credit carry-forwards of approximately \$825,000 and \$566,000, respectively, at June 30, 2006. The federal credits will expire starting in 2014 if not utilized. Utilization of the net operating loss carry-forward may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitation may result in the expiration of the net operating loss before utilization if certain changes in our ownership occur. Our initial public offering may have resulted in a change in ownership percentages that will result in a limitation of our operating loss carry-forwards.

Liquidity and Capital Resources

As of June 30, 2006, our accumulated deficit was \$60.4 million. We currently invest our cash and cash equivalents in large money market funds consisting of debt instruments of the U.S. government, its agencies and high-quality corporate issuers. We place our short-term investments primarily in auction rate preferred securities, corporate debt securities and debt instruments of the U.S. Government and its agencies. Since inception, we had financed our operations primarily through private sales of convertible preferred stock resulting in aggregate net proceeds of \$38.9 million and from long-term notes payable of \$13.3 million. In February 2006, we sold 3,700,000 shares of common stock in an initial public offering for aggregate net proceeds of \$32.6 million.

As of June 30, 2006, we did not have any off-balance sheet liabilities. We had cash, cash equivalents and short-term investments of \$32.1 million and total long-term debt of \$15.6 million.

The following table discloses aggregate information, as of June 30, 2006, about our contractual obligations and the periods in which payments are due.

Contractual Obligations	Total	Less Than	1-3	More Than
		1 Year	Years	3 Years
			(In thousands)	
Operating lease — real estate	\$ 979	\$ 460	\$ 519	\$ —
Convertible notes payable, Including interest	3,320	150	3,170	—
Notes payable and accrued interest	14,496	—	14,496	—
Total	<u>\$ 18,795</u>	<u>\$ 610</u>	<u>\$ 18,185</u>	<u>\$ —</u>

The long-term commitments under operating leases shown above consist of payments related to our real estate leases for our headquarters in Redwood City, California expiring in 2008.

The subordinated convertible notes payable were issued in connection with our Japan Distribution Agreement with Century. The subordinated convertible notes bear interest at 5% per year, payable quarterly, and are due in June 2008. The subordinated convertible notes were convertible at the option of the holder into our common stock at \$10.00 per share at any time prior to August 7, 2006. However, the holder did not convert the notes, and the notes are no longer convertible. The holder of the subordinated convertible notes has a continuing security interest in all of our personal property and assets, including intellectual property.

The notes payable and accrued interest are for a loan agreement with Guidant Investment Corporation, or Guidant Investment, with principal of \$10.3 million and accrued interest as of June 30, 2006 of \$2.3 million and

future interest of \$1.9 million due at maturity. The notes bear interest at the rate of 8.75% per year and principal and all accrued interest are due in August 2008. The holder of the notes has a first priority security interest in all our personal property and assets, including intellectual property.

As of June 30, 2006, we had entered into letters of credit totaling \$500,000 securing our operating lease. A certificate of deposit in the amount of \$500,000 has been recorded as restricted cash at June 30, 2006 and 2005 related to these letters of credit.

Summary cash flow data is as follows:

	Fiscal Year Ended June 30,		
	2006	2005	2004
	(In thousands)		
Net cash used in operating activities	\$ (8,997)	\$ (7,417)	\$ (7,776)
Net cash provided by (used in) investing activities	(21,593)	7,129	(1,795)
Net cash provided by financing activities	32,741	14	8,116

Net cash used in operating activities for fiscal years 2006, 2005 and 2004, was \$9.0 million, \$7.4 million and \$7.8 million, respectively. Our net use of cash for fiscal 2006 was attributable to our net loss adjusted for non-cash stock-based compensation charges, increases in prepaid expenses and other current assets due to higher unamortized balances of clinical trial and public company insurances and higher interest income receivable balances from our investments, higher accounts receivable reflecting initial product sales of the C-Port system in the United States, offset in part by an increase in accounts payable and other accrued liabilities reflecting higher trade payables for our operations and an increase in non-current liabilities as a result of \$897,000 of interest payable on the note to Guidant Investment. Our net use of cash for fiscal 2005 was attributable to our net loss adjusted for depreciation and non-cash stock-based compensation charges, offset by an increase in non-current liabilities as a result of \$897,000 of interest payable on the note to Guidant Investment. Our net use of cash for fiscal 2004 was attributable to our net loss adjusted for depreciation and non-cash stock-based compensation charges, offset by an increase in non-current liabilities as a result of \$539,000 of interest payable on the note to Guidant Investment.

Net cash used in investing activities was \$21.6 million for fiscal 2006, resulting from an increase in purchases of available-for-sale investments due to higher cash balances as a result of the initial public offering completed in February 2006. Net cash provided by investment activities was \$7.1 million for fiscal 2005, resulting from an increase in proceeds from the sale of available-for-sale investments and decrease in purchases of short-term investments offset by purchases of property and equipment of \$882,000. Net cash used in investing activities was \$1.8 million for fiscal 2004, due to an increase in purchases of available-for-sale investments as a result of additional cash available from the sale of convertible preferred stock of \$4.0 million during the year, partially offset by purchases of property and equipment of \$914,000.

Net cash provided by financing activities of \$32.7 million in fiscal 2006 was primarily attributable to cash received of \$32.6 million from the initial public offering completed in February 2006. Net cash provided by financing activities of \$14,000 in fiscal 2005 was attributable to cash received from stock option exercises. Net cash provided by financing activities in the fiscal 2004, of \$8.1 million was primarily attributable to proceeds from the sale of convertible preferred stock of \$4.0 million to Guidant Investment and proceeds from notes payable to Guidant Investment of \$10.3 million, less the repayment of a note payable and interest of \$6.3 million.

Our future capital requirements depend upon numerous factors. These factors include but are not limited to the following:

- market acceptance and adoption of our products;
- our revenue growth;
- costs associated with our sales and marketing initiatives and manufacturing activities;
- costs of obtaining and maintaining FDA and other regulatory clearances and approvals for our products;
- securing, maintaining and enforcing intellectual property rights;

- costs of developing marketing and distribution capabilities;
- the extent of our ongoing research and development programs;
- the progress of clinical trials; and
- the effects of competing technological and market developments.

We believe that our existing cash, cash equivalents and short-term investments, along with the cash that we expect to generate from operations, will be sufficient to meet our anticipated cash needs for working capital and capital expenditures for at least the next 18 months. If these sources of cash are insufficient to satisfy our liquidity requirements, we may seek to sell additional equity or debt securities, obtain a credit facility or enter into development or license agreements with third parties. The sale of additional equity or convertible debt securities could result in dilution to our stockholders. If additional funds are raised through the issuance of debt securities, these securities could have rights senior to those associated with our common stock and could contain covenants that would restrict our operations. Any licensing or strategic agreements we enter into may require us to relinquish valuable rights. Additional financing may not be available at all, or in amounts or upon terms acceptable to us. If we are unable to obtain this additional financing, we may be required to reduce the scope of our planned product development and marketing efforts.

Recent Accounting Pronouncements

In November 2005, FASB issued FASB Staff Position FSP FAS 115-1 and FAS 124-1, “*The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*” (“FSP FAS 115-1”), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other-than-temporary, and on measuring such impairment loss. FSP FAS 115-1 also includes accounting considerations subsequent to the recognition of an other-than-temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other-than-temporary impairments. We adopted FSP FAS 115-1 on January 1, 2006, and the adoption did not have a material impact on our results of operations or financial condition.

In May 2005, FASB issued SFAS 154, “Accounting Changes and Error Corrections—a replacement of APB Opinion No. 20 and FASB Statement No. 3”. SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle, and applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. This statement requires retrospective application to prior periods’ financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005. Consequently, we will adopt the provisions of SFAS 154 for our fiscal year beginning July 1, 2006. The adoption of the provisions of SFAS No. 154 will not have an impact on our financial statements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, including structured finance, special purpose or variable interest entities.

ITEM 7A. *Quantitative and Qualitative Disclosures About Market Risk*

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including auction rate preferred securities, corporate debt securities and debt instruments of the U.S. Government and its agencies. Due to the short-term nature of these instruments, a 1% movement in market interest rates would not have a significant impact on the total value of our portfolio as of June 30, 2006.

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We do not utilize derivative financial instruments, derivative commodity instruments or other market risk-sensitive instruments, positions or transactions to any material extent. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

Although substantially all of our sales and purchases are denominated in U.S. dollars, future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products outside the United States. We do not believe, however, that we currently have significant direct foreign currency exchange rate risk and have not hedged exposures denominated in foreign currencies.

The following table summarizes the expected maturity and average interest rate of our marketable securities at June 30, 2006 (in thousands):

	Year Ending June 30, 2007	Thereafter	Total Fair Value at June 30, 2006
Short-term investments	\$ 26,240	\$ 1,738	\$ 27,978
Average interest rate	4.92%	5.15%	4.96%

ITEM 8. Financial Statements and Supplemental Data

The following tables set forth selected unaudited quarterly consolidated statement of operations data for the eight most recent quarters. The information for each of these quarters has been prepared on the same basis as the audited consolidated financial statements included in this report and, in the opinion of management, includes all adjustments necessary for the fair presentation of the results of operations for such periods. This data should be read in conjunction with the audited consolidated financial statements and the related notes included in this report. These quarterly operating results are not necessarily indicative of our operating results for any future period.

Quarterly Financial Data

	<u>1st Quarter</u>	<u>2nd Quarter</u>	<u>3rd Quarter</u>	<u>4th Quarter</u>
	(Unaudited, in thousands, except per share data)			
Fiscal 2006:				
Total net revenue	\$ 168	\$ 199	\$ 803	\$ 889
Net loss	<u>(3,044)</u>	<u>(2,712)</u>	<u>(2,934)</u>	<u>(3,726)</u>
Basic and diluted net loss per share	<u>\$ (2.13)</u>	<u>\$ (1.70)</u>	<u>\$ (0.45)</u>	<u>\$ (0.39)</u>
Shares used in computing basic and diluted net loss per share	<u>1,430</u>	<u>1,595</u>	<u>6,587</u>	<u>9,660</u>
	<u>1st Quarter</u>	<u>2nd Quarter</u>	<u>3rd Quarter</u>	<u>4th Quarter</u>
Fiscal 2005:				
Total net revenue	\$ 1,177	\$ 294	\$ 369	\$ 216
Net loss	<u>(1,752)</u>	<u>(2,142)</u>	<u>(3,238)</u>	<u>(3,818)</u>
Basic and diluted net loss per share	<u>\$ (1.27)</u>	<u>\$ (1.53)</u>	<u>\$ (2.30)</u>	<u>\$ (2.70)</u>
Shares used in computing basic and diluted net loss per share	<u>1,384</u>	<u>1,398</u>	<u>1,408</u>	<u>1,415</u>

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.

Based on their evaluation as of June 30, 2006, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective to ensure that the information required to be disclosed by us in the reports we file with the SEC was recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and the instructions for such reports and to ensure that information required to be disclosed in this Annual Report on Form 10-K is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding timely disclosures.

Changes in internal controls.

There were no changes in our internal controls over financial reporting during the fiscal year ended June 30, 2006 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Limitations on the effectiveness of controls.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. *Other Information*

None.

PART III

ITEM 10. *Directors and Executive Officers of the Registrant*

We have adopted a code of business conduct and ethics which applies to all of our directors, officers and employees. A copy of our code of business conduct and ethics can be found on our website, www.cardica.com in the section titled "Investor Relations" under the subsection titled "Corporate Governance." To the extent required by law or Nasdaq rules, any amendments to, or waivers from, any provision of the code will be promptly disclosed publicly. To the extent permitted by such requirements, we intend to make such public disclosure by posting the

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relevant material on the corporate governance page of the investor relations section of our website in accordance with SEC rules.

All additional information required by this will be contained in our definitive Proxy Statement with respect to our Annual Meeting of Stockholders, to be held on November 8, 2006, under the caption “Directors and Executive Officers of the Registrant” and is incorporated herein by reference.

ITEM 11. *Executive Compensation*

The information required by this item will be contained in our definitive Proxy Statement with respect to our Annual Meeting of Stockholders, to be held on November 8, 2006, under the caption “Executive Compensation” and is incorporated herein by reference.

ITEM 12. *Security Ownership of Certain Beneficial Owners and Management*

The information required by this item will be contained in our definitive Proxy Statement with respect to our Annual Meeting of Stockholders, to be held on November 8, 2006, under the caption “Security Ownership of Certain Beneficial Owners and Management” and is incorporated herein by reference.

ITEM 13. *Certain Relationships and Related Transactions*

The information required by this item will be contained in our definitive Proxy Statement with respect to our Annual Meeting of Stockholders, to be held on November 8, 2006, under the caption “Certain Relationships and Related Transactions” and is incorporated herein by reference.

ITEM 14. *Principal Accountant Fees and Services*

The information required by this item will be contained in our definitive Proxy Statement with respect to our Annual Meeting of Stockholders, to be held on November 8, 2006, under the caption “Principal Accountant Fees and Services” and is incorporated herein by reference.

PART IV

ITEM 15. *Exhibits and Financial Statement Schedules*

(a) Documents filed as part of this report

1. *Financial Statements*

**Cardica, Inc.
Index to Financial Statements**

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
Cardica, Inc.

We have audited the accompanying balance sheets of Cardica, Inc. as of June 30, 2006 and 2005, and the related statements of operations, convertible preferred stock and stockholders' equity (deficit), and cash flows for each of the three years in the period ended June 30, 2006. 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 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 financial position of Cardica, Inc. at June 30, 2006 and 2005, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2006, in conformity with U.S. generally accepted accounting principles.

As discussed in Note 1 to the Financial Statements, under the heading Stock-Based Compensation, in fiscal 2006 Cardica, Inc. changed its method of accounting for stock-based compensation.

/s/ Ernst & Young LLP

Palo Alto, California
July 28, 2006

Cardica, Inc.
BALANCE SHEETS

	June 30,	
	2006	2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,102	\$ 1,951
Short-term investments	27,978	7,000
Accounts receivable	164	104
Accounts receivable from related party	—	5
Inventories	432	526
Shareholder note receivable	—	73
Interest receivable from stockholders	—	20
Prepaid expenses and other current assets	571	345
Total current assets	33,247	10,024
Property and equipment, net	1,401	1,611
Interest receivable from stockholders	—	1
Restricted cash	510	510
Total assets	\$ 35,158	\$ 12,146
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 629	\$ 244
Accrued compensation	236	133
Other accrued liabilities	565	431
Current portion of leasehold improvement obligation	122	122
Deferred rent	93	62
Total current liabilities	1,645	992
Deferred rent	120	214
Notes payable to related party	10,250	10,250
Interest payable to related party	2,333	1,436
Subordinated convertible note	3,000	3,000
Leasehold improvement obligation	133	255
Other non-current liabilities	—	1
Commitments and contingencies		
Convertible preferred stock, \$0.001 par value: no shares authorized, issued and outstanding at June 30, 2006; 4,259,328 shares issued and outstanding at June 30, 2005	—	39,683
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value: 5,000,000 shares authorized, no shares issued and outstanding at June 30, 2006	—	—
Common stock, \$0.001 par value, 45,000,000 shares authorized, 9,795,833 shares issued and outstanding at June 30, 2006; 1,748,960 shares issued and outstanding at June 30, 2005	10	2
Additional paid-in capital	79,843	5,202
Treasury stock at cost; (66,227 shares at June 30, 2006 and none at June 30, 2005)	(596)	—
Deferred stock compensation	(1,029)	(431)
Notes receivable from stockholders	—	(449)
Receivable from stock option exercises	(79)	—
Accumulated other comprehensive loss	(47)	—
Accumulated deficit	(60,425)	(48,009)
Total stockholders' equity (deficit)	17,677	(43,685)
Total liabilities and stockholders' equity (deficit)	\$ 35,158	\$ 12,146

See accompanying notes to financial statements.

Cardica, Inc.

STATEMENTS OF OPERATIONS

	Fiscal Year Ended June 30,		
	2006	2005	2004
	(In thousands, except per share data)		
Net revenue:			
Product revenue, net	\$ 1,028	\$ 719	\$ 212
Development revenue	1,000	—	—
Product and royalty revenue from related party, net	31	1,027	401
Development revenue from related party	—	310	223
Total net revenue	<u>2,059</u>	<u>2,056</u>	<u>836</u>
Operating costs and expenses:			
Cost of product revenue (includes related-party costs of \$1,180 and \$1,377 in fiscal 2005 and 2004, respectively)	2,102	2,478	2,105
Research and development	6,459	6,289	5,826
Selling, general and administrative	<u>5,645</u>	<u>3,753</u>	<u>1,809</u>
Total operating costs and expenses	<u>14,206</u>	<u>12,520</u>	<u>9,740</u>
Loss from operations	(12,147)	(10,464)	(8,904)
Interest income	782	305	209
Interest expense (includes related-party interest expense of \$897, \$897 and \$539 in fiscal 2006, 2005 and 2004, respectively)	(1,047)	(1,048)	(2,001)
Other income (expense) (includes \$250 income from related-party in fiscal 2005)	<u>(4)</u>	<u>257</u>	<u>(14)</u>
Net loss	<u>\$ (12,416)</u>	<u>\$ (10,950)</u>	<u>\$ (10,710)</u>
Basic and diluted net loss per common share	<u>\$ (2.58)</u>	<u>\$ (7.82)</u>	<u>\$ (8.24)</u>
Shares used in computing basic and diluted net loss per common share	<u>4,817</u>	<u>1,401</u>	<u>1,299</u>

See accompanying notes to financial statements.

Cardica, Inc.

Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Treasury Stock	Deferred Stock-Based Compensation	Notes Receivable from Stockholders	Receivable from Stock Option Exercises	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount								
(In thousands, except share data)												
Balance at June 30, 2003	3,929,895	\$ 35,038	1,556,825	\$ 2	\$ 1,663	\$ —	\$ —	\$ (420)	\$ —	\$ —	\$ (26,349)	\$ (25,104)
Issuance of common stock upon exercise of employee stock options for cash	—	—	160,960	—	200	—	—	—	—	—	—	200
Issuance of common stock upon exercise of stock options for promissory notes	—	—	16,666	—	12	—	—	(12)	—	—	—	—
Issuance of common stock to non-employees for services	—	—	8,142	—	22	—	—	—	—	—	—	22
Issuance of stock options to non-employees for services	—	—	—	—	127	—	—	—	—	—	—	127
Issuance of Series E convertible to related party for cash, including issuance costs of \$50	283,688	4,000	—	—	(50)	—	—	—	—	—	—	(50)
Issuance of Series E convertible preferred stock for prepayment of interest due on notes payable	45,745	645	—	—	—	—	—	—	—	—	—	—
Repurchase of common stock	—	—	(2,604)	—	(4)	—	—	4	—	—	—	—
Stock-based compensation expense related to variable accounting of certain employee stock options	—	—	—	—	85	—	—	—	—	—	—	85
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	—	—	(10,710)	(10,710)
Balance at June 30, 2004	4,259,328	39,683	1,739,989	2	2,055	—	—	(428)	—	—	(37,059)	(35,430)
Issuance of common stock upon exercise of stock options for promissory notes	—	—	—	—	21	—	—	(21)	—	—	—	—
Issuance of common stock upon exercise of employee stock options for cash	—	—	8,971	—	14	—	—	—	—	—	—	14
Stock-based compensation expense related to variable accounting of certain employee stock options	—	—	—	—	2,009	—	—	—	—	—	—	2,009
Stock-based compensation expense related to modifications of certain employee stock options	—	—	—	—	590	—	—	—	—	—	—	590
Issuance of stock options to non-employees through for services	—	—	—	—	25	—	—	—	—	—	—	25
Early exercise of stock options no longer subject to repurchase	—	—	—	—	35	—	—	—	—	—	—	35
Deferred stock-based compensation	—	—	—	—	453	—	(453)	—	—	—	—	—
Amortization of deferred stock-based compensation	—	—	—	—	—	—	22	—	—	—	—	22
Net loss and comprehensive loss	—	—	—	—	—	—	—	—	—	—	(10,950)	(10,950)
Balance at June 30, 2005	4,259,328	39,683	1,748,960	2	5,202	—	(431)	(449)	—	—	(48,009)	(43,685)
Issuance of common stock upon exercise of stock options for promissory note	—	—	—	—	7	—	—	(7)	—	—	—	—
Issuance of common stock upon exercise of employee stock options for cash	—	—	135,057	—	237	—	—	—	(79)	—	—	158
Repurchase of common stock	—	—	(4,618)	—	(6)	—	—	—	—	—	—	(6)
Stock-based compensation expense related to accounting of certain employee stock options	—	—	—	—	583	—	—	—	—	—	—	583
Issuance of stock options to non-employees for services	—	—	—	—	55	—	—	—	—	—	—	55
Conversion of preferred stock to common stock	(5,112)	(25)	5,112	—	25	—	—	—	—	—	—	25
Repayment of stockholders' notes with common stock	—	—	(66,227)	—	—	(596)	—	456	—	—	—	(140)
Issuance of common stock to preferred stockholders in connection with the automatic conversion upon the initial public offering	(4,254,216)	(39,658)	4,254,216	4	39,654	—	—	—	—	—	—	39,658
Issuance of common stock upon Initial public offering, net of offering expenses	—	—	3,700,000	4	32,585	—	—	—	—	—	—	32,589
Issuance of common stock to a director for services	—	—	3,333	—	30	—	—	—	—	—	—	30
Issuance of restricted stock award	—	—	20,000	—	—	—	—	—	—	—	—	—
Stock-based compensation expense accounted for under FAS 123(R)	—	—	—	—	392	—	—	—	—	—	—	392
Early exercise of stock options no longer subject to repurchase	—	—	—	—	39	—	—	—	—	—	—	39
Deferred stock-based compensation, net of forfeitures	—	—	—	—	1,040	—	(1,040)	—	—	—	—	—
Amortization of deferred stock-based compensation	—	—	—	—	—	—	442	—	—	—	—	442
Comprehensive loss:												
Net loss	—	—	—	—	—	—	—	—	—	—	(12,416)	(12,416)
Net change in unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	(47)	—	(47)
Comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(12,463)
Balance at June 30, 2006	—	\$ —	9,795,833	\$ 10	\$ 79,843	\$ (596)	\$ (1,029)	\$ —	\$ (79)	\$ (47)	\$ (60,425)	\$ 17,677

See accompanying notes to financial statements.

Cardica, Inc.

CONDENSED STATEMENTS OF CASH FLOWS

	Fiscal Year Ended June 30,		
	2006	2005	2004
	(In thousands)		
Operating activities:			
Net loss	\$ (12,416)	\$ (10,950)	\$ (10,710)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	750	850	672
Amortization of debt discount	—	—	460
Loss on disposal of property and equipment	28	24	205
Amortization of deferred stock-based compensation expense	442	22	—
Stock-based compensation on grants of stock options to non-employees	45	25	127
Stock-based compensation related to issuance of common shares for consulting services rendered	—	—	22
Stock-based compensation related to issuance of stock to a director for services	30	—	—
Stock-based compensation on grants of stock options to employees	1,006	2,599	85
Conversion of interest to preferred stock on prepayment of note payable	—	—	645
Changes in assets and liabilities:			
Accounts receivable	(60)	(46)	(58)
Accounts receivable from related party	5	126	(131)
Prepaid expenses and other current assets	(226)	(207)	42
Inventories	94	(56)	(310)
Interest receivable from shareholders	(3)	(9)	(9)
Other non-current assets	—	—	3
Restricted cash	—	—	72
Accounts payable and other accrued liabilities	493	(419)	258
Accrued compensation	103	(7)	5
Deferred rent	(63)	102	174
Deferred other income from related party	—	(250)	250
Leasehold improvement obligation	(122)	(118)	(117)
Interest payable to related party	897	897	539
Net cash used in operating activities	<u>(8,997)</u>	<u>(7,417)</u>	<u>(7,776)</u>
Investing activities:			
Purchases of property and equipment	(574)	(882)	(914)
Leasehold improvements reimbursement by landlord	—	—	118
Proceeds from sale of equipment	6	12	—
Purchases of short-term investments	(32,635)	(13,076)	(3,089)
Proceeds from sales and maturities of short-term investments	<u>11,610</u>	<u>21,075</u>	<u>2,090</u>
Net cash provided (used in) by investing activities	<u>(21,593)</u>	<u>7,129</u>	<u>(1,795)</u>
Financing activities:			
Proceeds from initial public offering, net of issuance costs	32,589	—	—
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	—	3,950
Proceeds from issuance of common stock pursuant to the exercise of stock options	158	14	198
Repurchase of common stock	(6)	—	—
Proceeds from early exercise of stock options	—	—	63
Issuance of stockholder promissory note	—	—	(73)
Proceeds from notes payable from related party	—	—	10,250
Repayment of principal on notes payable	—	—	(6,272)
Net cash provided by financing activities	<u>32,741</u>	<u>14</u>	<u>8,116</u>
Net increase (decrease) in cash and cash equivalents	2,151	(274)	(1,455)
Cash and cash equivalents at beginning of period	1,951	2,225	3,680
Cash and cash equivalents at end of period	<u>\$ 4,102</u>	<u>\$ 1,951</u>	<u>\$ 2,225</u>
Supplemental disclosure of cash flow information:			
Cash paid for interest	<u>\$ 150</u>	<u>\$ 150</u>	<u>\$ 328</u>
Supplemental disclosure of non-cash activities:			
Deferred stock-based compensation, net of forfeitures	<u>\$ 1,039</u>	<u>\$ 453</u>	<u>\$ —</u>
Repayment of shareholders notes payable with common stock	<u>\$ 596</u>	<u>\$ —</u>	<u>\$ —</u>
Notes receivable from exercise of stock options	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 47</u>
Leasehold improvements paid for directly by landlord	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 422</u>
Vesting of shares issued upon early exercise of stock options	<u>\$ 46</u>	<u>\$ 56</u>	<u>\$ 12</u>
Conversion of preferred stock into common stock	<u>\$ 39,658</u>	<u>\$ —</u>	<u>\$ —</u>

See accompanying notes to financial statements.

Cardica, Inc.

Notes to Financial Statements

Note 1. Organization and Summary of Significant Accounting Policies

Organization

Cardica, Inc. (the "Company") was incorporated in the state of Delaware on October 15, 1997, as Vascular Innovations, Inc. On November 26, 2001, the Company changed its name to Cardica, Inc. The Company designs, manufactures and markets proprietary automated anastomotic systems used in surgical procedures. The Company's first product, the PAS-Port system, received the CE Mark for sales in Europe in March 2003, and regulatory approval for sales in Japan in January 2004. The second product, the C-Port system, received the CE Mark for sales in Europe in April 2004 and 510(k) clearance in the United States in November 2005.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles generally requires management to make estimates and assumptions that affect the amounts reported in the financial statements. Actual results could differ from these estimates.

Cash and Cash Equivalents

The Company's cash and cash equivalents are maintained in checking, money market and mutual fund investment accounts. The Company considers all highly liquid investments with maturities remaining on the date of purchase of three months or less to be cash equivalents. The carrying amount reported in the balance sheets approximates fair value.

Available-for-Sale Securities

The Company has classified its investments in marketable securities as available-for-sale. Such investments are reported at market value, and unrealized gains and losses, if any, are excluded from earnings and are reported in other comprehensive income (loss) as a separate component of stockholders' equity until realized. The cost of securities sold is based on the specific-identification method. Interest on securities classified as available-for-sale is included in interest income. The net realized gains on sales of available-for-sale securities were not material in the periods presented.

Unrealized gains or losses on available-for-sale securities at June 30, 2006 and 2005 are classified as other comprehensive income or loss on the accompanying balance sheet.

Available-for-sale securities at June 30, 2006 consist primarily of auction rate preferred securities, corporate debt securities and debt instruments of the U.S. Government and its agencies, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. Although maturities may extend beyond one year, it is management's intent that these securities will be used for current operations, and therefore, are classified as short-term.

Restricted Cash

Under a facility-operating lease for its facility in Redwood City, California, the Company is required to secure a letter of credit with a restricted cash balance with the Company's bank. A certificate of deposit of \$500,000 has been recorded as restricted cash in the accompanying balance sheets at June 30, 2006 and 2005 related to the letter of credit (see Note 5).

A certificate of deposit of \$10,000 has been recorded as restricted cash in the accompanying balance sheets at June 30, 2006 and 2005 related to the deposit on the company credit card.

Cardica, Inc.

Notes to Financial Statements — (Continued)

Fair Value of Financial Instruments

The fair market value of the Company's financial instruments, based on quoted market prices of cash equivalents and short-term investments at June 30, 2006 and June 30, 2005 approximated their carrying value. The carrying amounts of the Company's other financial instruments approximates fair value due to their short maturities. Based on borrowing rates currently available to the Company for loans and capital lease obligations with similar terms, the carrying value of the Company's debt obligations approximates fair value.

Concentrations of Credit Risk and Certain Other Risks

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, available-for-sale securities and accounts receivable. The Company places its cash and cash equivalents and available-for-sale securities with high-credit quality financial institutions. The Company is exposed to credit risk in the event of default by the institutions holding the cash and cash equivalents, and available-for-sale securities to the extent of the amounts recorded on the balance sheet.

The Company sells its products to hospitals in the U.S. and Europe and to its distributor in Japan who in turn sells the product to hospitals. The Company does not require collateral to support credit sales. The Company has had no credit losses to date.

The following table illustrates revenue in the geographic location in which our customers are located.

	<u>Fiscal Year Ended June 30,</u>		
	<u>2006</u>	<u>2005</u>	<u>2004</u>
United States	64%	65%	75%
Japan	32%	33%	25%
Europe	4%	2%	—

The following table illustrates the concentration of credit risks for the periods presented.

	<u>Percent of Total Revenue for Fiscal Year Ended June 30,</u>			<u>Percent of Total Accounts Receivable as of June 30,</u>		
	<u>2006</u>	<u>2005</u>	<u>2004</u>	<u>2006</u>	<u>2005</u>	<u>2004</u>
Guidant, a related party	2%	65%	75%	—	4%	69%
Century Medical	32%	33%	25%	51%	79%	29%
Cook	49%	—	—	—	—	—

The Company depends upon a number of key suppliers, including single source suppliers, the loss of which would materially harm the Company's business. Single source suppliers are relied upon for certain components and services used in manufacturing of the Company's products. The Company does not have long-term contracts with any of the suppliers; rather, purchase orders are submitted for each order. Because long-term contracts do not exist, none of the suppliers are required to provide the Company any guaranteed minimum quantities.

Inventories

Inventories are recorded at the lower of standard cost (which approximates actual cost on a first-in, first-out basis) or market. The Company periodically assesses the recoverability of all inventories, including raw materials, work-in-process and finished goods, to determine whether adjustments for impairment are required. Inventory that is obsolete or in excess of forecasted usage is written down to its estimated net realizable value based on assumptions about future demand and market conditions.

Cardica, Inc.

Notes to Financial Statements — (Continued)

Property and Equipment

Property and equipment are stated at cost and depreciated on a straight-line basis over the estimated useful lives of the related assets, which are generally three to five years for all property and equipment categories. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the remaining lease term or the estimated useful life of the related assets. Upon sale or retirement of assets, the costs and related accumulated depreciation and amortization are removed from the balance sheet and the resulting gain or loss is reflected in the statement of operations.

Impairment of Long-Lived Assets

The Company reviews long-lived assets, including property and equipment, for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Impairment, if any, is assessed using discounted cash flows. Through June 30, 2006, there have been no indications of impairment, and the Company has recorded no such losses.

Revenue Recognition

The Company recognizes revenue in accordance with SEC Staff Accounting Bulletin (“SAB”) No. 104, “*Revenue Recognition*”. SAB No. 104 requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) title has transferred; (3) the fee is fixed or determinable; and (4) collectibility is reasonably assured. The Company generally uses contracts and customer purchase orders to determine the existence of an arrangement. The Company assesses whether the fee is fixed or determinable based upon the terms of the agreement associated with the transaction. To determine whether collection is probable, the Company assesses a number of factors, including past transaction history with the customer and the creditworthiness of the customer. If the Company determines that collection is not reasonably assured, the recognition of revenue is deferred until collection becomes reasonably assured, which is generally upon receipt of payment. Customers have the right to return products that are defective. There are no other return rights. The Company includes shipping and handling costs in cost of product revenue.

Revenue generated from development contracts is recognized upon acceptance of milestones by the customer to the extent such fees are non-refundable, collectibility is reasonably assured and the earning process is complete.

The Company entered into a Development and Supply Agreement with Guidant Corporation for the development and commercialization of an aortic cutter. The Company received advance payments which were classified as deferred revenue-related party on the balance sheet until such time that the Company commenced development activities under the agreement. The Company recognized revenue as determined by its performance under the agreement and there are no remaining deferred revenue amounts recorded as of June 30, 2006.

Research and Development

Research and development expenses consist of costs incurred for internally sponsored research and development, direct expenses, and research-related overhead expenses. Research and development costs are charged to research and development expense as incurred. Research and development expenses also include cost related to development revenue.

Clinical Trials

The Company accrues and expenses costs for clinical trial activities performed by third parties based upon estimates of the percentage of work completed over the life of the individual study in accordance with agreements established with contract research organizations and clinical trial sites. The Company determines the estimates

Cardica, Inc.**Notes to Financial Statements — (Continued)**

through discussion with internal clinical personnel and outside service providers as to progress or stage of completion of trials or services and the agreed upon fee to be paid for such services. If the Company has incomplete or inaccurate information, the Company may underestimate costs associated with various trials at a given point in time. Costs of setting up clinical trial sites for participation in the trials are expensed immediately as research and development expenses. Clinical trial site costs related to patient enrollment are accrued as patients are entered into the trial and reduced by any initial payment made to the clinical trial site when the first patient is enrolled.

Income Taxes

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between financial reporting and tax reporting bases of assets and liabilities and are measured using enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

Segments

The Company operates in one segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. All long-lived assets are maintained in the United States.

Comprehensive Loss

Comprehensive loss is comprised of net loss and unrealized holding gains and losses on available-for-sale securities as follows (in thousands):

	Fiscal Year Ended June 30,		
	2006	2005	2004
Net loss	\$ (12,416)	\$ (10,950)	\$ (10,710)
Unrealized loss on marketable securities	(47)	—	—
Comprehensive loss	<u>\$ (12,463)</u>	<u>\$ (10,950)</u>	<u>\$ (10,710)</u>

Accumulated comprehensive loss consisted solely of unrealized losses on marketable securities.

Net Loss per Common Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period less the weighted average unvested common shares subject to repurchase and without consideration for potential common shares. Diluted net loss per share is computed by dividing the net loss by the weighted-average number of common shares outstanding for the period less the weighted average unvested common shares subject to repurchase and dilutive potential common shares for the period determined using the treasury-stock method. For purposes of this calculation, preferred stock, options and warrants to purchase stock and unvested restricted stock awards are considered to be potential common shares and are only included in the calculation of diluted net loss per share when their effect is dilutive (in thousands, except per share data).

Cardica, Inc.

Notes to Financial Statements — (Continued)

	Fiscal Year Ended June 30,		
	2006	2005	2004
Numerator:			
Net loss	\$ (12,416)	\$ (10,950)	\$ (10,710)
Denominator:			
Weighted-average common shares outstanding	4,940	1,747	1,640
Less: Weighted-average common unvested common shares subject to repurchase	(22)	(73)	(119)
Less: Vested common shares outstanding exercised with promissory notes subject to variable accounting	(96)	(273)	(222)
Less: Unvested restricted stock award	(5)	—	—
Denominator for basic and diluted net loss per share	4,817	1,401	1,299
Basic and diluted net loss per share	\$ (2.58)	\$ (7.82)	\$ (8.24)

Outstanding securities not included in diluted net loss per share calculation

	Fiscal Year Ended June 30,		
	2006	2005 (In thousands)	2004
Convertible preferred stock	—	4,259	4,259
Options to purchase common stock	1,018	766	655
Unvested restricted stock award	20	—	—
Vested common shares outstanding exercised with promissory notes subject to variable accounting	—	273	222
Warrants	157	157	157
	<u>1,195</u>	<u>5,455</u>	<u>5,293</u>

Stock-Based Compensation

On November 4, 2005, upon filing of the initial Registration Statement on Form S-1, the Company adopted Statement of Financial Accounting Standards (“SFAS”) 123R, “Share-Based Payments”, which revises SFAS 123, “Accounting for Stock-Based Compensation”. SFAS 123R establishes accounting for stock-based awards exchanged for employee services. Accordingly, stock-based compensation cost is measured on the grant date, based on the fair value of the award, and is recognized as an expense over the employee requisite service period. Prior to the adoption of SFAS 123R, the Company accounted for stock-based employee compensation arrangements using the intrinsic value method in accordance with the provisions of Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (“APB 25”) and Financial Accounting Standard Board (“FASB”) Interpretation (“FIN”) No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB No. 25*. The Company adopted SFAS 123R applying the “prospective method” under which it would continue to account for nonvested equity awards outstanding at the date of adoption of SFAS 123R in the same manner as they had been accounted for prior to adoption, that is, it would continue to apply Opinion 25 in future periods to equity awards outstanding at the date it adopted SFAS 123R.

Cardica, Inc.

Notes to Financial Statements — (Continued)

SFAS 123R applies to new awards and to awards modified, repurchased, or cancelled after the required effective date. The Company uses the Black–Scholes model to value its new stock option grants under SFAS 123R, with the following assumptions:

	<u>Fiscal Year Ended June 30, 2006</u>
Risk-free interest rate	4.67%
Dividend yield	0.00%
Weighted-average expected life	6 years
Volatility	70%

Since the Company is a newly public entity with no historical data on volatility of its stock, the expected volatility used in fiscal 2006 is based on volatility of similar entities (referred to as “guideline” companies). In evaluating similarity, the Company considered factors such as industry, stage of life cycle, size, and financial leverage.

The expected term of options granted is determined using the “shortcut” method allowed by SAB 107. Under this approach, the expected term would be presumed to be the mid–point between the vesting date and the end of the contractual term. The shortcut approach is not permitted for options granted, modified or settled after December 31, 2007. The risk-free rate for periods within the contractual life of the option is based on a risk-free zero-coupon spot interest rate at the time of grant. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. SFAS 123R also requires the Company to estimate forfeitures in calculating the expense related to stock-based compensation. The Company recorded \$392,000, or \$0.08 per basic and diluted share in stock-based compensation expense for fiscal 2006. In addition, SFAS 123R requires the Company to reflect the benefits of tax deductions in excess of recognized compensation cost to be reported as both a financing cash inflow and an operating cash outflow upon adoption. The Company has recognized no tax benefits to date.

Included in the statement of operations are the following non-cash stock-based compensation amounts for the periods reported (in thousands).

	<u>Fiscal Year Ended June 30,</u>		
	<u>2006</u>	<u>2005</u>	<u>2004</u>
Cost of product revenue	\$ 30	\$ 52	\$ —
Research and development	413	583	67
Selling, general and administrative	<u>1,055</u>	<u>2,010</u>	<u>145</u>
Total	<u>\$ 1,498</u>	<u>\$ 2,645</u>	<u>\$ 212</u>

Options granted to non-employees, including lenders and consultants, are accounted for in accordance with the provisions of SFAS No. 123 and Emerging Issues Task Force (“EITF”) Consensus No. 96–18, “*Accounting for Equity Instruments That Are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*”. The Company applies the Black–Scholes method to determine the estimated fair value of such awards, which are periodically remeasured as they vest. The resulting value is recognized as an expense over the period of services received or the term of the related financing.

During fiscal years 2006 and 2005 certain stock options were granted with exercise prices that were below the estimated fair value of the common stock at the date of grant. In accordance with APB 25, a deferred stock-based compensation expense of \$1.0 million and \$287,000 was recorded during fiscal 2006 and 2005, respectively. The deferred stock compensation will be amortized over the related vesting terms of the options. The Company recorded deferred stock-based compensation expense of \$308,000 and \$22,000 for fiscal years 2006 and 2005, respectively. The Company also records deferred stock compensation resulting from variable accounting for option

Cardica, Inc.

Notes to Financial Statements — (Continued)

exercised with non–recourse promissory notes. Deferred stock compensation related to these notes, representing compensation related to unvested options, was \$134,000 and \$166,000 as of June 30, 2006 and 2005, respectively.

As of June 30, 2006, the expected future amortization expense for deferred stock compensation during each of the following periods is as follows (in thousands):

Fiscal year ending June 30,	
2007	\$ 367
2008	341
2009	298
2010	23
	<u>\$ 1,029</u>

Recent Accounting Pronouncements

In November 2005, FASB issued FASB Staff Position (“FSP”) FAS 115–1 and FAS 124–1, “*The Meaning of Other–Than–Temporary Impairment and Its Application to Certain Investments*” (“FSP FAS 115–1”), which provides guidance on determining when investments in certain debt and equity securities are considered impaired, whether that impairment is other–than–temporary, and on measuring such impairment loss. FSP FAS 115–1 also includes accounting considerations subsequent to the recognition of an other–than–temporary impairment and requires certain disclosures about unrealized losses that have not been recognized as other–than–temporary impairments. The Company adopted FSP FAS 115–1 on January 1, 2006, and this adoption did not have a material impact on the Company’s results of operations or financial condition.

In May 2005, FASB issued SFAS 154, “*Accounting Changes and Error Corrections—a replacement of APB Opinion No. 20 and FASB Statement No. 3*”. SFAS 154 changes the requirements for the accounting for and reporting of a change in accounting principle, and applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. This statement requires retrospective application to prior periods’ financial statements of changes in accounting principle, unless it is impracticable to determine either the period–specific effects or the cumulative effect of the change. SFAS 154 is effective for accounting changes made in fiscal years beginning after December 15, 2005. The adoption of this statement is not expected to have a material impact on the Company’s results of operations or financial condition.

Note 2. Short–Term Investments

Short–term investments are summarized as follows (in thousands):

	June 30, 2006			Fair Value
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	
Available–for–sale securities:				
Corporate bonds	\$ 3,838	\$ —	\$ (11)	\$ 3,827
Auction rate preferred	9,000	—	—	9,000
Commercial paper	8,413	—	(9)	8,404
Federal agency bonds	6,774	—	(27)	6,747
Total	<u>\$ 28,025</u>	<u>—</u>	<u>\$ (47)</u>	<u>\$ 27,978</u>

Commercial paper includes \$3.0 million in securities issued by issuers located in Japan, France and Switzerland. All available–for–sale securities at June 30, 2005 consisted of auction rate preferred securities. The underlying contractual maturities of the auction rate securities were greater than one year.

Cardica, Inc.

Notes to Financial Statements — (Continued)

	June 30, 2006		June 30, 2005	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Remaining contractual maturity:				
Maturing in one year or less	\$ 26,278	\$ 26,240	\$ 7,000	\$ 7,000
Maturing after one year through two years	1,747	1,738	—	—
Total	<u>\$ 28,025</u>	<u>\$ 27,978</u>	<u>\$ 7,000</u>	<u>\$ 7,000</u>

The gross realized losses and gains on the sale of available-for-sale securities during fiscal 2006, 2005 and 2004 were not material.

The primary objectives for the Company's fixed income investment portfolio are liquidity and safety of principal. Investments are made with the objective of achieving the highest rate of return consistent with these two objectives. The Company's investment policy limits investments to certain types of instruments issued by institutions primarily with investment grade ratings and places restrictions on maturities and concentration by type and issuer. None of the investments have been in a continuous unrealized loss position for 12 months or longer at June 30, 2006 and 2005. The gross unrealized losses related to investments are primarily due to changes in interest rates. The Company views these unrealized losses as temporary in nature. The Company reviews its investment portfolio for possible impairment based on an analysis of factors that may have adverse affects on the fair value of the investment. Factors considered in determining whether a loss is temporary include the stability of the credit quality and the structure of the security.

Note 3. Inventories

Inventories consisted of the following (in thousands):

	June 30,	
	2006	2005
Raw materials	\$ 122	\$ 280
Work in progress	155	194
Finished goods	155	52
	<u>\$ 432</u>	<u>\$ 526</u>

Note 4. Property and Equipment

Property and equipment consisted of the following (in thousands):

	June 30,	
	2006	2005
Computer hardware and software	\$ 409	\$ 375
Office furniture and equipment	154	154
Machinery and equipment	3,104	2,832
Leasehold improvements	470	461
Construction in process	187	11
	4,324	3,833
Less: accumulated depreciation and amortization	(2,923)	(2,222)
	<u>\$ 1,401</u>	<u>\$ 1,611</u>

Cardica, Inc.**Notes to Financial Statements — (Continued)**

Depreciation expense for fiscal years 2006, 2005 and 2004 was \$750,000, \$850,000 and \$672,000, respectively.

Note 5. Leases and Commitments

The Company entered into an agreement in April 2003 for office space under a non-cancelable operating lease through July 2008. The operating lease has a renewal option at the end of the lease for an additional three years. Pursuant to the terms of the operating lease agreement, the Company placed funds in the amount of \$500,000 in a certificate of deposit account. The amount is restricted until the expiration of the lease agreement in July 2008 and is recorded as non-current restricted cash.

Future minimum lease payments under the non-cancelable operating leases having initial terms in excess of one year as of June 30, 2006, are as follows (in thousands):

	Operating Leases
Fiscal Year ending June 30,	
2007	\$ 460
2008	478
2009	41
Total minimum lease payments	<u>\$ 979</u>

Rent expense for fiscal years 2006, 2005 and 2004, was \$245,000, \$249,000, and \$260,000, respectively. Deferred rent under the facility operating lease amounted to \$213,000 and \$276,000 at June 30, 2006 and 2005, respectively.

Note 6. License, Development and Commercialization Agreement

In December 2005, the Company entered into a license, development and commercialization agreement with Cook Incorporated, (“Cook”) relating to development of the X-Port Vascular Access Closure Device, (“X-Port”), a product candidate that the Company is studying in preclinical animal model studies. Under the agreement, the Company will develop the X-Port with Cook, and Cook will have exclusive commercialization rights to market the product for medical procedures anywhere in the body. During fiscal 2006, the Company received milestone payments aggregating \$1.0 million and recognized these amounts as development revenue in the accompanying statement of operations. Cook will also pay the Company up to a total of an additional \$1.0 million in future milestone payments if development milestones are achieved. The Company will receive a royalty based on Cook’s annual worldwide sales, if any, of the X-Port.

Note 7. Related Party Transactions***Financing Activities***

In June 2002, the Company issued to Guidant Investment Corporation (“Guidant Investment”) a total of 863,557 shares of Series D convertible preferred stock at \$11.58 per share resulting in cash proceeds of approximately \$10.0 million to the Company.

In August 2003, the Company issued to Guidant Investment a total of 283,688 shares of Series E convertible preferred stock at \$14.10 per share resulting in cash proceeds of approximately \$4.0 million to the Company.

Loan and Strategic Agreements

In March 2000, the Company entered into, and in December 2002 amended, a Master Loan and Security Agreement with an affiliate of Western Technology Investment, of which the Company’s director, J. Michael Egan,

Cardica, Inc.

Notes to Financial Statements — (Continued)

is also a director. See Note 8 for more information on notes payable and warrants issued under the Master Loan and Security Agreement.

In August 2003, the Company entered into a Loan Agreement with Guidant Investment. This agreement provided the Company with a five-year loan of \$10.3 million. The Company borrowed \$5.0 million in August 2003, and borrowed an additional \$5.3 million in February 2004. As the note holder, Guidant Investment has a first priority security interest in all personal property and assets of the Company, including intellectual property. The Loan Agreement provides for principal and accrued interest payment at a loan maturity date of August 2008. The interest rate on the notes is 8.75% per annum, calculated on actual principal outstanding based on actual days elapsed. As of June 30, 2006 and 2005, the Company had accrued interest payable to related party of \$2.3 million and \$1.4 million, respectively, on the accompanying balance sheet for this obligation.

In August 2003, in connection with this loan, Guidant Investment was granted a right to negotiate exclusively for the acquisition of the Company, and the Company also agreed not to enter into any change of control transaction during the period between the signing of the strategic agreement and November 2004. The Company received a strategic agreement fee of \$250,000 upon expiration of the strategic agreement in October 2004 and recorded the amount as other income in the statement of operations during fiscal 2005.

Development and Supply Agreement

In December 2003, the Company entered into a Development and Supply Agreement with Guidant Corporation (“Guidant”) for the development and commercialization of an aortic cutter for Guidant’s Heartstring product. The agreement called for the Company to develop and manufacture aortic cutters. Future production of the aortic cutter has been outsourced by Guidant to a third-party manufacturer, and the Company will receive royalties quarterly for each unit sold in the future. During fiscal 2006, the Company received \$24,000 of royalty revenue under this agreement. No royalties were received during fiscal 2005 or 2004.

In addition, the Company was entitled to receive payments of \$488,000 for development activities pertaining to the development of the product. In June 2004, the agreement was amended to include further development efforts for incremental consideration of \$45,000. The Company recognized development revenue of \$310,000 and \$223,000, for fiscal 2005 and 2004, respectively. No amounts were received or due for fiscal 2006. The Company also recognized product revenue from the sale of aortic cutters to Guidant of \$7,000 and \$396,000 for fiscal 2006 and 2005, respectively. No product revenue was recognized in fiscal 2004 for the aortic cutter.

Distribution Agreement Termination

In September 2004, Guidant terminated its distribution agreement with the Company for product sales in Europe of the PAS–Port and C–Port systems. The agreement called for minimum purchases by Guidant and upon termination the Company recorded \$510,000 in net product revenue from related party in fiscal 2005 as the difference between the minimum contractual purchases due from Guidant and actual purchases through the termination date. Guidant paid the Company the \$510,000 in October 2004. There are no additional payments due the Company related to the termination of the distribution agreement.

Note 8. Subordinated Convertible Note

In June 2003, the Company entered into a distribution agreement with Century Medical, Inc. (“CMI”). CMI issued a subordinated convertible note to the Company in the amount of \$3.0 million. The subordinated convertible notes were convertible at the option of the holder into our common stock at \$10.00 per share at any time prior to August 7, 2006. However, the holder did not convert the notes, and the notes are no longer convertible. The holder of the subordinated convertible notes has a continuing security interest in all of the Company’s personal property and assets, including intellectual property. Interest is compounded annually at 5% and is payable quarterly in arrears on January 31, April 30, July 31, and October 31 of each year. The principal of the note is due in June 2008.

Cardica, Inc.

Notes to Financial Statements — (Continued)

The Company made interest payments of \$150,000, \$150,000 and \$131,000 in fiscal 2006, 2005 and 2004, respectively. The interest payable at June 30, 2006 and 2005 was \$25,000 and is included in other accrued liabilities in the accompanying balance sheets.

Note 9. Notes Payable

In March 2000, the Company entered into, and in December 2002 amended, a Master Loan and Security Agreement with a financial institution. The amendment provided the Company with the ability to borrow up to a maximum of \$5.0 million in working capital financing and \$0.5 million in equipment financing under individual notes payable based upon the Company's financing requirements. In conjunction with this agreement and amendment, the Company issued various warrants exercisable to purchase an aggregate of 124,369 shares of preferred stock of the Company, valued at \$1.0 million to the lender. The value of the warrants was recorded as a discount of the debt.

During fiscal year 2004, the Company paid in full the entire balance of all notes payable and the associated accrued interest earlier than the contractual maturity dates. As a result of paying the obligations in full early, the Company recorded a charge in the amount of \$1.1 million consisting primarily of issuing to the debt holder a total of 45,745 shares of Series E preferred stock, valued at \$14.10 per share, totaling \$645,000 to pay for future interest that would have been due on the notes payable over the period from August 2003 to June 2005, and \$460,000 related to the acceleration of the amortization of warrant expense originally recorded as a discount of the debt.

Note 10. Stockholders' Equity (Deficit)

On December 12, 2005 the Board of Directors approved, and on January 6, 2006 the stockholders of the Company approved an amendment to the Company's amended and restated certificate of incorporation to be effective upon the completion of the Company's IPO (the "Post-IPO Certificate"). Under the terms of the Post-IPO Certificate, the total number of shares that the Corporation is authorized to issue is 50,000,000 shares, with 45,000,000 shares designated as common stock and 5,000,000 shares designated as preferred stock. The Post-IPO Certificate became effective on February 7, 2006.

Reverse Stock Split and Initial Public Offering

On December 12, 2005 the Board of Directors approved, and on January 6, 2006 the stockholders approved, a one-for-three reverse split of the Company's issued or outstanding shares of common stock and preferred stock and, on January 9, 2006 the Company filed an amended and restated certificate of incorporation effecting the reverse split. All issued or outstanding common stock, preferred stock and per share amounts contained in the financial statements have been retroactively adjusted to reflect this reverse stock split.

The Company issued 3,500,000 shares on February 8, 2006 for gross proceeds of \$35.0 million. On February 27, 2006, the Company sold an additional 200,000 shares of its common stock to underwriters pursuant to the exercise of the over-allotment option in part for gross proceeds of \$2.0 million. After deducting the underwriters' commission and the offering expenses, the Company received net proceeds of approximately \$32.6 million. Upon completion of the initial public offering all 4,254,216 shares of convertible preferred stock converted into common stock on a one-for-one basis.

Common Stock

Holders of common stock are entitled to one vote per share on all matters to be voted upon by the stockholders of the Company. Subject to the preferences that may be applicable to any outstanding shares of preferred stock, the holders of common stock are entitled to receive ratably such dividends, if any, as may be declared by the Board of Directors. No dividends have been declared to date.

Cardica, Inc.**Notes to Financial Statements — (Continued)*****Preferred Stock***

The Company has 5,000,000 shares of authorized preferred stock issuable in one or more series. Upon issuance the Company can determine the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock. The issuance of the preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payment and payments upon liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of the Company or other corporate action. There was no preferred stock outstanding as of June 30, 2006.

Notes Receivable from Stockholders

From inception on October 17, 1997, to June 30, 2002, the Company issued six promissory notes to three officers allowing them to exercise their stock options. These full-recourse notes, with aggregate principal of \$444,000, had annual rates of interest between 6.6% and 8.15% and were repayable commencing August 2003. In August 2002, one of the notes was paid in cash to the Company by an officer and in April 2003, the note was reissued to the officer. In January 2003, the Company modified the terms of the remaining five notes by reducing the interest rate of each note to 1.58% and extending the repayment date to January 2006. Accrued interest of \$40,000, as of the date of modification, was added into the new principal of the notes.

The modification of the notes triggered variable accounting for the options exercised with the notes and accordingly, the Company is required to record a non-cash compensation charge equal to the difference between the purchase price of the stock and the fair value of the stock securing all such notes in each reporting period during which the notes remain outstanding. The variable accounting resulted in stock-based compensation expense of \$134,000, \$2.0 million and \$85,000, which the Company has charged to general and administrative and research and development expense in the accompanying statements of operations for fiscal 2006, 2005 and 2004, respectively.

As of June 30, 2005, total notes receivable from stockholders of \$449,000 remained outstanding. Interest receivable on all promissory notes of \$21,000 was recorded in the accompanying balance sheets as of June 30, 2005. An additional stockholder note receivable of \$73,000 was classified on the balance sheet as a current asset as of June 30, 2005. In October 2005, the Company entered into agreements with three of its directors, including its chief executive officer and the chairman of the board, pursuant to which these directors agreed to tender to the Company shares of common stock owned by the directors, valued at \$9.00 per share, in full payment of the principal and interest due under the six promissory notes. An aggregate amount of 66,227 shares of common stock were exchanged to repay \$572,000 of stockholder notes and \$24,000 of accrued interest. The 66,227 shares are held by the Company as treasury shares. There are no amounts outstanding related to these notes as of June 30, 2006.

Shares Reserved

Shares of common stock reserved for future issuance are as follows:

	June 30, 2006
Stock options outstanding	1,017,739
Shares available for grant under stock option plan	242,847
Warrants for common stock	156,515
	<u>1,417,101</u>

Cardica, Inc.

Notes to Financial Statements — (Continued)

Stock Options

In 1997, the Company adopted the 1997 Equity Incentive Plan, referred to as the 1997 Plan. The 1997 Plan provides for the granting of options to purchase common stock and the issuance of shares of common stock, subject to Company repurchase rights, to directors, employees and consultants. Certain options are immediately exercisable, at the discretion of the board of directors. Shares issued pursuant to the exercise of an unvested option are subject to the Company's right of repurchase which lapses over periods specified by the board of directors, generally four years from the date of grant. In February 2006, the Company terminated all remaining unissued shares under the 1997 Plan. Although the 1997 Plan terminated, all outstanding options thereunder will continue to be governed by their existing terms.

In October 2005, the Company's Board of Directors adopted, and in December 2005 the stockholders approved, the 2005 Equity Incentive Plan, referred to as the 2005 Plan. A total of 400,000 shares of common stock were reserved for issuance under the 2005 Plan.

Stock awards granted under the 2005 Plan may either be incentive stock options, nonstatutory stock options, stock bonuses or rights to acquire restricted stock. Incentive stock options may be granted to employees with exercise prices of no less than the fair value, and nonstatutory options may be granted to employees, directors or consultants at exercise prices of no less than the fair value of the common stock on the date of grant, as determined by the Board of Directors. If, at the time the Company grants an option, the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant. Options may be granted with vesting terms as determined by the Board of Directors. Except as noted above, options expire no more than 10 years after the date of grant, or earlier if employment is terminated.

Common stock options may include a provision whereby the holder, while an employee, director or consultant, may elect at any time to exercise the option as to any part or all of the shares subject to the option prior to the full vesting of the option. Any unvested shares so purchased are subject to repurchase by the Company at its option and at a price equal to the original purchase price of the stock. In accordance with guidance in Issue 33b of EITF 00-23, the Company does not consider the stock issued upon exercise of an unvested stock option substantively exercised, and the cash paid for the exercise price is considered a deposit or a prepayment of the exercise price that is recognized by the Company as a liability. As the underlying shares vest, the deposit liability is reclassified as equity. At June 30, 2006, 10,917 shares of common stock were acquired through the early exercise of options and are subject to the Company's right of repurchase and are excluded from stockholders' equity since these shares have not vested. At June 30, 2005, 46,143 shares of common stock were acquired through the early exercise of options, of which 32,695 shares of common stock were subject to the Company's right of repurchase and were excluded from stockholders' equity since these shares have not vested.

Cardica, Inc.

Notes to Financial Statements — (Continued)

Option activity under all Plans is as follows:

	Shares Available for Grant	Outstanding Options	
		Number of shares	Weighted-Average Exercise Price Per Share
Balance at June 30, 2003	179,889	689,943	\$ 1.68
Options granted	(218,467)	218,467	2.85
Options exercised	—	(185,775)	1.77
Options forfeited	67,714	(67,714)	1.92
Unvested stock options forfeited	2,604	—	—
Balance at June 30, 2004	31,740	654,921	2.01
Shares reserved	333,333	—	—
Options granted	(148,264)	148,264	2.85
Options exercised	—	(8,972)	1.62
Options forfeited	27,962	(27,962)	2.19
Balance at June 30, 2005	244,771	766,251	2.16
Shares reserved	400,000	—	—
Options granted	(508,193)	508,193	6.37
Restricted stock awards	(20,000)	—	—
Options exercised	—	(135,054)	1.75
Options forfeited	121,651	(121,651)	2.14
Unvested stock options repurchased	4,618	—	1.35
Balance at June 30, 2006	242,847	1,017,739	\$ 4.32

The following table summarizes information about options outstanding, vested and exercisable at June 30, 2006:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number	Weighted- Average Remaining Contractual Life	Weighted Average	Number	Weighted Average
	Outstanding	(years)	Exercise Price	Exercisable	Exercise Price
\$0.30 – \$2.25	259,513	5.71	\$ 1.75	225,682	\$ 1.67
\$2.85	448,971	8.54	2.85	180,177	2.85
\$7.45 – \$9.00	202,695	9.73	8.03	10,223	8.22
\$9.75	106,560	9.46	9.75	1,944	9.75
Total outstanding	1,017,739	8.15	\$ 4.32	418,026	\$ 2.38
Options vested and expected to vest	962,924	7.94	\$ 4.08		

The aggregate intrinsic value at of June 30, 2006 of all outstanding options was \$3.9 million, options vested and expected to vest was \$3.7 million and options exercisable was \$2.3 million.

The weighted-average estimated fair value of options granted to employees at fair value during fiscal 2006, 2005 and 2004, was \$5.28, \$0.33 and \$0.30, respectively. The weighted-average estimated fair value of options granted to employees at below fair value during fiscal 2006, 2005 and 2004 was \$7.10, \$2.52 and none, respectively.

Cardica, Inc.**Notes to Financial Statements — (Continued)**

The Black–Scholes option pricing method was applied to all options granted to consultants using the weighted–average assumptions listed below in the table. The Company determined non–cash stock based compensation expense related to these options to be \$45,000, \$25,000 and \$127,000 for fiscal 2006, 2005 and 2004, respectively, which has been reflected in the statements of operations. In accordance with SFAS 123 and EITF 96–18, options granted to consultants are periodically revalued as such stock options vest.

	Fiscal Year Ended June 30,		
	2006	2005	2004
Volatility	100%	100%	100%
Risk–free interest rate	4.71%	4.23%	4.28%
Contractual expected life in years	4–6	6–10	7–10
Dividend yield	0.00%	0.00%	0.00%

Common Stock Subject to Repurchase

In connection with the issuance of common stock to employees and the exercise of options pursuant to the Company's 1997 Equity Incentive Plan, employees entered into restricted stock purchase agreements with the Company. Under the terms of these agreements, the Company has a right to repurchase any unvested shares at the original exercise price of the shares. With continuous employment with the company, the repurchase rights generally lapse at a rate of 25% at the end of the first year and at a rate of 1/36th of the remaining purchased shares for each continuous month of service thereafter. As of June 30, 2006 and 2005, a total of 10,918 and 37,806 shares, respectively, were subject to repurchase by the Company. In addition, during fiscal 2006 the Company granted a restricted stock award of 20,000 shares. The repurchase rights with respect to this restricted stock award lapse at a rate of 25% at the end of the first year and at a rate of 1/36th of the remaining purchased shares for each continuous month of service thereafter. As of June 30, 2006, a total of 20,000 shares were subject to repurchase by the Company.

Warrants

The Company has outstanding warrants to purchase common stock at June 30, 2006:

Shares	Exercise Price Per Share	Expiration
12,270	\$ 4.89	March 2010
52,082	8.40	July 2008
32,146	11.58	June 2009
60,017	11.58	October 2010
156,515		

Cardica, Inc.

Notes to Financial Statements — (Continued)

Note 11. Income Taxes

There is no provision for income taxes because the Company has incurred operating losses since its inception. Deferred income taxes reflect the net tax effects of net operating loss and tax credit carryovers and 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 are as follows (in thousands):

	June 30,	
	2006	2005
Net operating loss carry-forwards	\$ 21,513	\$ 17,149
Research credits	1,391	1,203
Capitalized research and development expenses	217	548
Other	392	559
Total deferred tax assets	23,513	19,459
Valuation allowance	(23,513)	(19,459)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

Realization of the deferred tax assets is dependent upon future taxable income, if any, the amount and timing of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The net valuation allowance increased by approximately \$4.1 million, \$3.8 million and \$4.6 million during fiscal 2006, 2005 and 2004, respectively.

As of June 30, 2006, the Company had federal net operating loss carry-forwards of approximately \$54.7 million. The Company also had federal and state research and development tax credit carry-forwards of approximately \$0.8 million and \$0.6 million respectively. The net operating loss and tax credit carry-forwards will expire at various dates beginning in 2014, if not utilized. As of June 30, 2006, the Company had a state net operating loss carry-forward of approximately \$48.7 million, which expires beginning in 2009.

The reconciliation of income tax benefits attributable to the net loss computed at the U.S federal statutory rates to income tax benefit (expense) (in thousands):

	Fiscal Year Ended June 30,		
	2006	2005	2004
Tax benefit at U.S. statutory rate	\$ (4,221)	\$ (3,723)	\$ (3,641)
Loss for which no tax benefit is currently recognizable	4,010	2,893	3,262
Other, net	212	830	379
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Utilization of the net operating loss and tax credit carry-forwards may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, that are applicable if the Company experiences an "ownership change," which may occur, for example, as a result of the Company's initial public offering and other sales of the Company's stock and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization.

Note 12. Employee Benefit Plan

In January 2001, the Company adopted a 401(k) Profit Sharing Plan that allows voluntary contributions by eligible employees. Employees may elect to contribute up to the maximum allowed under the Internal Revenue Service regulations. The Company may make discretionary contributions as determined by the Board of Directors. No amount was contributed by the Company to the plan during fiscal 2006, 2005 or 2004.

Cardica, Inc.

Notes to Financial Statements — (Continued)

Note 13. Indemnification

From time to time, the Company enters into contracts that require the Company, upon the occurrence of certain contingencies, to indemnify parties against third-party claims. These contingent obligations primarily relate to (i) claims against the Company's customers for violation of third-party intellectual property rights caused by the Company's products; (ii) claims resulting from personal injury or property damage resulting from the Company's activities or products; (iii) claims by the Company's office lessor arising out of the Company's use of the premises; and (iv) agreements with the Company's officers and directors under which the Company may be required to indemnify such persons for liabilities arising out of their activities on behalf of the Company. Because the obligated amounts for these types of agreements usually are not explicitly stated, the overall maximum amount of these obligations cannot be reasonably estimated. No liabilities have been recorded for these obligations on the Company's balance sheets as of June 30, 2006 or 2005.

Legal matters

On March 16, 2006, the Company received notice that the Board of Patent Appeals and Interferences of the U.S. Patent and Trademark Office (the "Patent Appeals Board") declared an interference between the Company's U.S. Patent No 6,391,038 (which relates to the Company's C-Port system) and a pending U.S. Patent Application 10/243,543, which patent application has been assigned to Integrated Vascular Interventional Technologies, LLC ("IVIT").

An interference is a proceeding within the U.S. Patent and Trademark Office to determine priority of invention of the subject matter of patent claims. The declaration of interference is made by the Patent Appeals Board only after claims in a patent application are deemed allowable but for the interfering subject matter (in this case our issued patent) and a determination that interfering subject matter exists. The declaration of interference initiates an adversarial proceeding in the U.S. Patent and Trademark Office before the Patent Appeals Board. The proceeding will involve issues including but not limited to whether an interference proceeding is appropriate, whether the involved claims of the parties are patentable and which party was first to invent the interfering subject matter.

The Company will vigorously defend its patents against such claim of interference, although there can be no assurance that the Company will succeed in doing so. The Company believes that if IVIT's patent claims are allowed in their present form, the Company's products would not infringe such claims. There can be no assurance that IVIT's patent claims, if allowed, will be in their present form, or that the Company's products would not be found to infringe such claims or any other claims that are issued.

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2. Financial Statement Schedules

All financial statement schedules are omitted because the information is not applicable or is presented in the Financial Statements or Notes thereto.

(b) Exhibits.

Exhibit Number	Description
3.1(4)	Amended and Restated Certificate of Incorporation of the Registrant as currently in effect.
3.3(1)	Bylaws of the Registrant as currently in effect.
3.5(5)	Specimen Common Stock certificate of the Registrant.
4.1(1)	Warrant dated March 17, 2000 exercisable for 12,270 shares of common stock.
4.2(1)	Warrant dated July 5, 2001 exercisable for 10,417 shares of common stock.
4.3(1)	Warrant dated July 5, 2001 exercisable for 41,665 shares of common stock.
4.4(1)	Warrant dated June 13, 2002 exercisable for 32,146 shares of common stock.
4.5(1)	Warrant dated October 31, 2002 exercisable for 60,017 shares of common stock.
10.1(1)	1997 Equity Incentive Plan and forms of related agreements and documents.
10.2(3)	2005 Equity Incentive Plan and forms of related agreements and documents.
10.3(1)	Amended and Restated Investor Rights Agreement, dated August 19, 2003, by and among the Registrant and certain stockholders.
10.4(5)	Benefit Agreement with Bernard Hausen, M.D., Ph.D.+
10.5(1)	Office Lease Agreement dated April 25, 2003, and First Amendment to Office Lease Agreement dated January 21, 2004.
10.6(6)	Distribution Agreement by and between Cardica, Inc. and Century Medical, Inc. dated June 16, 2003.†
10.7(2)	Subordinated Convertible Note Agreement with Century Medical, Inc. dated June 16, 2003, and Amendment No. 1 thereto, dated August 6, 2003.†
10.8(1)	Note issued pursuant to Subordinated Convertible Note Agreement with Century Medical, Inc.
10.9(2)	Agreement by and between the Company and the Guidant Investment Corporation, dated August 19, 2003.†
10.10(2)	Intellectual Property Security Agreement by the Company in favor of Guidant, dated August 19, 2003.†
10.11(1)	Notes issued pursuant to Omnibus Agreement.
10.12(1)	Allen & Company LLC letter of intent dated September 12, 2005.
10.13(5)	License, Development and Commercialization Agreement by and between Cardica, Inc. and Cook Incorporated, dated December 9, 2005.†
21.1(1)	Subsidiaries of Registrant.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see page II-5).
31.1	Certification of chief executive officer.
31.2	Certification of chief financial officer.
32.1	Section 1350 Certification.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the SEC.

+ Indicates management contract or compensatory plan.

- (1) Filed as an exhibit to the Registrant's Registration Statement on Form S-1 on November 4, 2005 and incorporated herein by reference.
- (2) Filed as an exhibit to the Registrant's Registration Statement on Form S-1/A on December 20, 2005 and incorporated herein by reference.

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- (3) Filed as an exhibit to the Registrant's Registration Statement on Form S-1/A on January 4, 2006 and incorporated herein by reference.
- (4) Filed as an exhibit to the Registrant's Registration Statement on Form S-1/A on January 13, 2006 and incorporated herein by reference.
- (5) Filed as an exhibit to the Registrant's Registration Statement on Form S-1/A on February 1, 2006 and incorporated herein by reference.
- (6) Filed as an exhibit to the Registrant's Registration Statement on Form S-1/A on February 2, 2006 and incorporated herein by reference.

(c) Financial Statement Schedules

None.

SIGNATURES

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

Cardica, Inc.
Registrant

September 14,
2006

/s/ Robert Y. Newell

Robert Y. Newell
Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Robert Y. Newell, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agents, and any of them or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the Registrant in the capacities indicated on September 14, 2006:

Name and Signature	Title	Date
/s/ Bernard A. Hausen Bernard A. Hausen, M.D., Ph.D.	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	September 14, 2006
/s/ Robert Y. Newell Robert Y. Newell	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	September 14, 2006
/s/ J. Michael Egan J. Michael Egan	Director	September 14, 2006
/s/ Kevin T. Larkin Kevin T. Larkin	Director	September 14, 2006
/s/ Jeffrey L. Purvin Jeffrey L. Purvin	Director	September 14, 2006
/s/ Richard P. Powers Richard P. Powers	Director	September 14, 2006
/s/ Robert C. Robbins Robert C. Robbins, M.D.	Director	September 14, 2006

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Name and Signature	Title	Date
/s/ John Simon John Simon, Ph.D.	Director	September 14, 2006
/s/ Stephen A. Yenko Stephen A. Yenko, Ph.D.	Director	September 14, 2006
/s/ William H. Younger, Jr. William H. Younger, Jr.	Director	September 14, 2006

Exhibit Index

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- (6) Filed as an exhibit to the Registrant's Registration Statement on Form S-1/A on February 2, 2006 and incorporated herein by reference.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Form S-8 No. 333-132155) pertaining to the 1997 Equity Incentive Plan, and the 2005 Equity Incentive Plan of Cardica, Inc. of our report dated July 28, 2006, with respect to the financial statements of Cardica, Inc. included in the Annual Report on Form 10-K for the year ended June 30, 2006.

/s/ Ernst & Young LLP

Ernst & Young LLP

Palo Alto, California

September 12, 2006

CERTIFICATION

I, Bernard A. Hausen, M.D., Ph.D., certify that:

1. I have reviewed this annual report on Form 10-K of Cardica, 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)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 14, 2006

/s/ Bernard A. Hausen
Bernard A. Hausen, M.D., Ph.D
President, Chief Executive Officer, Chief Medical
Officer and Director
(Principal Executive Officer)

CERTIFICATION

I, Robert Y. Newell, certify that:

1. I have reviewed this annual report on Form 10-K of Cardica, 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)) for the registrant and have:

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

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

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

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

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

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

Date: September 14, 2006

/s/ Robert Y. Newell
Robert Y. Newell
Vice President, Finance & Operations and Chief
Financial Officer
(Principal Financial and Accounting Officer)

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Bernard A. Hausen, M.D., Chief Executive Officer of Cardica, Inc. (the "Company"), and Robert Y. Newell, Chief Financial Officer of the Company, each hereby certifies that, to the best of his or her knowledge:

1. The Company's Annual Report on Form 10-K for the period ended June 30, 2006, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 14th day of September, 2006.

/s/ Bernard A. Hausen, M.D., Ph.D.
Bernard A. Hausen, M.D., Ph.D.
Chief Executive Officer

/s/ Robert Y. Newell
Robert Y. Newell
Chief Financial Officer

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cardica, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.