CARDIOVASCULAR SYSTEMS INC
Form 10-12G/A
December 17, 2008

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

AMENDMENT NO. 1 TO FORM 10 GENERAL FORM FOR REGISTRATION OF SECURITIES

Pursuant to Section 12(g) of the Securities Exchange Act of 1934

CARDIOVASCULAR SYSTEMS, INC.
(Name of Registrant as specified in its charter)

Minnesota	**41-1698056**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

651 Campus Drive
St. Paul, Minnesota 55112-3495
(Address of principal executive offices)
(651) 259-1600
(Registrant s Telephone Number)

David L. Martin
President and Chief Executive Officer
Cardiovascular Systems, Inc.
651 Campus Drive
St. Paul, Minnesota 55112-3495
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With a copy to:

Robert K. Ranum
Alexander Rosenstein
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Minneapolis, Minnesota 55402
(612) 492-7341

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

Title of each class	**Name of each exchange on which registered**
None	None

Securities to be registered pursuant to Section 12(g) of the Act:

Common Stock, no par value per share
(Title of Class)

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer o	Smaller reporting company þ

(Do not check if a smaller reporting company)

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Form 10 contains forward-looking statements that involve risks and uncertainties. In some cases, you can identify forward-looking statements by the following words: anticipate, believe, continue, could, estimate, exp intend, may, ongoing, plan, potential, predict, project, should, will, would, or the negative of thes comparable terminology, although not all forward-looking statements contain these words. These statements involve known and unknown risks, uncertainties and other factors that may cause our results or our industry s actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Forward-looking statements are only predictions and are not guarantees of performance. These statements are based on our management s beliefs and assumptions, which in turn are based on their interpretation of currently available information.

These important factors that may cause actual results to differ from our forward-looking statements include those that we discuss under the heading Risk Factors. You should read these risk factors and the other cautionary statements made in this Form 10 as being applicable to all related forward-looking statements wherever they appear in this Form 10. We cannot assure you that the forward-looking statements in this Form 10 will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. You should read this Form 10 completely. Other than as required by law, we undertake no obligation to update these forward-looking statements, even though our situation may change in the future.

This Form 10 also contains industry and market data obtained through surveys and studies conducted by third parties and industry publications. Industry publications and reports cited in this Form 10 generally indicate that the information contained therein was obtained from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. Although we believe that the publications and reports are reliable, we have not independently verified the data.

MARKET AND INDUSTRY DATA

Information and management estimates contained in this Form 10 concerning the medical device industry, including our general expectations and market position, market opportunity and market share, are based on publicly available information, such as clinical studies, academic research reports and other research reports, as well as information from industry reports provided by third-party sources, such as Millennium Research Group. The management estimates are also derived from our internal research, using assumptions made by us that we believe to be reasonable and our knowledge of the industry and markets in which we operate and expect to compete. Other than Millennium Research Group, none of the sources cited in this Form 10 has consented to the inclusion of any data from its reports, nor have we sought their consent. Our internal research has not been verified by any independent source, and we have not independently verified any third-party information. In addition, while we believe the market position, market opportunity and market share information included in this Form 10 is generally reliable, such information is inherently imprecise. Such data involves risks and uncertainties and are subject to change based on various factors, including those discussed under the heading Risk Factors.

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ITEM 1. BUSINESS

Our Corporate Information

Cardiovascular Systems, Inc. (also referred to in this Form 10 as we, us, our, the Company or CSI) was forme 1989 as Shturman Cardiology Systems, Inc. and incorporated in Minnesota. From 1989 to 1997, we engaged in research and development on several different product concepts that were later abandoned. Since 1997, we have devoted substantially all of our resources to the development of the Diamondback 360°. In 2003, we changed our name to Cardiovascular Systems, Inc.

Our principal executive office is located at 651 Campus Drive, Saint Paul, Minnesota 55112. Our telephone number is (651) 259-1600, and our website is www.csi360.com. The information contained in or connected to our website is not incorporated by reference into, and should not be considered part of, this Form 10.

We have applied for federal registration of certain marks, including Diamondback 360° and ViperWire. All other trademarks, trade names and service marks appearing in this Form 10 are the property of their respective owners.

Proposed Merger with Replidyne, Inc.

On November 3, 2008, CSI entered into an Agreement and Plan of Merger and Reorganization, referred to herein as the merger agreement, with Replidyne, Inc., or Replidyne, and Responder Merger Sub, Inc., a Minnesota corporation and wholly-owned subsidiary of Replidyne, or Merger Sub, pursuant to which, on the terms and subject to the conditions set forth in the merger agreement, Merger Sub will be merged with and into CSI, with CSI surviving the merger as a wholly-owned subsidiary of Replidyne. Immediately prior to the effective time of the merger, each share of CSI preferred stock outstanding at such time will be converted into shares of CSI common stock at the conversion ratio determined pursuant to CSI s articles of incorporation in accordance with an agreement entered into among certain of CSI s stockholders. At the effective time of the merger, each share of CSI common stock outstanding immediately prior to the effective time of the merger (excluding certain shares to be canceled pursuant to the merger agreement, and shares held by stockholders who have exercised and perfected dissenters rights) will be converted into the right to receive approximately 6.460 shares of Replidyne common stock, assuming that the net assets of Replidyne are between $37 million and $40 million as calculated in accordance with the terms of the merger agreement and that the number of shares of Replidyne and CSI common stock outstanding on a fully diluted basis using the treasury stock method of accounting for options and warrants immediately prior to the effective time of the merger has not changed from the number of such shares as of October 31, 2008, subject to adjustment to account for the effect of a reverse stock split of Replidyne common stock to be implemented prior to the consummation of the merger, which is referred to as the reverse stock split. As a result of the merger, holders of CSI stock, options and warrants are expected to own or have the right to acquire in the aggregate approximately 83% of the combined company and the holders of Replidyne stock, options and warrants are expected to own or have the right to acquire in the aggregate approximately 17% of the combined company. At the effective time of the merger, Replidyne will change its corporate name to Cardiovascular Systems, Inc. as required by the merger agreement. The merger is intended to qualify for federal income tax purposes as a tax-free reorganization under the provisions of Section 368(a) of the U.S. Internal Revenue Code of 1986, as amended.

To consummate the merger, Replidyne stockholders must approve the issuance of shares of Replidyne common stock in the merger and a certificate of amendment to the restated certificate of incorporation of Replidyne and CSI stockholders must approve and adopt the merger agreement and the merger contemplated therein. Consummation of the merger is also subject to additional closing conditions, including among other things, the filing by Replidyne with the Securities and Exchange Commission, or SEC, of a registration statement on Form S-4 with respect to the registration of the shares of Replidyne common stock to be issued in the merger and a declaration of its effectiveness by the SEC, and conditional approval for the listing of Replidyne common stock to be issued in the merger on the Nasdaq Global Market.

Several CSI stockholders have agreed with Replidyne to vote shares representing approximately 20% of the outstanding capital stock of CSI in favor of the merger and the other actions contemplated by the merger agreement. These stockholders represented the maximum number of the outstanding shares of CSI capital stock that could be made subject to these voting agreements under Minnesota corporate law. In addition, several Replidyne stockholders, who beneficially own approximately 52% of the outstanding common stock of Replidyne, have agreed with CSI to

vote shares representing approximately 35% of the outstanding common stock of Replidyne in favor of the issuance of the shares of Replidyne common stock pursuant to the merger and the other actions contemplated by the merger agreement.

The merger agreement contains certain termination rights for both Replidyne and CSI, and further provides that, upon termination of the merger agreement under specified circumstances, Replidyne or CSI may be required to pay the other party a termination fee of $1,500,000 plus reimbursement to the applicable party of all actual out-of-pocket legal, accounting and investment advisory fees paid or payable by such party in connection with the merger agreement and the transactions contemplated thereby.

Replidyne has agreed to appoint directors designated by CSI to Replidyne s Board of Directors, specified current directors of Replidyne will resign from the Board of Directors and Replidyne will appoint new officers designated by CSI.

As used in this Form 10, references to the combined company refer to Replidyne following the proposed merger described above.

On December 3, 2008, Replidyne filed a registration statement on Form S-4 to register with the SEC the offer and sale of the shares of Replidyne common stock to be issued to CSI stockholders in the merger, which constitutes a prospectus of Replidyne and a proxy statement of Replidyne and CSI.

Business Overview

We are a medical device company focused on developing and commercializing interventional treatment systems for vascular disease. Our initial product, the Diamondback 360° Orbital Atherectomy System, is a minimally invasive catheter system for the treatment of peripheral arterial disease, or PAD. PAD affects approximately eight to 12 million people in the United States, as cited by the authors of the PARTNERS study published in the Journal of the American Medical Association in 2001. PAD is caused by the accumulation of plaque in peripheral arteries, most commonly occurring in the pelvis and legs. However, as reported in an article published in Podiatry Today in 2006, only approximately 2.5 million of those eight to 12 million people are treated. PAD is a progressive disease, and if left untreated can lead to limb amputation or death. In August 2007, the U.S. Food and Drug Administration, or FDA, granted us 510(k) clearance for use of the Diamondback 360° as a therapy in patients with PAD. We commenced a limited commercial introduction of the Diamondback 360° in the United States in September 2007. This limited commercial introduction intentionally limited the size of our sales force and the number of customers each member of the sales force served in order to focus on obtaining quality and timely product feedback on initial product usages. During the quarter ended March 31, 2008, we began our full commercial launch.

The Diamondback 360° s single-use catheter incorporates a flexible drive shaft with an offset crown coated with diamond grit. Physicians position the crown with the aid of fluoroscopy at the site of an arterial plaque lesion and remove the plaque by causing the crown to orbit against it, creating a smooth lumen, or channel, in the vessel. The Diamondback 360° is designed to differentiate between plaque and compliant arterial tissue, a concept that we refer to as differential sanding. The particles of plaque resulting from differential sanding are generally smaller than red blood cells and are carried away by the blood stream. The small size of the particles avoids the need for plaque collection reservoirs and the delay involved in removing the collection reservoir when it fills up during the procedure. Physicians are able to keep the Diamondback 360° in the artery until the desired vessels have been treated, potentially reducing the overall procedure time. As the physician increases the rotational speed of the drive shaft, the crown not only rotates faster but also, due to centrifugal force, begins to orbit with an increasing circumference. The Diamondback 360° can create a lumen that is approximately 100% larger than the actual diameter of the device, for a device-to-lumen ratio of 1.0 to 2.0. By giving physicians the ability to create different lumen diameters with a change in rotational speed, the Diamondback 360° can reduce the need to use multiple catheters of different sizes to treat a single lesion.

We have conducted three clinical trials involving 207 patients to demonstrate the safety and efficacy of the Diamondback 360° in treating PAD. In particular, our pivotal OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions and met FDA targets. We were the first, and so far the only, company to conduct a prospective multi-center clinical trial with a prior investigational device exemption, or IDE, in support of a 510(k) clearance for an atherectomy device. We believe that the Diamondback 360° provides a platform that can be leveraged across multiple market segments. In the future, we expect to launch additional products to treat lesions in larger vessels, provided that we obtain appropriate 510(k) clearance from the FDA. We also plan to seek premarket

approval (PMA) from the FDA to use the Diamondback 360° to treat patients with coronary artery disease.

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Market Overview

Peripheral Artery Disease

PAD is a circulatory problem in which plaque deposits build up on the walls of arteries, reducing blood flow to the limbs. The most common early symptoms of PAD are pain, cramping or tiredness in the leg or hip muscles while walking. Symptoms may progress to include numbness, tingling or weakness in the leg and, in severe cases, burning or aching pain in the leg, foot or toes while resting. As PAD progresses, additional signs and symptoms occur, including cooling or color changes in the skin of the legs or feet, and sores on the legs or feet that do not heal. If untreated, PAD may lead to critical limb ischemia, a condition in which the amount of oxygenated blood being delivered to the limb is insufficient to keep the tissue alive. Critical limb ischemia often leads to large non-healing ulcers, infections, gangrene and, eventually, limb amputation or death.

PAD affects approximately eight to 12 million people in the United States, as cited by the authors of the PARTNERS study published in the Journal of the American Medical Association in 2001. According to 2007 statistics from the American Heart Association, PAD becomes more common with age and affects approximately 12% to 20% of the population over 65 years old. An aging population, coupled with increasing incidence of diabetes and obesity, is likely to increase the prevalence of PAD. In many older PAD patients, particularly those with diabetes, PAD is characterized by hard, calcified plaque deposits that have not been successfully treated with existing non-invasive treatment techniques. PAD may involve arteries either above or below the knee. Arteries above the knee are generally long, straight and relatively wide, while arteries below the knee are shorter and branch into arteries that are progressively smaller in diameter.

Despite the severity of PAD, it remains relatively underdiagnosed. According to an article published in Podiatry Today in 2006, only approximately 2.5 million of the eight to 12 million people in the United States with PAD are diagnosed. Although we believe the rate of diagnosis of PAD is increasing, underdiagnosis continues due to patients failing to display symptoms or physicians misinterpreting symptoms as normal aging. Recent emphasis on PAD education from medical associations, insurance companies and other groups, coupled with publications in medical journals, is increasing physician and patient awareness of PAD risk factors, symptoms and treatment options. The PARTNERS study advocated increased PAD screening by primary care physicians.

Physicians treat a significant portion of the 2.5 million people in the United States who are diagnosed with PAD using medical management, which includes lifestyle changes, such as diet and exercise and drug treatment. For instance, within a reference group of over 1,000 patients from the PARTNERS study, 54% of the patients with a prior diagnosis of PAD were receiving antiplatelet medication treatment. While medications, diet and exercise may improve blood flow, they do not treat the underlying obstruction and many patients have difficulty maintaining lifestyle changes. Additionally, many prescribed medications are contraindicated, or inadvisable, for patients with heart disease, which often exists in PAD patients. As a result of these challenges, many medically managed patients develop more severe symptoms that require procedural intervention.

Conventional Interventional Treatments for PAD and Their Limitations

According to the Millennium Research Group, in 2006 there were approximately 1.3 million procedural interventions for the treatment of PAD in the United States, including 227,400 surgical bypass procedures, and 1,080,000 endovascular-based interventions, such as angioplasty and stenting.

Surgical Procedures. Bypass surgery and amputation are the most common surgical interventions that are used to treat PAD. In bypass surgery, the surgeon reroutes blood around a lesion using a vessel from another part of the body or a tube made of synthetic fabric. Bypass surgery has a high risk of procedure-related complications from blood loss, post-procedural infection or reaction to general anesthesia. Due to these complications, patients may have to remain hospitalized for several days and are exposed to mortality risk. According to clinical research published by EuroIntervention in 2005, bypass surgery has a five year survival rate of 60%. Amputation of all or a portion of a limb may be necessary as critical limb ischemia progresses to an advanced state, which results in approximately 160,000 to 180,000 amputations per year in the United States, according to an article published in Podiatry Today in July 2007.

Catheter-Based Interventions. Minimally invasive catheter-based interventions include angioplasty, stenting and atherectomy procedures. Angioplasty involves inserting a catheter with a balloon tip into the site of arterial blockage and then inflating the balloon to compress plaque and expand the artery wall. Stenting involves implanting and expanding a cylindrical metal tube into the diseased artery to hold the arterial wall open. Both angioplasty and stenting can improve blood flow in plaque-lined arteries by opening lumens and are relatively fast and inexpensive compared to surgical procedures. However, these techniques are not as effective in long or calcified lesions or in lesions located below the knee, nor do they remove any plaque from the artery. Moreover, most stents are not FDA-approved for use in arteries in the lower extremities. Additional concerns include the potential to damage the artery when the balloon is expanded in angioplasty and the potential for stent fracture during normal leg movement. Both angioplasty and stenting

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have also been associated with high rates of restenosis, or re-narrowing of the arteries, in the months following the procedure.

A third category of catheter-based interventions is atherectomy, which involves removing plaque from the arterial wall by using cutting technologies or energy sources, such as lasers, or by sanding with a diamond grit coated crown. Atherectomy techniques that preceded the introduction of the Diamondback 360° include cutting atherectomy, laser atherectomy and rotational atherectomy. Cutting atherectomy devices are guided into an artery along a catheter to the target lesion, where the device is manipulated to remove plaque by cutting the tissue when the device is advanced. However, there is a risk that when plaque is cut away from a vessel wall, the removed plaque will flow into other parts of the body, where it will block the blood flow by obstructing the lumen, known as embolization. Laser atherectomy devices remove plaque through vaporization. Rotational atherectomy devices remove plaque by abrading the lesion with a spinning, abrasive burr, but lack the Diamondback 360° s ability to create larger lumen diameters by increasing rotational speed. These earlier catheter-based treatments also require the extensive use of fluoroscopy, which is an imaging technique to capture real-time images of an artery, but results in potentially harmful radiological exposure for the physician and patient.

The atherectomy technologies that preceded the introduction of the Diamondback 360° have significant drawbacks, including one or more of the following:

potential safety concerns, as these methods of plaque removal do not always discriminate between compliant arterial tissue and plaque, thus potentially damaging the arterial wall;

difficulty treating calcified lesions, diffuse disease and lesions located below the knee;

an inability to create lumens larger than the catheter itself in a single insertion (resulting in device-to-lumen ratios of 1.00 to 1.00 or worse), necessitating the use of multiple catheters, which increases the time, complexity and expense of the procedure;

the creation of rough, uneven lumens with deep grooves, which may impact blood flow dynamics following the procedure;

the potential requirement for greater physician skill, specialized technique or multiple operators to deliver the catheter and remove plaque;

the potential requirement for reservoirs or aspiration to capture and remove plaque, which often necessitates larger catheters and adds time, complexity and expense to the procedure;

the potential need for ancillary distal embolization protection devices to prevent large particles of dislodged plaque from causing distal embolisms or blockages downstream;

the potential requirement for large, expensive capital equipment used in conjunction with the procedure; and

the potential requirement for extensive use of fluoroscopy and increased emitted radiation exposure for physicians and patients during the procedure.

We believe that there is a significant market opportunity for a technology that opens lumens, similar to the lumen sizes achieved with angioplasty and stenting, in a simple, fast, cost-effective procedure that avoids the risks and potential restenosis associated with those procedures and addresses the historical limitations of atherectomy technologies.

Our Solution

The Diamondback 360° represents a new approach to the treatment of PAD that provides physicians and patients with a procedure that addresses many of the limitations of traditional treatment alternatives. The Diamondback 360° s single-use catheter incorporates a flexible drive shaft with an offset crown coated with diamond grit. Physicians

position the crown at the site of an arterial plaque lesion and remove the plaque by causing the crown to orbit against it, creating a smooth lumen, or channel, in the vessel. The Diamondback 360° is a rotational atherectomy catheter designed to differentiate between plaque and compliant arterial tissue, a concept that we refer to as differential sanding. The particles of plaque resulting from differential sanding are generally smaller than red blood cells and are carried away by the blood stream. As the physician increases the rotational speed of the drive shaft, the crown not only rotates faster but also, due to centrifugal force, begins to orbit with an increasing circumference. The Diamondback 360° can create a lumen that is approximately 100% larger than the actual diameter of the device, for a device-to-lumen ratio of 1.0 to 2.0. By giving physicians the ability to create different lumen diameters with a change in rotational speed, the Diamondback 360° can reduce the need to use multiple catheters of different sizes to treat a single lesion, thus reducing hospital inventory costs and procedure times.

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We believe that the Diamondback 360° offers the following key benefits:

Strong Safety Profile

Differential Sanding Reduces Risk of Adverse Events. The Diamondback 360° is designed to differentiate between plaque and compliant arterial tissue. The diamond grit coated offset crown engages and removes plaque from the artery wall with minimal likelihood of penetrating or damaging the fragile, internal elastic lamina layer of the arterial wall because compliant tissue flexes away from the crown. Furthermore, the Diamondback 360° rarely penetrates even the middle inside layer of the artery and the two elastic layers that border it. The Diamondback 360° s perforation rates were 2.4% during our pivotal OASIS trial. Analysis by an independent pathology laboratory of more than 436 consecutive cross sections of porcine arteries treated with the Diamondback 360° revealed there was minimal to no damage, on average, to the medial layer, which is typically associated with restenosis. In addition, the safety profile of the Diamondback 360° was found to be non-inferior to that of angioplasty, which is often considered the safest of interventional methods. This was demonstrated in our OASIS trial, which had a 4.0% rate of device-related serious adverse events, or SAEs.

Reduces the Risk of Distal Embolization. The Diamondback 360° sands plaque away from artery walls in a manner that produces particles of such a small size generally smaller than red blood cells that they are carried away by the blood stream. The small size of the particles avoids the need for plaque collection reservoirs on the catheter and reduces the need for ancillary distal protection devices, commonly used with directional cutting atherectomy, and also significantly reduces the risk that larger pieces of removed plaque will block blood flow downstream.

Allows Continuous Blood Flow During Procedure. The Diamondback 360° allows for continuous blood flow during the procedure, except when used in chronic total occlusions. Other atherectomy devices may restrict blood flow due to the size of the catheter required or the use of distal protection devices, which could result in complications such as excessive heat and tissue damage.

Proven Efficacy

Efficacy Demonstrated in a 124-Patient Clinical Trial. Our pivotal OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions and performance targets established cooperatively with the FDA before the trial began. Despite 55% of the lesions consisting of calcified plaque and 48% of the lesions having a length greater than three centimeters, the performance of the device in the OASIS trial met the FDA s study endpoints.

Treats Difficult and Calcified Lesions. The Diamondback 360° enables physicians to remove plaque from long, calcified or bifurcated lesions in peripheral arteries both above and below the knee. Existing PAD devices have demonstrated limited effectiveness in treating calcified lesions.

Orbital Motion Improves Device-to-Lumen Ratio. The orbiting action of the Diamondback 360° can create a lumen of approximately 2.0 times the diameter of the crown. The variable device-to-lumen ratio allows the continuous removal of plaque as the opening of the lumen increases during the operation of the device. Other rotational atherectomy catheters remove plaque by abrading the lesion with a spinning, abrasive burr, which acts in a manner similar to a drill and only creates a lumen the same size or slightly smaller than the size of the burr.

Differential Sanding Creates Smooth Lumens. The differential sanding of the Diamondback 360° creates a smooth surface inside the lumen. This feature reduces the need to introduce a balloon after treatment to improve the surface of the artery, which is commonly done after cutting atherectomy. We believe that the smooth lumen created by the Diamondback 360° increases the velocity of blood flow and decreases the resistance to blood flow which may decrease potential for restenosis, or renarrowing of the arteries.

Ease of Use

Utilizes Familiar Techniques. Physicians using the Diamondback 360° employ techniques similar to those used in angioplasty, which are familiar to interventional cardiologists, vascular surgeons and interventional radiologists who are trained in endovascular techniques. The Diamondback 360° s simple user interface requires minimal additional training and technique. The system s ability to differentiate between diseased and compliant tissue reduces the risk of complications associated with user error and potentially broadens the user population beyond those currently using atherectomy devices.

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Single Insertion to Complete Treatment. The Diamondback 360° s orbital technology and differential sanding process in most cases allows for a single insertion to treat lesions. Because the particles of plaque sanded away are of such small sizes, the Diamondback 360° does not require a collection reservoir that needs to be repeatedly emptied or cleaned during the procedure. Rather, the Diamondback 360° allows for multiple passes of the device over the lesion until plaque is removed and a smooth lumen is created.

Limited Use of Fluoroscopy. The relative simplicity of our process and predictable crown location allows physicians to significantly reduce fluoroscopy use, thus limiting radiation exposure.

Cost and Time Efficient Procedure

Single Crown Can Create Various Lumen Sizes Limiting Hospital Inventory Costs. The Diamondback 360° s orbital mechanism of action allows a single-sized device to create various diameter lumens inside the artery. Adjusting the rotational speed of the crown changes the orbit to create the desired lumen diameter, thereby potentially avoiding the need to use multiple catheters of different sizes. The Diamondback 360° can create a lumen that is 100% larger than the actual diameter of the device, for a device-to-lumen ratio of approximately 1.0 to 2.0.

Less Expensive Capital Equipment. The control unit used in conjunction with the Diamondback 360° has a current retail list price of $19,995, significantly less than the cost of capital equipment used with laser atherectomy, which may cost from $125,000 to more than $150,000.

Single Insertion Reduces Procedural Time. Since the physician does not need to insert and remove multiple catheters or clean a plaque collection reservoir to complete the procedure, there is a potential for decreased procedure time.

Our Strategy

Our goal is to be the leading provider of minimally invasive solutions for the treatment of vascular disease. The key elements of our strategy include:

Drive Adoption with Key Opinion Leaders Through Direct Sales Organization. We expect to continue to drive adoption of the Diamondback 360° through our direct sales force, which targets interventional cardiologists, vascular surgeons and interventional radiologists. Initially, we plan to focus primarily on key opinion leaders who are early adopters of new technology and can assist in peer-to-peer selling. We commenced a limited commercial introduction in September 2007 and broadened our commercialization efforts to a full commercial launch in the quarter ended March 31, 2008. As of October 31, 2008, we had a 108 person direct sales force. As a key element of our strategy, we focus on educating and training physicians on the Diamondback 360° through seminars where industry leaders discuss case studies and treatment techniques using the Diamondback 360°.

Collect Additional Clinical Evidence on Benefits of the Diamondback 360°. We are focused on using clinical evidence to demonstrate the advantages of our system and drive physician acceptance. We have conducted three clinical trials to demonstrate the safety and efficacy of the Diamondback 360° in treating PAD, involving 207 patients, including our pivotal OASIS trial. We have requested clinical data from each subsequent use of the system following these clinical trials. These data are tabulated and disseminated internally to our sales, marketing and research and development departments in an effort to better understand the system s performance, identify any potential trends in the data, and drive product improvements. The data are also presented to groups of physicians for their education, comments and feedback. We are considering other clinical studies to further demonstrate the advantages of the Diamondback 360° but have not yet undertaken any additional studies.

Expand Product Portfolio within the Market for Treatment of Peripheral Arteries. We are currently developing a new product generation to further reduce treatment times and allow treatment of larger vessels.

Leverage Technology Platform into Coronary Market. We have initiated preclinical studies investigating the use of the Diamondback 360° in the treatment of coronary artery disease. We believe that the key product attributes of the Diamondback 360° will also provide substantial benefits in treating the coronary arteries, subject to FDA approval.

Pursue Strategic Acquisitions and Partnerships. In addition to adding to our product portfolio through internal development efforts, we intend to explore the acquisition of other product lines, technologies or companies that may leverage our sales force or complement our strategic objectives. We may also evaluate distribution agreements, licensing transactions and other strategic partnerships.

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Our Product

Components of the Diamondback 360°

The Diamondback 360° consists of a single-use, low-profile catheter that travels over our proprietary ViperWire guidewire. The system is used in conjunction with an external control unit.

Catheter. The catheter consists of:

a control handle, which allows precise movement of the crown and predictable crown location;

a flexible drive shaft with a diamond grit coated offset crown, which tracks and orbits over the guidewire; and

a sheath, which covers the drive shaft and permits delivery of saline or medications to the treatment area.

The crown is available in multiple sizes, including 1.25, 1.50, 1.75, 2.00 and 2.25 mm diameters. The catheter is available in two lengths, 95 cm and 135 cm, to address procedural approach and target lesion location.

ViperWire Guidewire. The ViperWire, which is located within the catheter, maintains device position in the vessel and is the rail on which the catheter operates. The ViperWire is available in three levels of firmness.

Control Unit. The control unit incorporates a touch-screen interface on an easily maneuverable, lightweight pole. Using an external air supply, the control unit regulates air pressure to drive the turbine located in the catheter handle to speeds ranging up to 200,000 revolutions per minute. Saline, delivered by a pumping mechanism on the control unit, bathes the device shaft and crown. The constant flow of saline reduces the risk of heat generation.

The following diagram depicts the components of the Diamondback 360°:

Technology Overview

The two technologies used in the Diamondback 360° are orbital atherectomy and differential sanding.

Orbital Atherectomy. The system operates on the principles of centrifugal force. As the speed of the crown s rotation increases, it creates centrifugal force, which increases the crown s orbit and presses the diamond grit coated offset crown against the lesion or plaque, removing a small amount of plaque with each orbit. The characteristics of the orbit and the resulting lumen size can be adjusted by modifying three variables:

Speed. An increase in speed creates a larger lumen. Our current system allows the user to choose between three rotational speeds. The fastest speed can result in a device-to-lumen ratio of 1.0 to 2.0, for a lumen that is approximately 100% larger than the actual diameter of the device.

Crown Characteristics. The crown can be designed with various weights (as determined by different materials and density) and coated with diamond grit of various width, height and configurations. Our current system offers the choice between a hollow, lightweight crown and a solid, heavier crown, which could potentially increase the device-to-lumen ratio.

Drive Shaft Characteristics. The drive shaft can be designed with various shapes and degrees of rigidity. We are developing a drive shaft that we call the Sidewinder, which is a heat-set, pre-bent shaft. When the guidewire is inserted into the Sidewinder, the shaft is straightened, allowing for deliverability to the lesion. However, the propensity of the Sidewinder s pre-bent shaft to return to its bent shape creates a larger diameter orbit, which will potentially allow for the creation of a larger lumen. We are also developing a version of our shaft that has a diamond grit coated tip for ease of penetrating a chronic total occlusion.

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We view the Diamondback 360° as a platform that can be used to develop additional products by adjusting one or more of the speed, crown and shaft variables.

Differential Sanding. The Diamondback 360° s design allows the device to differentiate between compliant and diseased arterial tissue. This property is common with sanding material such as the diamond grit used in the Diamondback 360º. The diamond preferentially engages and sands harder material. The Diamondback 360° also treats soft plaque, which is less compliant than a normal vessel wall. Arterial lesions tend to be harder and stiffer than compliant, undiseased tissue, and they often are calcified, and the Diamondback 360º sands the lesion but does not damage more compliant parts of the artery. The mechanism is a function of the centrifugal force generated by the Diamondback 360º as it rotates. As the crown moves outward, the centrifugal force is offset by the counterforce exerted by the arterial wall. If the tissue is compliant, it flexes away, rather than generating an opposing force that would allow the Diamondback 360º to engage and sand the wall. Diseased tissue, particularly heavily calcified lesions, provides resistance and is able to generate an opposing force that allows the Diamondback 360º to engage and sand the plaque. The sanded plaque is broken down into particles generally smaller than circulating red blood cells that are washed away downstream with the patient s natural blood flow. Of 36 consecutive experiments that we performed in carbon blocks, animal and cadaver models:

- 93.1% of particles were smaller than a red blood cell, with a 99% confidence interval; and
- 99.3% of particles were smaller than the lumen of the capillaries (which provide the connection between the arterial and venous system), with a 99% confidence interval.

The small particle size minimizes the risk of vascular bed overload, or a saturation of the peripheral vessels with large particles, which may cause slow or reduced blood flow to the foot. We believe that the small size of the particle also allows it to be managed by the body s natural cleansing of the blood, whereby various types of white blood cells eliminate worn-out cells and other debris in the bloodstream.

One of our competitors claims that its rotational atherectomy catheter is also able to differentiate between compliant and diseased tissue.

Applications

The Diamondback 360° can be delivered to the lesion by a single physician, and on average required three minutes to treat a lesion in our OASIS trial.

Below-the-Knee Peripheral Artery Disease. Arteries below the knee have small diameters and may be diffusely diseased, calcified or both, limiting the effectiveness of traditional atherectomy devices. The Diamondback 360° is effective in both diffuse and calcified vessels as demonstrated in the OASIS trial, where 94.5% of lesions treated were below the knee.

Above-the-Knee Peripheral Artery Disease. Plaque in arteries above the knee may also be diffuse and calcific; however, these arteries are longer, straighter and wider than below-the-knee vessels. While effective in difficult-to-treat below-the-knee vessels, and indicated for vessels up to four millimeters in diameter, our product is also being used to treat lesions above the knee, in particular, calcified lesions. We intend to seek expanded labeling from the FDA for treatment of vessels larger than four millimeters in diameter before the end of 2009. The Millennium Research Group estimates that there will be approximately 258,600 procedures to treat above-the-knee PAD in 2008 and that there will be approximately 71,220 procedures to treat below-the-knee PAD in 2008.

Coronary Artery Disease. Given the many similarities between peripheral and coronary artery disease, we have developed and are completing pre-clinical testing of a modified version of the Diamondback 360° to treat coronary arteries. We have conducted numerous bench studies and four pre-clinical animal studies to evaluate the Diamondback 360º in coronary artery disease. In the bench studies, we evaluated the system for conformity to specifications and patient safety, and under conditions of expected clinical use no safety issues were observed. In three of the animal studies, the system was used to treat a large number of stented and non-stented arterial lesions. The system was able to safely debulk lesions without evidence or observations of significant distal embolization, and the treated vessels in the animal studies showed only minimal to no damage. The fourth animal study evaluated the safety of the system for the treatment of coronary stenosis. There were no device-related adverse events associated with system treatment during this study, with some evidence of injury observed in 17% of the tissue sections analyzed, although 75% of these injuries were minimal or mild. A coronary application would require us to conduct a clinical trial and receive PMA

from the FDA. We participated in three pre-IDE meetings with the FDA and completed the human feasibility portion of a coronary trial in the summer of 2008 in India, enrolling 50 patients. The FDA has agreed to accept the data from the India trial to support an IDE submission should we determine to proceed with an IDE submission based on the results of this trial.

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Clinical Trials and Studies for our Products

We have conducted three clinical trials to demonstrate the safety and efficacy of the Diamondback 360° in treating PAD, enrolling a total of 207 patients in our PAD I and PAD II pilot trials and our pivotal OASIS trial.

The common metrics used to evaluate the efficacy of atherectomy devices for PAD include:

Metric	Description
Absolute Plaque Reduction	Absolute plaque reduction is the difference between the pre-treatment percent stenosis, or the narrowing of the vessel, and the post-treatment percent stenosis as measured angiographically.
Target Lesion Revascularization	Target lesion revascularization rate, or TLR rate, is the percentage of patients at follow-up who have another peripheral intervention precipitated by their worsening symptoms, such as an angioplasty, stenting or surgery to reopen the treated lesion site.
Ankle Brachial Index	The Ankle Brachial Index, or ABI, is a measurement that is useful to evaluate the adequacy of circulation in the legs and improvement or worsening of leg circulation over time. The ABI is a ratio between the blood pressure in a patient s ankle and a patient s arm, with a ratio above 0.9 being normal.

The common metrics used to evaluate the safety of atherectomy devices for PAD include:

Metric	Description
Serious Adverse Events	Serious adverse events, or SAEs, include any experience that is fatal or life-threatening, is permanently disabling, requires or prolongs hospitalization, or requires intervention to prevent permanent impairment or damage. SAEs may or may not be related to the device.
Perforations	Perforations occur when the artery is punctured during atherectomy treatment. Perforations may be nonserious or an SAE depending on the treatment required to repair the perforation.

Inclusion criteria for trials often limit size of lesion and severity of disease, as measured by the Rutherford Class, which utilizes a scale of I to VI, with I being mild and VI being most severe, and the Ankle Brachial Index.

PAD I Feasibility Trial

Our first trial was a two-site, 17-patient feasibility clinical trial in Europe, which we refer to as PAD I, that began in March 2005. Patients enrolled in the trial had lesions that were less than 10 cm in length in arteries between 1.5 mm and 6.0 mm in diameter, with Rutherford Class scores of IV or lower. Patients were evaluated at the time of the procedure and at 30 days following treatment. The purpose of PAD I was to obtain the first human clinical experience and evaluate the safety of the Diamondback 360°. This was determined by estimating the cumulative incidence of patients experiencing one or more SAEs within 30 days post-treatment.

The results of PAD I were presented at the Transcatheter Therapeutics conference, or TCT, in 2005 and published in American Journal of Cardiology. Results confirmed that the Diamondback 360° and orbital atherectomy were safe and established that the Diamondback 360° could be used to treat vessels in the range of 1.5 mm to 4.0 mm, which are found primarily below the knee. Also, PAD I showed that effective debulking, or removal of plaque, could be accomplished and the resulting device-to-lumen ratio was approximately 1.0 to 2.0. The SAE rate in PAD I was 6% (one of 17 patients).

PAD II Feasibility Trial

After being granted the CE Mark in May 2005, we began a 66-patient European clinical trial at seven sites, which we refer to as PAD II, in August 2005. All patients had stenosis in vessels below the femoral artery of between 1.5

mm and 4.0 mm in diameter, with at least 50% blockage. The primary objectives of this study were to evaluate the acute (30 days or less) risk of experiencing an SAE post procedure and provide evidence of device effectiveness. Effectiveness was confirmed angiographically and based on the percentage of absolute plaque reduction.

The PAD II results demonstrated safe and effective debulking in vessels with diameters ranging from 1.5 mm to 4.0 mm

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with a mean absolute plaque reduction of 55%. The SAE rate in PAD II was 9% (six of 66 patients), which did not differ significantly from existing non-invasive treatment options.

OASIS Pivotal Trial

We received an IDE to begin our pivotal United States trial, OASIS, in September 2005. OASIS was a 124-patient, 20-center, prospective trial that began enrollment in January 2006.

Patients included in the trial had:

an ABI of less than 0.9;

a Rutherford Class score of V or lower; and

treated arteries of between 1.5 mm and 4.0 mm or less in diameter via angiogram measurement, with a well-defined lesion of at least 50% diameter stenosis and lesions of no greater than 10.0 cm in length.

The primary efficacy study endpoint was absolute plaque reduction of the target lesions from baseline to immediately post procedure. The primary safety endpoint was the cumulative incidence of SAEs at 30 days.

In the OASIS trial, 94.5% of lesions treated were below the knee, an area where lesions have traditionally gone untreated until they require bypass surgery or amputation. Of the lesions treated in OASIS, 55% were comprised of calcified plaque which presents a challenge to proper expansion and apposition of balloons and stents, and 48% were diffuse, or greater then 3 cm in length, which typically requires multiple balloon expansions or stent placements. Competing atherectomy devices are often ineffective with these difficult to treat lesions.

The average time of treatment in the OASIS trial was three minutes per lesion, which compares favorably to the treatment time required by other atherectomy devices. We believe physicians using other atherectomy devices require approximately ten to 20 minutes of treatment time to achieve desired results, although treatment times may vary depending upon the nature of the procedure, the condition of the patient and other factors. The following table is a summary of the OASIS trial results:

Item	FDA Target	OASIS Result
Absolute Plaque Reduction	55%	59.4%
SAEs at 30 days	8% mean, with an upper bound of 16%	4.0% mean, device-related 9.7% mean, overall
TLR	20% or less	2.4%
Perforations	N/A	1 serious perforation
ABI at baseline	N/A	0.68 ± 0.2*
ABI at 30 days	N/A	0.9 ± 0.18*
ABI at 6 months	N/A	0.83 ± 0.23*

* Mean ± Standard Deviation

We submitted our OASIS data and received 510(k) clearance from the FDA for use of the Diamondback 360°, including the initial version of the control unit, with a hollow crown as a therapy for patients with PAD in August 2007. The FDA s labeling requirements reflected the inclusion criteria for the OASIS trial listed above. We received 510(k) clearances in October 2007 for the updated control unit used with the Diamondback 360° and in November 2007 for the Diamondback 360° with a solid crown. In May 2005, we received the CE mark, allowing for the commercial use of the Diamondback 360° within the European Union; however, our current plans are to focus sales in the United States.

Sales and Marketing

We market and sell the Diamondback 360° through a direct sales force in the United States. As of October 31, 2008, we had a 108-person direct sales force, including our Vice President of Sales, 15 associate sales managers, 72 district sales managers, 12 regional sales managers, four sales directors, a national training manager, a director of

customer operations, and two customer service specialists. Upon receiving 510(k) clearance from the FDA on August 30, 2007, we began limited commercialization of the Diamondback 360° in September 2007. We commenced our full commercial launch in the quarter ended March 31, 2008.

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While we sell directly to hospitals, we have targeted our initial sales and marketing efforts to thought-leading interventional cardiologists, vascular surgeons and interventional radiologists with experience using similar catheter-based procedures, such as angioplasty and cutting or laser atherectomy. Physician referral programs and peer-to-peer education are other key elements of our sales strategy. Patient referrals come from general practitioners, podiatrists, nephrologists and endocrinologists.

We target our marketing efforts to practitioners through physician education, medical conferences, seminars, peer reviewed journals and marketing materials. Our sales and marketing program focuses on:

- educating physicians regarding the proper use and application of the Diamondback 360°;
- developing relationships with key opinion leaders; and
- facilitating regional referral marketing programs.

We are not marketing our products internationally and we do not expect to do so in the near future; however, we will continue to evaluate international opportunities.

Research and Development

As of October 31, 2008, we had 32 employees in our research and development department, comprised primarily of scientists, engineers and physicians, all of whom report to our Executive Vice President. Our research and development efforts are focused in the development of products to penetrate our three key target markets: below-the-knee, above-the-knee and coronary vessels. Research and development expenses for fiscal 2006, fiscal 2007 and fiscal 2008 were $3.2 million, $8.4 million and $16.1 million, respectively, and for the three months ended September 30, 2007 and 2008 were $3.3 million and $5.0 million, respectively.

Manufacturing

We use internally-manufactured and externally-sourced components to manufacture the Diamondback 360°. Most of the externally-sourced components are available from multiple suppliers; however, a few key components, including the diamond grit coated crown, are single sourced. We assemble the shaft, crown and handle components on-site, and test, pack, seal and label the finished assembly before sending the packaged product to a contract sterilization facility. The sterilization facility sends samples to an independent laboratory to test for sterility. Upon return from the sterilizer, product is held in inventory prior to shipping to our customers.

The current floor plan at our manufacturing facility allows for finished goods of approximately 8,000 units of the Diamondback 360° and for approximately 50 control units. The manufacturing areas, including the shaft manufacturing and the controlled-environment assembly areas, are equipped to accommodate approximately 30,000 units per shift annually.

We are registered with the FDA as a medical device manufacturer. We have opted to maintain quality assurance and quality management certifications to enable us to market our products in the member states of the European Union, the European Free Trade Association and countries that have entered into Mutual Recognition Agreements with the European Union. We are ISO 13485:2003 certified, and our renewal is due by December 2009. During our time of commercialization, we have not had any instances requiring consideration of a recall.

Third-Party Reimbursement and Pricing

Third-party payors, including private insurers, and government insurance programs, such as Medicare and Medicaid, pay for a significant portion of patient care provided in the United States. The single largest payor in the United States is the Medicare program, a federal governmental health insurance program administered by the Centers for Medicare and Medicaid Services, or CMS. Medicare covers certain medical care expenses for eligible elderly and disabled individuals, including a large percentage of the population with PAD who could be treated with the Diamondback 360°. In addition, private insurers often follow the coverage and reimbursement policies of Medicare. Consequently, Medicare s coverage and reimbursement policies are important to our operations.

CMS has established Medicare reimbursement codes describing atherectomy products and procedures using atherectomy products, and many private insurers follow these policies. We believe that physicians and hospitals that treat PAD with the Diamondback 360° will generally be eligible to receive reimbursement from Medicare and private insurers for the cost of the single-use catheter and the physician s services.

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The continued availability of insurance coverage and reimbursement for newly approved medical devices is uncertain. The commercial success of our products in both domestic and international markets will be dependent on whether third-party coverage and reimbursement is available for patients that use our products and our monitoring services. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medical devices, and, as a result, they may not continue to provide adequate payment for our products. To position our device for acceptance by third-party payors, we may have to agree to a lower net sales price than we might otherwise charge. The continuing efforts of governmental and commercial third-party payors to contain or reduce the costs of healthcare may limit our revenue.

In some foreign markets, pricing and profitability of medical devices are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed healthcare in the United States and proposed legislation intended to reduce the cost of government insurance programs could significantly influence the purchase of healthcare services and products and may result in lower prices for our products or the exclusion of our products from reimbursement programs.

Competition

The medical device industry is highly competitive, subject to rapid change and significantly affected by new product introductions and other activities of industry participants. The Diamondback 360° competes with a variety of other products or devices for the treatment of vascular disease, including stents, balloon angioplasty catheters and atherectomy catheters, as well as products used in vascular surgery. Large competitors in the stent and balloon angioplasty market segments include Abbott Laboratories, Boston Scientific, Cook, Johnson & Johnson and Medtronic. We also compete against manufacturers of atherectomy catheters including, among others, ev3, Spectranetics, Boston Scientific and Pathway Medical Technologies, as well as other manufacturers that may enter the market due to the increasing demand for treatment of vascular disease. Several other companies provide products used by surgeons in peripheral bypass procedures. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of mild to moderate PAD and companies that provide products used by surgeons in peripheral bypass procedures. We are not aware of any competing catheter systems either currently on the market or in development that also use an orbital motion to create lumens larger than the catheter itself.

Because of the size of the peripheral and coronary market opportunities, competitors and potential competitors have historically dedicated significant resources to aggressively promote their products. We believe that the Diamondback 360° competes primarily on the basis of:

- safety and efficacy;
- predictable clinical performance;
- ease of use;
- price;
- physician relationships;
- customer service and support; and
- adequate third-party reimbursement.

Patents and Intellectual Property

We rely on a combination of patent, copyright and other intellectual property laws, trade secrets, nondisclosure agreements and other measures to protect our proprietary rights. As of October 31, 2008, we held 20 issued U.S. patents and have 24 U.S. patent applications pending, as well as 33 issued or granted foreign patents and 20 foreign patent applications, each of which corresponds to aspects of our U.S. patents and applications. Our issued U.S. patents expire between 2010 and 2022, and our most important patent, U.S. Patent No. 6,494,890, is due to expire in 2017.

Our issued patents and patent applications relate primarily to the design and operation of certain interventional atherectomy devices, including the Diamondback 360°. These patents and applications include claims covering key aspects of certain rotational atherectomy devices including the design, manufacture and therapeutic use of certain atherectomy abrasive heads, drive shafts, control systems, handles and couplings. As we continue to research and develop our atherectomy technology, we intend to file additional U.S. and foreign patent applications related to the design, manufacture and therapeutic uses of atherectomy devices. In addition, we hold two registered U.S. trademarks and have three U.S. trademark applications pending.

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We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. We seek to protect our proprietary information and other intellectual property by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from bringing the proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials.

Government Regulation of Medical Devices

Governmental authorities in the United States at the federal, state and local levels and in other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, marketing and export and import of medical devices such as the Diamondback 360°. Failure to obtain approval to market our products under development and to meet the ongoing requirements of these regulatory authorities could prevent us from marketing and continuing to market our products.

United States

The Federal Food, Drug, and Cosmetic Act, or FDCA, and the FDA s implementing regulations govern medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Medical devices and their manufacturers are also subject to inspection by the FDA. The FDCA, supplemented by other federal and state laws, also provides civil and criminal penalties for violations of its provisions. We manufacture and market medical devices that are regulated by the FDA, comparable state agencies and regulatory bodies in other countries.

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require marketing authorization from the FDA prior to distribution. The two primary types of FDA marketing authorization are premarket notification (also called 510(k) clearance) and premarket approval (also called PMA approval). The type of marketing authorization applicable to a device 510(k) clearance or PMA approval is generally linked to classification of the device. The FDA classifies medical devices into one of three classes (Class I, II or III) based on the degree of risk FDA determines to be associated with a device and the extent of control deemed necessary to ensure the device s safety and effectiveness. Devices requiring fewer controls because they are deemed to pose lower risk are placed in Class I or II. Class I devices are deemed to pose the least risk and are subject only to general controls applicable to all devices, such as requirements for device labeling, premarket notification, and adherence to the FDA s current good manufacturing practice requirements, as reflected in its Quality System Regulation, or QSR. Class II devices are intermediate risk devices that are subject to general controls and may also be subject to special controls such as performance standards, product-specific guidance documents, special labeling requirements, patient registries or postmarket surveillance. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls, and include life-sustaining, life-supporting or implantable devices, and devices not substantially equivalent to a device that is already legally marketed.

Most Class I devices and some Class II devices are exempted by regulation from the 510(k) clearance requirement and can be marketed without prior authorization from FDA. Class I and Class II devices that have not been so exempted are eligible for marketing through the 510(k) clearance pathway. By contrast, devices placed in Class III generally require PMA approval prior to commercial marketing. The PMA approval process is generally more stringent, time-consuming and expensive than the 510(k) clearance process.

510(k) Clearance. To obtain 510(k) clearance for a medical device, an applicant must submit a premarket notification to the FDA demonstrating that the device is substantially equivalent to a predicate device legally marketed in the United States. A device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and the information submitted demonstrates that the device is as safe and effective as a legally marketed device and does not raise different questions of safety or effectiveness. A showing of substantial equivalence sometimes, but not always, requires clinical data. Generally, the 510(k) clearance process can exceed 90 days and may extend to a year or more.

After a device has received 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, such as a significant change in the design, materials, method of manufacture or intended use, will require a new 510(k) clearance or PMA approval (if the device as modified is not substantially equivalent to a legally marketed predicate device). The determination as to whether new authorization is needed is initially left to the manufacturer; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is

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obtained. The manufacturer may also be subject to significant regulatory fines or penalties.

We received 510(k) clearance for use of the Diamondback 360° as a therapy in patients with PAD in the United States on August 22, 2007. We received additional 510(k) clearances for the control unit used with the Diamondback 360° on October 25, 2007 and for the solid crown version of the Diamondback 360° on November 9, 2007.

Premarket Approval. A PMA application requires the payment of significant user fees and must be supported by valid scientific evidence, which typically requires extensive data, including technical, preclinical, clinical and manufacturing data, to demonstrate to the FDA s satisfaction the safety and efficacy of the device. A PMA application must also include a complete description of the device and its components, a detailed description of the methods, facilities and controls used to manufacture the device, and proposed labeling. After a PMA application is submitted and found to be sufficiently complete, the FDA begins an in-depth review of the submitted information. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, 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. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the FDA s Quality System Regulations, or QSR, which requires manufacturers to follow design, testing, control, documentation and other quality assurance procedures.

FDA review of a PMA application is required by statute to take no longer than 180 days, although the process typically takes significantly longer, and may require several years to complete. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

the systems may not be safe or effective to the FDA s satisfaction;

the data from preclinical studies and clinical trials may be insufficient to support approval;

the manufacturing process or facilities used may not meet applicable requirements; and

changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device for certain indications. If the FDA s evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Even if a PMA application is approved, the FDA may approve the device with an indication that is narrower or more limited than originally sought. The agency can also impose restrictions on the sale, distribution or use of the device as a condition of approval, or impose post approval requirements such as continuing evaluation and periodic reporting on the safety, efficacy and reliability of the device for its intended use.

New PMA applications or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process. PMA approval supplements often require submission of the same type of information as an initial 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.

We plan to seek PMA to use the Diamondback 360° as a therapy in treating patients with coronary artery disease.

Clinical Trials. Clinical trials are almost always required to support a PMA application and are sometimes required for a 510(k) clearance. These trials generally require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant

risk device and eligible for more abbreviated IDE requirements. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate institutional review boards at the clinical trial sites.

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FDA approval of an IDE allows clinical testing to go forward but does not bind the FDA to accept the results of the trial as sufficient to prove the product s safety and efficacy, even if the trial meets its intended success criteria. With certain exceptions, changes made to an investigational plan after an IDE is approved must be submitted in an IDE supplement and approved by FDA (and by governing institutional review boards when appropriate) prior to implementation.

All clinical trials must be conducted in accordance with regulations and requirements collectively known as good clinical practice. Good clinical practices include the FDA s IDE regulations, which describe the conduct of clinical trials with medical devices, including the recordkeeping, reporting and monitoring responsibilities of sponsors and investigators, and labeling of investigation devices. They also prohibit promotion, test marketing or commercialization of an investigational device and any representation that such a device is safe or effective for the purposes being investigated. Good clinical practices also include the FDA s regulations for institutional review board approval and for protection of human subjects (such as informed consent), as well as disclosure of financial interests by clinical investigators.

Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant approval or clearance of a product. The commencement or completion of any clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a premarket notification for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial (or a change to a previously approved protocol or trial that requires approval), or place a clinical trial on hold;
- patients do not enroll in clinical trials or follow up at the rate expected;
- patients do not comply with trial protocols or experience greater than expected adverse side effects;
- institutional review boards and third-party clinical investigators may delay or reject the trial protocol or changes to the trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on the anticipated schedule or consistent with the clinical trial protocol, investigator agreements, good clinical practices or other FDA requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of the clinical trials or manufacturing facilities, which may, among other things, require corrective action or suspension or termination of the clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that the trial design is inadequate to demonstrate safety and efficacy.

Continuing Regulation. After a device is approved and placed in commercial distribution, numerous regulatory requirements continue to apply. These include:

- establishment registration and device listing upon the commencement of manufacturing;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow design, testing, control, documentation and other quality assurance procedure during medical device design and manufacturing processes;

labeling regulations, which prohibit the promotion of products for unapproved or off-label uses and impose other restrictions on labeling and promotional activities;

medical device reporting regulations, which require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if malfunctions were to recur;

corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections; and

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product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health.

In addition, the FDA may require a company to conduct postmarket surveillance studies or order it to establish and maintain a system for tracking its products through the chain of distribution to the patient level.

Failure to comply with applicable regulatory requirements, including those applicable to the conduct of clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

warning letters or untitled letters;

fines, injunctions and civil penalties;

product recall or seizure;

unanticipated expenditures;

delays in clearing or approving or refusal to clear or approve products;

withdrawal or suspension of FDA approval;

orders for physician notification or device repair, replacement or refund;

operating restrictions, partial suspension or total shutdown of production or clinical trials; and

criminal prosecution.

We and our contract manufacturers, specification developers and suppliers are also required to manufacture our products in compliance with current Good Manufacturing Practice, or GMP, requirements set forth in the QSR. The QSR requires a quality system for the design, manufacture, packaging, labeling, storage, installation and servicing of marketed devices, and includes extensive requirements with respect to quality management and organization, device design, buildings, equipment, purchase and handling of components, production and process controls, packaging and labeling controls, device evaluation, distribution, installation, complaint handling, servicing and record keeping. The FDA enforces the QSR through periodic announced and unannounced inspections that may include the manufacturing facilities of subcontractors. If the FDA believes that we or any of our contract manufacturers or regulated suppliers is not in compliance with these requirements, it can shut down our manufacturing operations, require recall of our products, refuse to clear or approve new marketing applications, institute legal proceedings to detain or seize products, enjoin future violations or assess civil and criminal penalties against us or our officers or other employees. Any such action by the FDA would have a material adverse effect on our business.

Fraud and Abuse

Our operations will be directly, or indirectly through our customers, subject to various state and federal fraud and abuse laws, including, without limitation, the FDCA, federal Anti-Kickback Statute and False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, these laws require us to screen individuals and other companies, suppliers and vendors in order to ensure that they are not debarred by the federal government and therefore prohibited from doing business in the healthcare industry.

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program such as the Medicare and Medicaid programs. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services

reimbursed by any source, not only the Medicare and Medicaid programs.

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The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false claim to, or the knowing use of false statements to obtain payment from, the federal government. Various states have also enacted laws modeled after the federal False Claims Act.

In addition to the laws described above, the Health Insurance Portability and Accountability Act of 1996 created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Voluntary industry codes, federal guidance documents and a variety of state laws address the tracking and reporting of marketing practices relative to gifts given and other expenditures made to doctors and other healthcare professionals. In addition to impacting our marketing and educational programs, internal business processes will be affected by the numerous legal requirements and regulatory guidance at the state, federal and industry levels.

International Regulation

International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country. The time required to obtain approval in a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ. For example, the primary regulatory environment in Europe with respect to medical devices is that of the European Union, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout European Union, although actual implementation of the these directives may vary on a country-by-country basis. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of submission of a design dossier, self-assessment by the manufacturer, a third-party assessment and, review of the design dossier by a Notified Body. This third-party assessment generally consists of an audit of the manufacturer s quality system and manufacturing site, as well as review of the technical documentation used to support application of the CE mark to one s product and possibly specific testing of the manufacturer s product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. We obtained CE marking approval for sale of the Diamondback 360° in May 2005.

Employees

As of October 31, 2008, we had 224 employees, including 50 employees in manufacturing, 108 employees in sales, 11 employees in marketing, five employees in clinicals, 18 employees in general and administrative, and 32 employees in research and development. None of our employees are represented by a labor union or parties to a collective bargaining agreement, and we believe that our employee relations are good.

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ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below and all other information in this Form 10 before making an investment decision. The risks described below are not the only ones facing our company.

Our business, financial condition and results of operations could be materially adversely affected by any of these risks. The trading price of our common stock could decline due to any of these risks, and you may lose all or part of your investment. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Relating to Our Business and Operations

Negative conditions in the global credit markets have impaired the liquidity of our auction rate securities, and these securities have experienced an other-than-temporary decline in value, which has adversely affected our income. These circumstances, along with our history of incurring substantial operating losses and negative cash flows from operations, raise substantial doubt about our ability to continue as a going concern.

As of September 30, 2008, our investments included $23.0 million of AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program. These auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals, primarily every 28 days, through auctions. The recent conditions in the global credit markets have prevented us from liquidating our holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. In February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $23.0 million in auction rate securities held at June 30, 2008 and September 30, 2008. Currently, these affected securities are not liquid and will not become liquid until a future auction for these investments is successful or they are redeemed by the issuer or they mature. In the event that we need to access the funds of our auction rate securities that have experienced insufficient demand at auctions, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them to maturity and we may have insufficient funds to operate our business. For the year ended June 30, 2008, we recorded an other-than-temporary impairment loss of $1.3 million relating to these securities in our statement of operations, and for the three months ended September 30, 2008, we recorded an unrealized loss of $0.3 million relating to these securities in other comprehensive income (loss). We will continue to monitor and evaluate the value of our investments each reporting period for further possible impairment or unrealized loss. Although we currently do not intend to do so, we may consider selling our auction rate securities in the secondary markets in the future, which may require a sale at a substantial discount to the stated principal value of these securities.

In addition, because we have incurred substantial operating losses and negative cash flows from operations, all of which will require us to obtain additional funding to continue our operations, management has concluded that there is substantial doubt about our ability to continue as a going concern. Based on the factors described above, our independent registered public accountants have included an explanatory paragraph in their report for our fiscal year ended June 30, 2008 with respect to our ability to continue as a going concern. On March 28, 2008, we obtained a margin loan from UBS Financial Services, Inc., the entity through which we originally purchased our auction rate securities, for up to $12.0 million, which was secured by the $23.0 million par value of our auction rate securities. On August 21, 2008, we replaced this loan with a margin loan from UBS Bank USA, which increased maximum borrowings available to $23.0 million, and on September 12, 2008, we obtained additional debt financing from Silicon Valley Bank with maximum available borrowings of $13.5 million. Based on anticipated operating requirements, combined with limited capital resources, financing our operations will require that we raise additional equity or debt capital prior to or during the quarter ending September 30, 2009. We have entered into the merger agreement with Replidyne to obtain the working capital necessary to execute our business plan. If the merger is not completed or we fail to raise sufficient equity or debt capital through other means, management would implement cost reduction measures, including workforce reductions, as well as reductions in overhead costs and capital expenditures. There can be no assurance that these sources will provide sufficient cash flows to enable us to continue as a going concern. We

currently have no commitments for additional debt or equity financing and may experience difficulty in obtaining additional financing on favorable terms, if at all, if the merger is not consummated.

The existence of the explanatory paragraph may adversely affect our relationships with current and prospective customers, suppliers and investors, and therefore could have a material adverse effect on our business, financial condition, results of operations and cash flows.

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We have a history of net losses and anticipate that we will continue to incur losses.

We are not profitable and have incurred net losses in each fiscal year since our formation in 1989. In particular, we had net losses of $3.5 million in fiscal 2005, $4.9 million in fiscal 2006, $15.6 million in fiscal 2007, and $39.2 million in fiscal 2008, and $13.7 million for the three months ended September 30, 2008. As of September 30, 2008, we had an accumulated deficit of approximately $132.0 million. We only commenced commercial sales of the Diamondback 360° Orbital Atherectomy System in September 2007, and our short commercialization experience makes it difficult for us to predict future performance. We also expect to incur significant additional expenses for sales and marketing and manufacturing as we continue to commercialize the Diamondback 360° and additional expenses as we seek to develop and commercialize future versions of the Diamondback 360° and other products. Additionally, we expect that our general and administrative expenses will increase as our business grows and we incur the legal and regulatory costs associated with being a public company. As a result, we expect to continue to incur significant operating losses.

We have a very limited history selling the Diamondback 360°, which is currently our only product, and our inability to market this product successfully would have a material adverse effect on our business and financial condition.

The Diamondback 360° is our only product, and we are wholly dependent on it. The Diamondback 360° received 510(k) clearance from the FDA in the United States for use as a therapy in patients with PAD in August 2007. We initiated a limited commercial introduction of the Diamondback 360° in the United States in September 2007 and we therefore have very limited experience in the commercial manufacture and marketing of this product. Our ability to generate revenue will depend upon our ability to successfully commercialize the Diamondback 360° and to develop, manufacture and receive required regulatory clearances and approvals and patient reimbursement for treatment with future versions of the Diamondback 360°. As we seek to commercialize the Diamondback 360°, we will need to expand our sales force significantly to reach our target market. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. Thus, we may not be able to expand our sales and marketing capabilities on a timely basis or at all. If we are unable to adequately increase these capabilities, we will need to contract with third parties to market and sell the Diamondback 360° and any other products that we may develop. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services on our behalf, our product revenues could be lower than if we marketed and sold our products on a direct basis. Furthermore, any revenues resulting from co-promotion or other marketing and sales arrangements with other companies will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. Some of these companies may have current products or products under development that compete with ours, and they may have an incentive not to devote sufficient efforts to marketing our products. If we fail to successfully develop, commercialize and market the Diamondback 360° or any future versions of this product that we develop, our business will be materially adversely affected.

The Diamondback 360° and future products may never achieve market acceptance.

The Diamondback 360° and future products we may develop may never gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of our products will depend on a number of factors, including:

- the actual and perceived effectiveness and reliability of our products;
- the prevalence and severity of any adverse patient events involving our products, including infection, perforation or dissection of the artery wall, internal bleeding, limb loss and death;
- the results of any long-term clinical trials relating to use of our products;
- the availability, relative cost and perceived advantages and disadvantages of alternative technologies or treatment methods for conditions treated by our systems;

the degree to which treatments using our products are approved for reimbursement by public and private insurers;

the strength of our marketing and distribution infrastructure; and

the level of education and awareness among physicians and hospitals concerning our products.

Failure of the Diamondback 360° to significantly penetrate current or new markets would negatively impact our business, financial condition and results of operations.

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If longer-term or more extensive clinical trials performed by us or others indicate that procedures using the Diamondback 360° or any future products are not safe, effective and long lasting, physicians may choose not to use our products. Furthermore, unsatisfactory patient outcomes or injuries could cause negative publicity for our products. Physicians may be slow to adopt our products if they perceive liability risks arising from the use of these products. It is also possible that as our products become more widely used, latent defects could be identified, creating negative publicity and liability problems for us, thereby adversely affecting demand for our products. If the Diamondback 360° and our future products do not achieve an adequate level of acceptance by physicians, patients and the medical community, our overall business and profitability would be harmed.

Our future growth depends on physician adoption of the Diamondback 360°, which requires physicians to change their screening and referral practices.

We believe that we must educate physicians to change their screening and referral practices. For example, although there is a significant correlation between PAD and coronary artery disease, many physicians do not routinely screen for PAD while screening for coronary artery disease. We target our sales efforts to interventional cardiologists, vascular surgeons and interventional radiologists because they are often the primary care physicians diagnosing and treating both coronary artery disease and PAD. However, the initial point of contact for many patients may be general practitioners, podiatrists, nephrologists and endocrinologists, each of whom commonly treats patients experiencing complications resulting from PAD. If we do not educate referring physicians about PAD in general and the existence of the Diamondback 360° in particular, they may not refer patients to interventional cardiologists, vascular surgeons or interventional radiologists for the procedure using the Diamondback 360°, and those patients may instead be surgically treated or treated with an alternative interventional procedure. If we are not successful in educating physicians about screening for PAD or referral opportunities, our ability to increase our revenue may be impaired.

Our customers may not be able to achieve adequate reimbursement for using the Diamondback 360°, which could affect the acceptance of our product and cause our business to suffer.

The availability of insurance coverage and reimbursement for newly approved medical devices and procedures is uncertain. The commercial success of our products is substantially dependent on whether third-party insurance coverage and reimbursement for the use of such products and related services are available. We expect the Diamondback 360° to generally be purchased by hospitals and other providers who will then seek reimbursement from various public and private third-party payors, such as Medicare, Medicaid and private insurers, for the services provided to patients. We can give no assurance that these third-party payors will provide adequate reimbursement for use of the Diamondback 360° to permit hospitals and doctors to consider the product cost-effective for patients requiring PAD treatment. In addition, the overall amount of reimbursement available for PAD treatment could decrease in the future. Failure by hospitals and other users of our product to obtain sufficient reimbursement could cause our business to suffer.

Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement, and, as a result, they may not cover or provide adequate payment for use of the Diamondback 360°. In order to position the Diamondback 360° for acceptance by third-party payors, we may have to agree to lower prices than we might otherwise charge. The continuing efforts of governmental and commercial third-party payors to contain or reduce the costs of healthcare may limit our revenue.

We expect that there will continue to be federal and state proposals for governmental controls over healthcare in the United States. Governmental and private sector payors have instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. Also, the trend toward managed healthcare in the United States and proposed legislation intended to reduce the cost of government insurance programs could significantly influence the purchase of healthcare services and products and may result in necessary price reductions for our products or the exclusion of our products from reimbursement programs. It is uncertain whether the Diamondback 360° or any future products we may develop will be viewed as sufficiently cost-effective to warrant adequate coverage and reimbursement levels.

If third-party coverage and reimbursement for the Diamondback 360° is limited or not available, the acceptance of the Diamondback 360° and, consequently, our business will be substantially harmed.

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We have limited data and experience regarding the safety and efficacy of the Diamondback 360°. Any long-term data that is generated may not be positive or consistent with our limited short-term data, which would affect market acceptance of this product.

Our success depends on the acceptance of the Diamondback 360° by the medical community as safe and effective. Because our technology is relatively new in the treatment of PAD, we have performed clinical trials only with limited patient populations. The long-term effects of using the Diamondback 360° in a large number of patients are not known and the results of short-term clinical use of the Diamondback 360° do not necessarily predict long-term clinical benefit or reveal long-term adverse effects. For example, we do not have sufficient experience with the Diamondback 360° to evaluate its relative effectiveness in different plaque morphologies, including hard, calcified lesions and soft, non-calcified lesions. If the results obtained from any future clinical trials or clinical or commercial experience indicate that the Diamondback 360° is not as safe or effective as other treatment options or as current short-term data would suggest, adoption of this product may suffer and our business would be harmed. Even if we believe that the data collected from clinical trials or clinical experience indicate positive results, each physician s actual experience with our device will vary. Clinical trials conducted with the Diamondback 360° have involved procedures performed by physicians who are very technically proficient. Consequently, both short and long-term results reported in these studies may be significantly more favorable than typical results achieved by physicians, which could negatively impact market acceptance of the Diamondback 360°.

We will face significant competition and may be unable to sell the Diamondback 360° at profitable levels.

We compete against very large and well-known stent and balloon angioplasty device manufacturers, including Abbott Laboratories, Boston Scientific, Cook, Johnson & Johnson and Medtronic. We may have difficulty competing effectively with these competitors because of their well-established positions in the marketplace, significant financial and human capital resources, established reputations and worldwide distribution channels. We also compete against manufacturers of atherectomy catheters including, among others, ev3, Spectranetics, Boston Scientific and Pathway Medical Technologies, as well as other manufacturers that may enter the market due to the increasing demand for treatment of vascular disease. Several other companies provide products used by surgeons in peripheral bypass procedures. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of mild to moderate PAD and companies that provide products used by surgeons in peripheral bypass procedures.

Our competitors may:

- develop and patent processes or products earlier than we will;
- obtain regulatory clearances or approvals for competing medical device products more rapidly than we will;
- market their products more effectively than we will; or
- develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive.

We have encountered and expect to continue to encounter potential customers who, due to existing relationships with our competitors, are committed to or prefer the products offered by these competitors. If we are unable to compete successfully, our revenue will suffer. Increased competition might lead to price reductions and other concessions that might adversely affect our operating results. Competitive pressures may decrease the demand for our products and could adversely affect our financial results.

Our ability to compete depends on our ability to innovate successfully. If our competitors demonstrate the increased safety or efficacy of their products as compared to ours, our revenue may decline.

The market for medical devices is highly competitive, dynamic and marked by rapid and substantial technological development and product innovations. Our ability to compete depends on our ability to innovate successfully, and there are few barriers that would prevent new entrants or existing competitors from developing products that compete directly with our products. Demand for the Diamondback 360° could be diminished by equivalent or superior products and technologies offered by competitors. Our competitors may produce more advanced products than ours or demonstrate superior safety and efficacy of their products. If we are unable to innovate successfully, the Diamondback

360° could become obsolete and our revenue would decline as our customers purchase competitor products.

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We have limited commercial manufacturing experience and could experience difficulty in producing the Diamondback 360° or will need to depend on third parties to manufacture the product.

We have limited experience in commercially manufacturing the Diamondback 360° and have no experience manufacturing this product in the volume that we anticipate will be required if we achieve planned levels of commercial sales. As a result, we may not be able to develop and implement efficient, low-cost manufacturing capabilities and processes that will enable us to manufacture the Diamondback 360° or future products in significant volumes, while meeting the legal, regulatory, quality, price, durability, engineering, design and production standards required to market our products successfully. If we fail to develop and implement these manufacturing capabilities and processes, we may be unable to profitably commercialize the Diamondback 360° and any future products we may develop because the per unit cost of our products is highly dependent upon production volumes and the level of automation in our manufacturing processes. There are technical challenges to increasing manufacturing capacity, including equipment design and automation capabilities, material procurement, problems with production yields and quality control and assurance. Increasing our manufacturing capacity will require us to invest substantial additional funds and to hire and retain additional management and technical personnel who have the necessary manufacturing experience. We may not successfully complete any required increase in manufacturing capacity in a timely manner or at all. If we are unable to manufacture a sufficient supply of our products, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand and our business will suffer.

Since we have little actual commercial experience with the Diamondback 360°, the forecasts of demand we use to determine order quantities and lead times for components purchased from outside suppliers may be incorrect. Lead times for components may vary significantly depending on the type of component, the size of the order, time required to fabricate and test the components, specific supplier requirements and current market demand for the components and subassemblies. Failure to obtain required components or subassemblies when needed and at a reasonable cost would adversely affect our business.

In addition, we may in the future need to depend upon third parties to manufacture the Diamondback 360° and future products. We also cannot assure you that any third-party contract manufacturers will have the ability to produce the quantities of our products needed for development or commercial sales or will be willing to do so at prices that allow the products to compete successfully in the market. In addition, we can give no assurance that even if we do contract with third-party manufacturers for production that these manufacturers will not experience manufacturing difficulties or experience quality or regulatory issues. Any difficulties in locating and hiring third-party manufacturers, or in the ability of third-party manufacturers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business.

We depend upon third-party suppliers, including single source suppliers to us and our customers, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers to provide us certain components of our products and to provide key components or supplies to our customers for use with our products. We rely on single source suppliers for the following components of the Diamondback 360°: diamond grit coated crowns, ABS molded products, components within the brake assembly and the turbine assembly, and the air-and-saline cable assembly. We purchase components from these suppliers on a purchase order basis and carry only very limited levels of inventory for these components. If we underestimate our requirements, we may not have an adequate supply, which could interrupt manufacturing of our products and result in delays in shipments and loss of revenue. Our customers depend on a single source supplier for the catheter lubricant used with our Diamondback 360° system. If our customers are unable to obtain adequate supplies of this lubricant, our customers may reduce or cease purchases of our product. We depend on these suppliers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers may encounter problems during manufacturing for a variety of reasons, including unanticipated demand from larger customers, failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction, quality or yield problems, and environmental factors, any of which could delay or impede their ability to meet our demand and our customers demand. Our reliance on these outside suppliers also subjects us to other risks that could harm our business, including:

interruption of supply resulting from modifications to, or discontinuation of, a supplier s operations;

delays in product shipments resulting from defects, reliability issues or changes in components from suppliers;

price fluctuations due to a lack of long-term supply arrangements for key components with our suppliers;

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- our suppliers may make errors in manufacturing components, which could negatively affect the efficacy or safety of our products or cause delays in shipment of our products;
- our suppliers may discontinue production of components, which could significantly delay our production and sales and impair operating margins;
- we and our customers may not be able to obtain adequate supplies in a timely manner or on commercially acceptable terms;
- we and our customers may have difficulty locating and qualifying alternative suppliers for our and their sole-source supplies;
- switching components may require product redesign and new regulatory submissions, either of which could significantly delay production and sales;
- we may experience production delays related to the evaluation and testing of products from alternative suppliers and corresponding regulatory qualifications;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us or our customers in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our or our customers demand for components or other products, which could inhibit their ability to fulfill orders and meet requirements.

Other than existing, unfulfilled purchase orders, our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of our supplies. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations. We have no reason to believe that any of our current suppliers could not be replaced if they were unable to deliver components to us in a timely manner or at an acceptable price and level of quality. However, if we lost one of these suppliers and were unable to obtain an alternate source on a timely basis or on terms acceptable to us, our production schedules could be delayed, our margins could be negatively impacted, and we could fail to meet our customers demand. Our customers rely upon our ability to meet committed delivery dates and any disruption in the supply of key components would adversely affect our ability to meet these dates and could result in legal action by our customers, cause us to lose customers or harm our ability to attract new customers, any of which could decrease our revenue and negatively impact our growth. In addition, to the extent that our suppliers use technology or manufacturing processes that are proprietary, we may be unable to obtain comparable materials or components from alternative sources.

Manufacturing operations are often faced with a supplier s decision to discontinue manufacturing a component, which may force us or our customers to make last time purchases, qualify a substitute part, or make a design change which may divert engineering time away from the development of new products.

We will need to increase the size of our organization and we may experience difficulties managing growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.

The growth we may experience in the future will provide challenges to our organization, requiring us to rapidly expand our sales and marketing personnel and manufacturing operations. Our sales and marketing force has increased from six employees on January 1, 2007 to 119 employees on October 31, 2008, and we expect to continue to grow our sales and marketing force. We also expect to significantly expand our manufacturing operations to meet anticipated growth in demand for our products. Rapid expansion in personnel means that less experienced people may be

producing and selling our product, which could result in unanticipated costs and disruptions to our operations. If we cannot scale and manage our business appropriately, our anticipated growth may be impaired and our financial results will suffer.

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We anticipate future losses and will require additional financing, and our failure to obtain additional financing when needed could force us to delay, reduce or eliminate our product development programs or commercialization efforts.

We anticipate significant future losses and are therefore dependent on additional financing to execute our business plan. We expect that the merger with Replidyne will provide additional working capital for our business operations that, together with funds available under our debt financing arrangements and from operations, will be sufficient to satisfy our working capital needs for the foreseeable future. If, however, the merger is not completed or delays in our business plan reduce the amount of cash available from operations, we will require additional financing in order to satisfy our capital requirements. In particular, we may require additional capital in order to continue to conduct the research and development and obtain regulatory clearances and approvals necessary to bring any future products to market and to establish effective marketing and sales capabilities for existing and future products. Our operating plan may change, and we may need additional funds sooner than anticipated to meet our operational needs and capital requirements for product development, clinical trials and commercialization. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available on a timely basis, we may terminate or delay the development of one or more of our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products.

Our future capital requirements will depend on many factors, including:

whether the merger with Replidyne is completed and, if so, Replidyne s level of net assets at the effective time of the merger;

the costs of expanding our sales and marketing infrastructure and our manufacturing operations;

the degree of success we experience in commercializing the Diamondback 360°;

the number and types of future products we develop and commercialize;

the costs, timing and outcomes of regulatory reviews associated with our future product candidates;

the costs of preparing, filing and prosecuting patent applications and maintaining, enforcing and defending intellectual property-related claims; and

the extent and scope of our general and administrative expenses.

Raising additional capital may cause dilution to our shareholders or restrict our operations.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures or declaring dividends. Any of these events could adversely affect our ability to achieve our product development and commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

We do not currently intend to market the Diamondback 360° internationally, which will limit our potential revenue from this product.

As a part of our product development and regulatory strategy, we do not currently intend to market the Diamondback 360° internationally in order to focus our resources and efforts on the U.S. market, as international efforts would require substantial additional sales and marketing, regulatory and personnel expenses. Our decision to market this product only in the United States will limit our ability to reach all of our potential markets and will limit our potential sources of revenue. In addition, our competitors will have an opportunity to further penetrate and achieve market share abroad until such time, if ever, that we market the Diamondback 360° or other products internationally.

We are dependent on our senior management team and scientific personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success.

We are highly dependent on our senior management, especially David L. Martin, our President and Chief Executive Officer. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel and to integrate current and additional personnel in all departments. Competition for senior management personnel, as well as scientists, clinical and regulatory specialists, engineers and sales personnel, is intense and we may not be able to retain our personnel. The loss of members of our senior management, scientists, clinical and regulatory specialists, engineers and sales personnel could prevent us from achieving our objectives of continuing to grow our company. The loss of a member of our senior management or our professional staff would require the remaining senior executive officers to divert immediate and substantial attention to seeking a replacement. In particular, we expect to substantially increase the size of our sales force,

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which will require management s attention. In that regard, ev3 Inc., ev3 Endovascular, Inc., and FoxHollow Technologies, Inc. have brought an action against us that, if successful, could limit our ability to retain the services of certain sales personnel that were formerly employed by those companies and make it more difficult to recruit and hire such sales and other personnel in the future. We do not carry key person life insurance on any of our employees, other than Michael J. Kallok, our Chief Scientific Officer and former Chief Executive Officer.

We have a new management team and may experience instability in the short term as a result.

Since July 2006, we have added six new executives to our management team, including our Chief Executive Officer, who joined us in February 2007, and our Chief Financial Officer, who joined us in April 2008. During the preparation for our initial public offering, which was abandoned due to unfavorable market conditions in order to proceed with the merger with Replidyne, our board of directors determined that it would be in our best interests to replace James Flaherty in his role as Chief Financial Officer due to his consent to a court order enjoining him from any violation of certain provisions of federal securities law in connection with events that occurred while he was the Chief Financial Officer of Zomax Incorporated. The board of directors desired to retain Mr. Flaherty as a member of our executive team, and, accordingly, Mr. Flaherty became our Chief Administrative Officer, giving him responsibility over non-financial operations matters, and Mr. Martin became Interim Chief Financial Officer until the hiring of Laurence L. Betterley as our Chief Financial Officer. Our new executives lack long-term experience with us. We may experience instability in the short term as our new executives become integrated into our company. Competition for qualified employees is intense and the loss of service of any of our executive officers or certain key employees could delay or curtail our research, development, commercialization and financial objectives.

We may incur significant costs due to the application of Section 409A of the Internal Revenue Code.

The estimated fair value of the common stock underlying our stock options was originally estimated in good faith by our board of directors based upon the best information available regarding us on the dates of grant, including financing activity, development of our business, the FDA process and launch of our product, the initial public offering process and our financial results. During the fiscal years ended June 30, 2007 and June 30, 2008, we did not obtain valuations from an independent valuation firm contemporaneously with each option grant date. As further discussed under Management s Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies and Significant Judgments and Estimates, we hired an independent valuation firm to determine the estimated fair value of our common stock for financial reporting purposes as of various dates, including June 29, 2007, September 30, 2007, December 31, 2007, March 31, 2008 and June 30, 2008. Our board considered these estimates when estimating the fair market value of our common stock on each option grant date that followed the board s receipt of an estimate from the valuation firm, but certain grants were later deemed to have been made at less than fair market value when such valuation estimates were retrospectively applied. With respect to options granted from June 12, 2007 through February 14, 2008, the estimated fair value of the common stock determined by the independent valuation firm was higher than the exercise price of stock options we had previously granted at or near such dates by a weighted average per share amount of approximately $0.79.

If the Internal Revenue Service were to determine that the fair market value of our common stock was higher than the exercise price of any of our stock options as of the grant date of such options, either in accordance with our financial reporting valuations or under a different methodology, and if we take no remedial action, then we and our optionholders may experience adverse tax consequences under Section 409A of the Internal Revenue Code and related provisions, including the imposition of future tax liabilities and penalties based on the spread between the fair market value and the exercise price at the time of option vesting and on future increases (if any) in the value of the stock of us or the combined company after the vesting date. These liabilities may be significant.

The imposition of such liabilities may affect a significant portion of our employees and could adversely affect employee morale and our business operations. As a result, we may take remedial action to address this risk. Such action may include an offer to amend or replace affected options or other possibilities. We cannot predict whether it will take such remedial actions, the costs of the remedial actions if we do take them or the costs to satisfy any associated liabilities.

Becoming a public company will cause us to incur increased costs and demands on our management.

As a public reporting company, we will need to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations adopted by the SEC, including expanded disclosures, accelerated reporting requirements, more complex accounting rules and internal control requirements. These obligations will require significant additional expenditures, place additional demands on our management and divert management s time and attention away from our core business. These additional obligations will also require us to hire additional personnel. For example, we are evaluating our internal controls systems in order to allow us to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act. We cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that will be applicable to us as a public company. If we fail to staff our accounting and finance function adequately or maintain internal controls adequate to meet the demands that will be placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act, we may be unable to report our financial results accurately or in a timely manner and our business and stock price may suffer. The costs of being a public company, as well as diversion of management s time and attention, may have a material adverse effect on our business, financial condition and results of operations.

Additionally, these laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We may be subject to damages or other remedies as a result of pending litigation.

On December 28, 2007, ev3 Inc., ev3 Endovascular, Inc. and FoxHollow Technologies, Inc. filed a complaint against us and certain of our employees alleging, among other things, misappropriation and use of their confidential information by us and certain of our employees who were formerly employees of FoxHollow. The complaint also alleges that certain of our employees violated their employment agreements with FoxHollow requiring them to refrain from soliciting FoxHollow employees. This litigation is in an early stage and there can be no assurance as to its outcome. We are defending this litigation vigorously. If we are not successful in defending it, we could be required to pay substantial damages and be subject to equitable relief that could include a requirement that we terminate the employment of certain employees, including certain key sales personnel who were formerly employed by FoxHollow. In any event, the defense of this litigation, regardless of the outcome, could result in substantial legal costs and diversion of our management s time and efforts from the operation of our business. If the plaintiffs in this litigation are successful, it could have a material adverse effect on our business, operations and financial condition.

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In addition, we are currently involved in a dispute with our founder, Dr. Leonid Shturman. Although we settled certain claims we had against Dr. Shturman in September 2008, Dr. Shturman raised counterclaims with regard to two shaft winding machines that we imported from Russia, which have not been resolved. Dr. Shturman is seeking monetary damages, which he believes to be in excess of $1.0 million. In an attempted settlement of these counterclaims, the parties entered into a settlement conditioned upon our agreement to pay Dr. Shturman $50,000 by November 14, 2008, and in connection with Dr. Shturman s desire to sell 22,000 shares of our common stock held by him by November 14, 2008 at a fixed price, we agreed to refer to Dr. Shturman the names of parties that may be interested in purchasing such shares in private transactions. As of November 19, 2008, we had referred Dr. Shturman names of parties that were interested in purchasing these shares and had also paid Dr. Shturman $50,000. In addition, CSI and Dr. Shturman have executed a settlement agreement, and pending execution of the settlement agreement by all co-defendants in the lawsuit, CSI anticipates that Dr. Shturman s counterclaim against it will be dismissed. If Dr. Shturman s counterclaims against us have not been settled, it is possible that we may incur substantial costs as a result of this litigation. The technology that is the subject of these disputes is not used in the Diamondback 360° and the shaft winding machines represent obsolete technology that we will likely never use.

Risks Related to Government Regulation

Our ability to market the Diamondback 360° in the United States is limited to use as a therapy in patients with PAD, and if we want to expand our marketing claims, we will need to file for additional FDA clearances or approvals and conduct further clinical trials, which would be expensive and time-consuming and may not be successful.

The Diamondback 360° received FDA 510(k) clearance in the United States for use as a therapy in patients with PAD. This general clearance restricts our ability to market or advertise the Diamondback 360° beyond this use and could affect our growth. While off-label uses of medical devices are common and the FDA does not regulate physicians choice of treatments, the FDA does restrict a manufacturer s communications regarding such off-label use. We will not actively promote or advertise the Diamondback 360° for off-label uses. In addition, we cannot make comparative claims regarding the use of the Diamondback 360° against any alternative treatments without conducting head-to-head comparative clinical trials, which would be expensive and time consuming. If our promotional activities fail to comply with the FDA s regulations or guidelines, we may be subject to FDA warnings or enforcement action.

If we determine to market the Diamondback 360° in the United States for other uses, for instance, use in the coronary arteries, we will need to conduct further clinical trials and obtain premarket approval from the FDA. Clinical trials are complex, expensive, time consuming, uncertain and subject to substantial and unanticipated delays. Before we may begin clinical trials, we must submit and obtain approval for an investigational device exemption, or IDE, that describes, among other things, the manufacture of, and controls for, the device and a complete investigational plan. Clinical trials generally involve a substantial number of patients in a multi-year study. We may encounter problems with our clinical trials, and any of those problems could cause us or the FDA to suspend those trials, or delay the analysis of the data derived from them.

A number of events or factors, including any of the following, could delay the completion of our clinical trials in the future and negatively impact our ability to obtain FDA clearance or approval for, and to introduce, a particular future product:

- failure to obtain approval from the FDA or any foreign regulatory authority to commence an investigational study;
- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining or maintaining required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply of our future product candidates or other materials necessary to conduct our clinical trials;

difficulties in enrolling patients in our clinical trials;

negative or inconclusive results from clinical trials, results that are inconsistent with earlier results, or the likelihood that the part of the human anatomy involved is more prone to serious adverse events, necessitating additional clinical trials;

serious or unexpected side effects experienced by patients who use our future product candidates; or

failure by any of our third-party contractors or investigators to comply with regulatory requirements or meet other contractual obligations in a timely manner.

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Our clinical trials may not begin as planned, may need to be redesigned, and may not be completed on schedule, if at all. Delays in our clinical trials may result in increased development costs for our future product candidates, which could cause our stock price to decline and limit our ability to obtain additional financing. In addition, if one or more of our clinical trials are delayed, competitors may be able to bring products to market before we do, and the commercial viability of our future product candidates could be significantly reduced.

Even if we believe that a clinical trial demonstrates promising safety and efficacy data, such results may not be sufficient to obtain FDA clearance or approval. Without conducting and successfully completing further clinical trials, our ability to market the Diamondback 360° will be limited and our revenue expectations may not be realized.

We may become subject to regulatory actions if we are found to have promoted the Diamondback 360° for unapproved uses.

If the FDA determines that our promotional materials, training or other activities constitute promotion of our product for an unapproved use, it could request that we cease use of or modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of an untitled or 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 promotional, training or other materials to constitute promotion of our product for an unapproved or uncleared use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

The Diamondback 360° may in the future be subject to product recalls that could harm our reputation.

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. We have not had any instances requiring consideration of a recall, although as we continue to grow and develop our products, including the Diamondback 360°, we may see instances of field performance requiring a recall. Any recalls of our product would divert managerial and financial resources, harm our reputation with customers and have an adverse effect on our financial condition and results of operations.

If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems, our products could be subject to restrictions or withdrawal from the market.

The Diamondback 360° and related manufacturing processes, clinical data, adverse events, recalls or corrections and promotional activities, are subject to extensive regulation by the FDA and other regulatory bodies. In particular, we and our component suppliers are required to comply with the FDA s Quality System Regulation, or QSR, and other regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain marketing clearance or approval. The FDA enforces the QSR through announced and unannounced inspections. We and certain of our third-party manufacturers have not yet been inspected by the FDA. Failure by us or one of our component suppliers to comply with the QSR requirements or other statutes and regulations administered by the FDA and other regulatory bodies, or failure to adequately respond to any observations, could result in, among other things:

warning or other letters from the FDA;

fines, injunctions and civil penalties;

product recall or seizure;

unanticipated expenditures;

delays in clearing or approving or refusal to clear or approve products;

withdrawal or suspension of approval or clearance by the FDA or other regulatory bodies;

orders for physician notification or device repair, replacement or refund;

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operating restrictions, partial suspension or total shutdown of production or clinical trials; and

criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales to suffer.

Furthermore, any modification to a device that has received FDA clearance or approval that could significantly affect its safety or efficacy, or that would constitute a major change in its intended use, design or manufacture, requires a new clearance or approval from the FDA. If the FDA disagrees with any determination by us that new clearance or approval is not required, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval. In addition, we could be subject to significant regulatory fines or penalties.

Regulatory clearance or approval of a product may also require costly post-marketing testing or surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

The use, misuse or off-label use of the Diamondback 360° may increase the risk of injury, which could result in product liability claims and damage to our business.

The use, misuse or off-label use of the Diamondback 360° may result in injuries that lead to product liability suits, which could be costly to our business. The Diamondback 360° is not FDA-cleared or approved for treatment of the carotid arteries, the coronary arteries, within bypass grafts or stents, of thrombus or where the lesion cannot be crossed with a guidewire or a significant dissection is present at the lesion site. We cannot prevent a physician from using the Diamondback 360° for off-label applications. The application of the Diamondback 360° to coronary or carotid arteries, as opposed to peripheral arteries, is more likely to result in complications that have serious consequences, including heart attacks or strokes which could result, in certain circumstances, in death.

We will face risks related to product liability claims, which could exceed the limits of available insurance coverage.

If the Diamondback 360° is defectively designed, manufactured or labeled, contains defective components or is misused, we may become subject to costly litigation by our customers or their patients. The medical device industry is subject to substantial litigation, and we face an inherent risk of exposure to product liability claims in the event that the use of our product results or is alleged to have resulted in adverse effects to a patient. In most jurisdictions, producers of medical products are strictly liable for personal injuries caused by medical devices. We may be subject in the future to claims for personal injuries arising out of the use of our products. Product liability claims could divert management s attention from our core business, be expensive to defend and result in sizable damage awards against us. A product liability claim against us, even if ultimately unsuccessful, could have a material adverse effect on our financial condition, results of operations and reputation. While we have product liability insurance coverage for our products and intend to maintain such insurance coverage in the future, there can be no assurance that we will be adequately protected from the claims that will be brought against us.

Compliance with environmental laws and regulations could be expensive. Failure to comply with environmental laws and regulations could subject us to significant liability.

Our operations are subject to regulatory requirements relating to the environment, waste management and health and safety matters, including measures relating to the release, use, storage, treatment, transportation, discharge, disposal and remediation of hazardous substances. Although we are currently classified as a Very Small Quantity Hazardous Waste Generator within Ramsey County, Minnesota, we cannot ensure that we will maintain our licensed status as such, nor can we ensure that we will not incur material costs or liability in connection with our operations, or that our past or future operations will not result in claims or injury by employees or the public. Environmental laws and regulations could also become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations.

We and our distributors must comply with various federal and state anti-kickback, self-referral, false claims and similar laws, any breach of which could cause a material adverse effect on our business, financial condition and results of operations.

Our relationships with physicians, hospitals and the marketers of our products are subject to scrutiny under various federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws.

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Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to claims that the relevant law has been violated. If our operations are found to be in violation of these laws, we, as well as our employees, may be subject to penalties, including monetary fines, civil and criminal penalties, exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers compensation programs and TRICARE (the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents, retirees and their dependents), and forfeiture of amounts collected in violation of such prohibitions. Individual employees may need to defend such suits on behalf of us or themselves, which could lead to significant disruption in our present and future operations. Certain states in which we intend to market our products have similar fraud and abuse laws, imposing substantial penalties for violations. Any government investigation or a finding of a violation of these laws would likely have a material adverse effect on our business, financial condition and results of operations.

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Anti-kickback laws and regulations prohibit any knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for the referral of an individual or the ordering or recommending of the use of a product or service for which payment may be made by Medicare, Medicaid or other government-sponsored healthcare programs. In addition, the cost of non-compliance with these laws could be substantial, since we could be subject to monetary fines and civil or criminal penalties, and we could also be excluded from federally funded healthcare programs, including Medicare and Medicaid, for non-compliance.

We have entered into consulting agreements with physicians, including some who may make referrals to us or order our product. One of these physicians was one of 20 principal investigators in our OASIS clinical trial at the same time he was acting as a paid consultant for us. In addition, some of these physicians own our stock, which they purchased in arm s-length transactions on terms identical to those offered to non-physicians, or received stock options from us as consideration for consulting services performed by them. We believe that these consulting agreements and equity investments by physicians are common practice in our industry, and while these transactions were structured with the intention of complying with all applicable laws, including the federal ban on physician self-referrals, commonly known as the Stark Law, state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory or enforcement agencies or courts may in the future view these transactions as prohibited arrangements that must be restructured or for which we would be subject to other significant civil or criminal penalties, or prohibit us from accepting referrals from these physicians. Because our strategy relies on the involvement of physicians who consult with us on the design of our product, we could be materially impacted if regulatory or enforcement agencies or courts interpret our financial relationships with our physician advisors who refer or order our product to be in violation of applicable laws and determine that we would be unable to achieve compliance with such applicable laws. This could harm our reputation and the reputations of our clinical advisors.

The scope and enforcement of all of these laws is uncertain and subject to rapid change, especially in light of the lack of applicable precedent and regulations. There can be no assurance that federal or state regulatory or enforcement authorities will not investigate or challenge our current or future activities under these laws. Any investigation or challenge could have a material adverse effect on our business, financial condition and results of operations. Any state or federal regulatory or enforcement review of us, regardless of the outcome, would be costly and time consuming. Additionally, we cannot predict the impact of any changes in these laws, whether these changes are retroactive or will have effect on a going-forward basis only.

Risks Relating to Intellectual Property

Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.

Our success and ability to compete depends, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patents, copyrights and trademarks, as well as trade secrets and nondisclosure agreements, to protect our intellectual property. As of October 31, 2008, we had a portfolio of 16 issued U.S. patents and 33 issued or granted non-U.S. patents covering aspects of our core technology, which expire between 2017 and 2022. However, our issued patents and related intellectual property may not be adequate to protect us or permit us to gain or maintain a competitive advantage. The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our issued patents can be challenged in litigation or proceedings before the U.S. Patent and Trademark Office, or the USPTO. In addition, our pending patent applications include claims to numerous important aspects of our products under development that are not currently protected by any of our issued patents. We cannot assure you that any of our pending patent applications will result in the issuance of patents to us. The USPTO may deny or require significant narrowing of claims in our pending patent applications. Even if any patents are issued as a result of pending patent applications, they may not provide us with significant commercial protection or be issued in a form that is advantageous to us. Proceedings before the USPTO could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. Further, if any patents we obtain or license are deemed invalid and unenforceable, or have their scope narrowed, it could impact our ability to commercialize or license our technology.

Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. For instance, the U.S. Supreme Court has recently modified some tests

used by the USPTO in granting patents during the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license. In addition, the USPTO has adopted new rules of practice (the application of which has been enjoined as a result of litigation) that limit the number of claims that may be filed in a patent application and the number of continuation or continuation-in-part applications that may be filed. These new rules may result in patent applicants being unable to secure all of the rights that they would otherwise have been entitled to in the absence of the new rules and, therefore, may negatively affect our ability to obtain comprehensive patent coverage. The laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all.

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To protect our proprietary rights, we may, in the future, need to assert claims of infringement against third parties to protect our intellectual property. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our financial condition, reputation and results of operations regardless of the final outcome of such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, invalid or unenforceable, and could order us to pay third-party attorneys fees. Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technology or other information that we regard as proprietary. In addition, we may not have sufficient resources to litigate, enforce or defend our intellectual property rights. Additionally, third parties may be able to design around our patents.

We also rely on trade secrets, technical know-how and continuing innovation to develop and maintain our competitive position. In this regard, we seek to protect our proprietary information and other intellectual property by requiring our employees, consultants, contractors, outside scientific collaborators and other advisors to execute non-disclosure and assignment of invention agreements on commencement of their employment or engagement. Agreements with our employees also forbid them from bringing the proprietary rights of third parties to us. We also require confidentiality or material transfer agreements from third parties that receive our confidential data or materials. However, trade secrets are difficult to protect. We cannot provide any assurance that employees and third parties will abide by the confidentiality or assignment terms of these agreements, or that we will be effective securing necessary assignments from these third parties. Despite measures taken to protect our intellectual property, unauthorized parties might copy aspects of our products or obtain and use information that we regard as proprietary. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Finally, others may independently discover trade secrets and proprietary information, and this would prevent us from asserting any such trade secret rights against these parties.

Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.

Claims of infringement or misappropriation of the intellectual property rights of others could prohibit us from commercializing products, require us to obtain licenses from third parties or require us to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief.

The medical technology industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. The likelihood that patent infringement or misappropriation claims may be brought against us increases as we achieve more visibility in the marketplace and introduce products to market. All issued patents are entitled to a presumption of validity under the laws of the United States. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Our competitors may assert that our products are covered by U.S. or foreign patents held by them. We are aware of numerous patents issued to third parties that relate to the manufacture and use of medical devices for interventional cardiology. The owners of each of these patents could assert that the manufacture, use or sale of our products infringes one or more claims of their patents. Because patent applications may take years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that we infringe. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings can be substantial, and it is possible that such efforts would be unsuccessful if unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. There could also be existing patents of which we are unaware that one or more aspects of our technology may inadvertently infringe. In some cases, litigation may be threatened or brought by a patent-holding company or other adverse patent owner who has no relevant product revenues and against whom our

patents may provide little or no deterrence.

Any infringement or misappropriation claim could cause us to incur significant costs, place significant strain on our financial resources, divert management s attention from our business and harm our reputation. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. Although patent and intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with

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such arrangements may be substantial and could include ongoing royalties. If the relevant patents were upheld in litigation as valid and enforceable and we were found to infringe, we could be prohibited from commercializing any infringing products unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign any infringing products to avoid infringement. Further, any redesign may not receive FDA clearance or approval or may not receive such clearance or approval in a timely manner. Any such license could impair operating margins on future product revenue. A court could also order us to pay compensatory damages for such infringement, and potentially treble damages, plus prejudgment interest and third-party attorneys fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing infringing products, or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties. Adverse determinations 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 significant adverse impact on our business.

Risks Relating to Ownership of Our Common Stock

Because there has not been a public market for our common stock, you may not be able to resell your shares.

Currently, there is no public market for any of our common stock and no public market will develop as a result of the filing of this registration statement on Form 10. To date, we have not registered or qualified the offer or sale, or resale, of our common stock under federal or state securities laws and, if you buy any such shares, you may not resell them unless such sale is registered or qualified under federal and state securities laws or exemptions from federal and state registration and qualification are available. In addition, our stockholders agreement places certain transfer restrictions upon the holders of our stock party thereto. Any investor in our common stock must be prepared to bear the economic risk of investing in our common stock for an indefinite period of time.

We cannot predict the extent to which an active trading market for our common stock will develop or whether, if a trading market does develop, the market price of our common stock will be volatile. If an active trading market does not develop, you may have difficulty selling any of our common stock that you buy. The risks related to our company discussed above, as well as decreases in market valuations of similar companies, could cause the price of our common stock to decrease significantly.

In addition, the volatility of medical technology company stocks often does not correlate to the operating performance of the companies represented by such stocks. Some of the factors that may cause the price of our common stock to fluctuate include:

- our ability to develop, obtain regulatory clearances or approvals for and market new and enhanced products on a timely basis;
- changes in governmental regulations or in the status of our regulatory approvals, clearances or future applications;
- our announcements or our competitors announcements regarding new products, product enhancements, significant contracts, number of hospitals and physicians using our products, acquisitions or strategic investments;
- announcements of technological or medical innovations for the treatment of vascular disease;
- delays or other problems with the manufacturing of the Diamondback 360°;
- volume and timing of orders for the Diamondback 360° and any future products, if and when commercialized;
- changes in the availability of third-party reimbursement in the United States and other countries;

quarterly variations in our or our competitors results of operations;

changes in earnings estimates or recommendations by securities analysts, if any, who cover our common stock;

failure to meet estimates or recommendations by securities analysts, if any, who cover our stock;

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changes in healthcare policy;

product liability claims or other litigation involving us;

product recalls;

accusations that we have violated a law or regulation;

sales of large blocks of our common stock, including sales by our executive officers, directors and significant shareholders;

disputes or other developments with respect to intellectual property rights;

changes in accounting principles; and

general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

In addition, if securities class action litigation is initiated against us, we would incur substantial costs and our management s attention would be diverted from our operations. All of these factors could cause the price of our stock to decline, and you may lose some or all of your investment.

If equity research analysts do not publish research or reports about our business or if they issue unfavorable research or downgrade our common stock, the price of our common stock could decline.

As a public company, investors may look to reports of equity research analysts for additional information regarding our industry and operations. Therefore, any trading market for our common stock will rely in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts. Equity research analysts may elect not to provide research coverage of our common stock, which may adversely affect the market price of our common stock. If equity research analysts do provide research coverage of our common stock, the price of our common stock could decline if one or more of these analysts downgrade our common stock or if they issue other unfavorable commentary about us or our business. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline.

Our directors and executive officers and our preferred shareholders have substantial control over us and could limit your ability to influence the outcome of key transactions, including changes of control.

Our executive officers and directors and entities affiliated with them, in the aggregate, beneficially owned 21.6% of our outstanding common stock as of September 30, 2008. Our executive officers, directors and affiliated entities, if acting together, would be able to control or influence significantly all matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other significant corporate transactions. In addition, our preferred shareholders have approval rights under our articles of incorporation over certain transactions in which we may wish to engage. These shareholders may have interests that differ from yours, and they may vote in a way with which you disagree and that may be adverse to your interests. The concentration of ownership of our common stock and preferred stock may have the effect of delaying, preventing or deterring a change of control of our company, could deprive our shareholders of an opportunity to receive a premium for their common stock as part of a sale of our company, and may affect the market price of our common stock. This concentration of ownership of our common stock and preferred stock may also have the effect of influencing the completion of a change in control that may not necessarily be in the best interests of all of our shareholders.

The rights of our preferred shareholders are superior to the rights of our common shareholders.

The holders of our outstanding preferred stock have certain rights that are superior to the rights of holders of our common stock, including dividend and liquidation preferences over our common stock. For example, the holders of our preferred stock will be entitled to receive dividends at the rate of 8% of the original purchase price of their preferred shares, and the holders of the preferred stock have the right to participate in dividends with the common

shareholders on an as converted basis. We are also required to pay a preferential liquidating distribution to the holder of preferred stock before any distributions can be made to the holders of our common stock in the case of our liquidation, dissolution or winding up. Under the terms of the preferred stock, a liquidation may be deemed to occur upon other circumstances, such as certain mergers and business combination transaction.

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Certain provisions of Minnesota law and our articles of incorporation and bylaws may make a takeover of our company more difficult, depriving shareholders of opportunities to sell shares at above-market prices.

Certain provisions of Minnesota law and our bylaws may have the effect of discouraging attempts to acquire us without the approval of our board of directors. Section 302A.671 of the Minnesota Statutes, with certain exceptions, requires approval of any acquisition of the beneficial ownership of 20% or more of our voting stock then outstanding by a majority vote of our shareholders prior to its consummation. In general, shares acquired in the absence of such approval are denied voting rights and are redeemable by us at their then fair market value within 30 days after the acquiring person failed to give a timely information statement to us or the date our shareholders voted not to grant voting rights to the acquiring person s shares. Section 302A.673 of the Minnesota Statutes generally prohibits any business combination by us with an interested shareholder, which includes any shareholder that purchases 10% or more of our voting shares, within four years following such interested shareholder s share acquisition date, unless the business combination or share acquisition is approved by a committee of one or more disinterested members of our board of directors before the interested shareholder s share acquisition date. In addition, our bylaws provide for an advance notice procedure for nomination of candidates to our board of directors that could have the effect of delaying, deterring or preventing a change in control. Consequently, holders of our common stock may lose opportunities to sell their stock for a price in excess of the prevailing market price due to these statutory protective measures. Please see Description of Capital Stock Potential Anti-Takeover Effects of Certain Provisions of Minnesota State Law and Our Articles of Incorporation and Bylaws for a more detailed description of these provisions.

We do not intend to declare dividends on our stock.

We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends on our common stock will be at the discretion of our board of directors and will depend upon our results of operations, earnings, capital requirements, financial condition, future prospects, contractual restrictions and other factors deemed relevant by our board of directors. Therefore, you should not expect to receive dividends from shares of our common stock.

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Risks Relating to the Proposed Merger with Replidyne

If any of the events described in Risks Relating to Our Business and Operations occur, those events could cause the potential benefits of the merger with Replidyne not to be realized.

Following the effective time of the merger with Replidyne, current CSI officers and directors will direct the business and operations of the combined company. Additionally, CSI s business is expected to constitute all of the business of the combined company following the merger. As a result, the risks described above in the section entitled Risks Relating to Our Business and Operations are among the most significant risks to the combined company if the merger is completed. To the extent any of the events in the risks described above in the section entitled Risks Relating to Our Business and Operations occur, those events could cause the market price of the combined company s common stock to decline.

In the event that Replidyne s level of net assets at the effective time of the merger, as calculated pursuant to the merger agreement, is lower than $37 million, the combined company will have less working capital for future operations.

Subject to the terms of the merger agreement with Replidyne, at the effective time of the merger, each share of CSI common stock issued and outstanding immediately prior to the merger will be canceled, extinguished and automatically converted into the right to receive that number of shares of Replidyne common stock as determined pursuant to the conversion factor described in the merger agreement. The conversion factor depends on Replidyne s level of net assets as of the effective time of the merger. Under the merger agreement, Replidyne s net assets is defined as Replidyne s total current assets minus all of its liabilities and other outstanding and future obligations as of the effective time of the merger, subject to certain adjustments. Replidyne currently anticipates that its level of net assets as of the effective time of the merger will be at or above $37 million, which would result in Replidyne s current stockholders, together with holders of its options and warrants, owning approximately 17% of the common stock of the combined company on a fully diluted basis as calculated in accordance with the merger agreement. However, if any of the following circumstances arise, Replidyne s level of net assets will be lower than Replidyne expects and Replidyne stockholders would hold a smaller percentage ownership of the combined company following the consummation of the merger than is currently anticipated, thus making the merger less attractive to Replidyne stockholders:

- Replidyne is unable to generate any proceeds from the sale of its REP3123 and DNA replication inhibition programs;

- Replidyne is unable to terminate, sublease or otherwise assign to a third party its remaining obligations under the lease for its headquarters in Louisville, Colorado;

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Replidyne does not receive reimbursement from Forest Laboratories for certain decontamination costs incurred by Replidyne under its former supply agreement with MEDA Manufacturing GmbH;

the costs associated with the winding up of Replidyne s business are greater than anticipated; or

Replidyne expends more resources than is currently anticipated as a result of a delay in the closing of the merger or otherwise.

In addition, if Replidyne s net assets are lower than expected, the combined company will have less working capital for future operations, which could adversely affect the ability of the combined company to achieve its business plan.

The costs associated with the merger are difficult to estimate, may be higher than expected and may harm the financial results of the combined company.

Replidyne and CSI estimate that they will incur aggregate direct transaction costs of approximately $5.7 million associated with the merger, and additional costs associated with the commencement of CSI s operation as a public company, which cannot be estimated accurately at this time. The costs associated with the merger may increase if any CSI stockholders elect to dissent from the merger and seek payment of the fair value of their shares as permitted by Minnesota law. If the total costs of the merger exceed Replidyne s and CSI s estimates, the combined company will have less working capital for future operations, which will adversely affect the ability of the combined company to achieve its business plan.

Nasdaq considers the anticipated merger a reverse merger and therefore requires the combined company to submit a new listing application, which will require certain actions by the combined company and may not be successful, which would result in you having difficulty selling your shares.

Nasdaq considers the merger to be a reverse merger and requires the combined company to submit a new listing application. Nasdaq may not approve the combined company s new listing application. If this occurs and the merger is still consummated, you may have difficulty selling your shares.

Additionally, as part of the new listing application, the combined company will be required to submit, among other things, a plan for the combined company to conduct a reverse stock split. A reverse stock split would increase the per share trading price by a yet undetermined multiple. The change in share price may affect the volatility and liquidity of the combined company s stock, as well as the marketplace s perception of the stock. As a result, the relative price of the combined company s stock may decline and/or fluctuate more than in the past, and you may have trouble converting your investments in the combined company into cash effectively.

The market price of Replidyne common stock has fallen significantly since the public announcement of the proposed merger. If the merger is completed, the market price of the combined company s common stock may decline further.

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On November 3, 2008, the last day prior to the public announcement of the proposed merger, the closing price per share of Replidyne common stock as reported on The Nasdaq Global Market was $1.12. On December 12, 2008, the closing price per share of Replidyne common stock as reported on The Nasdaq Global Market was $0.75, which represents a 33% decrease from the closing price on November 3, 2008. This decrease may increase the risk that Replidyne would become subject to securities class action litigation, which could result in substantial costs and a delay in the completion of the merger. If the merger is completed, the market price of the combined company s common stock may decline further for a number of reasons, including if:

the effect of the merger on the combined company s business and prospects is not consistent with the expectations of financial or industry analysts; or

investors react negatively to the effect on the combined company s business and prospects from the merger.

Because the lack of a public market for CSI s outstanding shares makes it difficult to evaluate the fairness of the merger, CSI stockholders may receive consideration in the merger that is greater than or less than the fair market value of the CSI shares.

The outstanding capital stock of CSI is privately held and is not traded in any public market. The lack of a public market makes it extremely difficult to determine the fair market value of CSI. Since the percentage of Replidyne s equity to be issued to CSI stockholders was determined based on negotiations between the parties, it is possible that the value of the Replidyne common stock to be issued in connection with the merger will be greater than the fair market value of CSI. Alternatively, it is possible that the value of the shares of Replidyne common stock to be issued in connection with the merger will be less than the fair market value of CSI.

Replidyne and CSI executive officers and directors may have interests in the merger that are different from, or in addition to, those of Replidyne and CSI stockholders generally.

The executive officers and directors of Replidyne and CSI may have interests in the merger that are different from, or are in addition to, those of Replidyne and CSI stockholders generally. The directors of the combined company will consist of two directors from Replidyne s board and eight directors from CSI s board. Further, certain Replidyne executive officers will receive change in control payments in connection with the merger.

Replidyne and CSI may not be able to complete the merger or may elect to pursue a different strategic transaction, which may not occur on commercially reasonably terms or at all.

Neither Replidyne nor CSI can assure you that they will close the pending merger in a timely manner or at all. The merger agreement is subject to many closing conditions and termination rights. If Replidyne and CSI do not complete the pending merger, Replidyne s and CSI s board of directors may elect to attempt to complete a different strategic transaction. Attempting to complete a different strategic transaction would prove to be costly and time consuming, and neither Replidyne nor CSI can make any assurances that a future strategic transaction will occur on commercially reasonable terms or at all.

Failure to complete the merger could adversely affect CSI s future business and operations.

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The merger is subject to the satisfaction of closing conditions, including approval by Replidyne and CSI stockholders, and neither Replidyne nor CSI can assure you that the merger will be completed. In the event that the merger is not completed, Replidyne and CSI may be subject to many significant costs, including legal, accounting and advisory fees related to the merger, which must be paid even if the merger is not completed, and the payment of a termination fee and certain expenses under certain circumstances. If the merger is not completed, the market price of Replidyne common stock could decline as a result. If the merger is not completed, CSI will need additional debt or equity financing to carry out its business plan and there is no assurance that such debt or equity financing will be available on acceptable terms or at all.

During the pendency of the merger, Replidyne and CSI may not be able to enter into a business combination with another party because of restrictions in the merger agreement.

The merger agreement restricts the ability of Replidyne and CSI to make acquisitions or complete other transactions. While the merger agreement is in effect, subject to limited exceptions, each party is prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to such party entering into certain extraordinary transactions with any third party, such as a sale of assets, an acquisition of common stock, a tender offer for capital stock or a merger or other business combination outside the ordinary course of business. Any such transactions could be favorable to Replidyne or CSI stockholders.

The merger may be completed even though material adverse changes may result from the announcement of the merger, industry-wide changes and other causes.

In general, either party can refuse to complete the merger if there is a material adverse change affecting the other party between November 3, 2008, the date of the merger agreement, and the closing of the merger. However, some types of changes do not permit either party to refuse to complete the merger, even if such changes would have a material adverse effect on Replidyne or CSI. If adverse changes occur but Replidyne and CSI must still complete the merger, the combined company s stock price may suffer.

Because there has not been a public market for CSI common stock, the combined company s stock price is expected to be volatile and you may not be able to resell your shares in the combined company.

The market price of the combined company s common stock could be subject to significant fluctuations following the merger. Market prices for securities of early-stage pharmaceutical, medical device, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of the combined company s common stock to fluctuate include:

difficulties in integrating Replidyne and CSI following the merger;

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its ability to develop, obtain regulatory clearances or approvals for and market new and enhanced products on a timely basis;

changes in governmental regulations or in the status of its regulatory approvals, clearances or future applications;

its announcements or its competitors announcements regarding new products, product enhancements, significant contracts, number of hospitals and physicians using CSI s products, acquisitions or strategic investments;

announcements of technological or medical innovations for the treatment of vascular disease;

delays or other problems with the manufacturing of the Diamondback 360°;

volume and timing of orders for the Diamondback 360° and any future products, if and when commercialized;

changes in the availability of third-party reimbursement in the United States and other countries;

quarterly variations in the combined company s or its competitors results of operations;

changes in earnings estimates or recommendations by securities analysts, if any, who cover the combined company s common stock;

failure to meet estimates or recommendations by securities analysts, if any, who cover the combined company s stock;

changes in healthcare policy;

product liability claims or other litigation involving CSI or the combined company;

product recalls;

accusations that CSI or the combined company has violated a law or regulation;

sales of large blocks of the combined company s common stock, including sales by CSI s executive officers, directors and significant stockholders;

disputes or other developments with respect to intellectual property rights;

changes in accounting principles; and

general market conditions and other factors, including factors unrelated to the combined company s operating performance or the operating performance of its competitors.

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In addition, if securities class action litigation is initiated against the combined company, it would incur substantial costs and its management s attention would be diverted from operations. All of these factors could cause the price of the combined company s stock to decline, and you may lose some or all of your investment.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of the combined company s common stock.

In the past, following periods of volatility in the market price of a company s securities, stockholders have often instituted class action securities litigation against such company. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm the combined company s profitability and reputation.

Replidyne and CSI do not expect the combined company to pay cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment in the combined company.

Replidyne and CSI anticipate that the combined company will retain its earnings, if any, for future growth and therefore do not anticipate that the combined company will pay cash dividends in the future. As a result, appreciation of the price of the combined company s common stock is the only potential source of return to stockholders. Investors seeking cash dividends should not invest in the combined company s common stock.

If equity research analysts do not publish research or reports about the combined company s business or if they issue unfavorable research or downgrade the combined company s common stock, the price of its common stock could decline.

Investors may look to reports of equity research analysts for additional information regarding the combined company s industry and operations. Therefore, any trading market for the combined company s common stock will rely in part on the research and reports that equity research analysts publish about the combined company and its business. The combined company does not control these analysts. Equity research analysts may elect not to provide research coverage of the combined company s common stock, which may adversely affect the market price of its common stock. If equity research analysts do provide research coverage of the combined company s common stock, the price of its common stock could decline if one or more of these analysts downgrade the common stock or if they issue other unfavorable commentary about the combined company or its business. If one or more of these analysts ceases coverage of the combined company, it could lose visibility in the market, which in turn could cause its stock price to decline.

The combined company will not be able to utilize Replidyne s net operating loss carryforwards.

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Under Section 382 of the Internal Revenue Code, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation s ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. Further, if the continuity of business requirement defined in Section 382 is not met in a change of control transaction, the pre-transaction net operating loss carryforward deductions become substantially reduced or unavailable for use by the surviving corporation in the transaction. An ownership change will occur as a result of the merger and there will not be a continuation of Replidyne s business following completion of the merger, which will substantially reduce or eliminate the ability of the combined company to utilize Replidyne s net operating loss carryforwards.

Some provisions of the charter documents of the combined company and Delaware law may have anti-takeover effects that could discourage an acquisition of the combined company by others, even if an acquisition would be beneficial to the combined company s stockholders.

Provisions in Replidyne s restated certificate of incorporation and bylaws, which will be the charter documents of the combined company, as well as provisions of Delaware law, could make it more difficult for a third party to acquire the combined company, even if doing so would benefit the combined company s stockholders. These provisions include:

- authorizing the issuance of blank check preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

In addition, the combined company will be subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by such corporation s board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to the combined company s stockholders.

Future sales and issuances of the combined company s common stock or rights to purchase common stock, including pursuant to equity incentive plans, could result in additional dilution of the percentage ownership of the combined company s stockholders and could cause the stock price to fall.

Sales of a substantial number of shares of the combined company s common stock in the

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public market or the perception that these sales might occur, could depress the market price of the combined company s common stock and could impair its ability to raise capital through the sale of additional equity securities. Replidyne and CSI are unable to predict the effect that sales may have on the prevailing market price of the common stock.

To the extent the combined company raises additional capital by issuing equity securities, including in a debt financing where the combined company issues convertible notes or notes with warrants, the combined company s stockholders may experience substantial dilution. The combined company may sell common stock in one or more transactions at prices and in a manner it determines from time to time. If the combined company sells common stock in more than one transaction, existing stockholders may be materially diluted. In addition, new investors could gain rights superior to existing stockholders, such as liquidation and other preferences. In connection with the merger, the combined company will assume the equity incentive plans of CSI as well as all outstanding options and warrants to purchase shares of CSI common stock that will become exercisable for shares of the combined company s common stock. In addition, the number of shares available for future grant under the equity incentive plans that the combined company will be assuming in connection with the merger will be increased. In addition, Replidyne and CSI also have warrants outstanding to purchase shares of capital stock. The combined company s stockholders will incur dilution upon exercise of any outstanding stock options or warrants.

All of Replidyne s outstanding shares of common stock are, and any shares that are issued in the merger will be, freely tradable without restrictions or further registration under the Securities Act of 1933, as amended, except for any shares subject to lock-up agreements executed in connection with the merger and any shares held by affiliates, as defined in Rule 144 under the Securities Act. Rule 144 defines an affiliate as a person who directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the combined company and would include persons such as the combined company s directors and executive officers.

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ITEM 2. FINANCIAL INFORMATION

SELECTED CONSOLIDATED FINANCIAL DATA

The following table presents our selected historical consolidated financial data. We derived the selected statements of operations data for the years ended June 30, 2006, 2007 and 2008 and balance sheet data as of June 30, 2007 and 2008 from our audited consolidated financial statements and related notes that are included elsewhere in this Form 10. We derived the selected consolidated statements of operations data for the years ended June 30, 2004 and 2005 and the balance sheet data as of June 30, 2004, 2005, and 2006 from our audited consolidated financial statements that do not appear in this Form 10. We derived the consolidated statements of operations data for the three months ended September 30, 2007 and 2008 and the balance sheet data as of September 30, 2008 from our unaudited consolidated financial statements and related notes that are included elsewhere in this Form 10. We have prepared this unaudited information on the same basis as the audited consolidated financial statements and have included all adjustments, consisting only of normal recurring adjustments, that we consider necessary for a fair presentation of our financial position and operating results for such period. We have prepared the unaudited interim consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, or GAAP, and the rules and regulations of the SEC for interim financial statements. Our historical results are not necessarily indicative of the results that may be expected in the future and the results for the three months ended September 30, 2008 are not necessarily indicative of the results for the full year. You should read this data together with our consolidated financial statements and related notes included elsewhere in this Form 10 and the information under Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Years Ended June 30,					Three Months Ended September 30,	
	2004	2005	2006	2007(1)	2008(1)	2007(1)	2008(1)
	(in thousands, except share and per share amounts)						
Consolidated Statements of Operations Data:							
Revenues	$	$	$	$	$ 22,177	$	$ 11,646
Cost of goods sold					8,927	(539)	3,881
Gross profit					13,250	(539)	7,765
Expenses(1):							
Selling, general and administrative	984	1,177	1,735	6,691	35,326	3,552	16,424
Research and development	3,246	2,371	3,168	8,446	16,068	3,328	4,955
Total expenses	4,230	3,548	4,903	15,137	51,394	6,880	21,379
Loss from operations	(4,230)	(3,548)	(4,903)	(15,137)	(38,144)	(7,419)	(13,614)
Other income (expense):							
Interest expense			(48)	(1,340)	(923)	(300)	(227)
Interest income	18	37	56	881	1,167	278	142
Impairment on investments					(1,267)		

Total other income (expense)	18	37	8	(459)	(1,023)	(22)	(85)
Net loss	(4,212)	(3,511)	(4,895)	(15,596)	(39,167)	(7,441)	(13,699)
Accretion of redeemable convertible preferred stock(2)				(16,835)	(19,422)	(4,853)	
Net loss available to common shareholders	$ (4,212)	$ (3,511)	$ (4,895)	$ (32,431)	$ (58,589)	$ (12,294)	$ (13,699)
Loss per common share:							
Basic and diluted(3)	$ (0.78)	$ (0.61)	$ (0.79)	$ (5.22)	$ (8.57)	$ (1.95)	$ (1.78)
Weighted average common shares used in computation:							
Basic and diluted(3)	5,375,795	5,779,942	6,183,715	6,214,820	6,835,126	6,291,512	7,692,248

(1) Operating expenses in the years ended June 30, 2007 and 2008 and three months ended September 30, 2007 and 2008 include stock-based compensation expense as a result of the adoption of SFAS No. 123(R), *Share-Based Payment* on July 1, 2006, as follows:

	Years Ended June 30,	Three Months Ended September 30,

	2007	2008	2007	2008
Cost of goods sold	$	$ 232	$	$ 176
Selling, general and administrative	327	6,852	277	1,384
Research and development	63	297	73	112

(2) See Notes 1 and 10 of the notes to our consolidated financial statements for a discussion of the accretion of redeemable convertible preferred stock.

(3) See Note 12 of the notes to our consolidated financial statements for a description of the method used to compute basic and diluted net loss per common share and basic and diluted weighted-average number of shares used in per common share calculations.

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	2004	2005	As of June 30, 2006	2007	2008	As of September 30, 2008
			(in thousands)			
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$3,144	$1,780	$ 1,554	$ 7,908	$ 7,595	$ 14,727
Short-term investments				11,615		
Working capital(1)	2,868	1,349	(1,240)	18,171	(3,118)	(11,144)
Total current assets	3,166	2,116	2,424	20,828	18,204	24,914
Total assets	4,031	2,874	3,296	22,025	41,958	48,612
Redeemable convertible preferred stock warrants				3,094	3,986	4,047
Total liabilities	298	767	3,723	5,830	25,408	42,605
Redeemable convertible preferred stock				48,498	98,242	98,242
Total shareholders (deficiency) equity	3,733	2,107	(427)	(32,303)	(81,692)	(92,235)

(1) Working capital is calculated as total current assets less total current liabilities as of the balance sheet date indicated.

Quarterly Results of Operations

The following table presents our unaudited quarterly results of operations for each of our last nine quarters ended September 30, 2008. You should read the following table in conjunction with the consolidated financial statements and related notes contained elsewhere in this Form 10. We have prepared the unaudited information on the same basis as our audited consolidated financial statements. These interim financial statements reflect all adjustments consisting of normal recurring accruals, which, in the opinion of management, are necessary to present fairly the results of our operations for the interim periods. Results of operations for any quarter are not necessarily indicative of results for any future quarters or for a full year.

	September 30, 2006	December 31, 2006	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007	March 31, 2008	June 30, 2008	September 30, 2008
					(in thousands)				
Consolidated Statements of Operations Data:									
Revenues	$	$	$	$	$	$ 4,631	$ 7,654	$ 9,892	$ 11,646
					(539)	2,438	5,142	6,209	7,765

Gross profit (loss)									
Loss from operations	(1,571)	(2,964)	(3,984)	(6,618)	(7,419)	(10,187)	(9,291)	(11,247)	(13,614)
Net loss	(1,328)	(3,139)	(4,187)	(6,942)	(7,441)	(9,768)	(10,611)	(11,347)	(13,699)
Net loss available to common shareholders (1)	(5,207)	(7,266)	(8,584)	(11,374)	(12,294)	(10,121)	(24,827)	(11,347)	(13,699)

(1) Net loss available to common shareholders includes accretion of redeemable convertible preferred stock.

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MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this Form 10. This discussion and analysis contains forward-looking statements about our business and operations, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those we currently anticipate as a result of many important factors, including the factors we describe under Risk Factors and elsewhere in this Form 10.

Overview

We are a medical device company focused on developing and commercializing interventional treatment systems for vascular disease. Our initial product, the Diamondback 360° Orbital Atherectomy System, is a minimally invasive catheter system for the treatment of peripheral arterial disease, or PAD.

We were incorporated in Minnesota in 1989. From 1989 to 1997, we engaged in research and development on several different product concepts that were later abandoned. Since 1997, we have devoted substantially all of our resources to the development of the Diamondback 360°.

From 2003 to 2005, we conducted numerous bench and animal tests in preparation for application submissions to the FDA. We initially focused our testing on providing a solution for coronary in-stent restenosis but later changed the focus to PAD. In 2006, we obtained an investigational device exemption from the FDA to conduct our pivotal OASIS clinical trial, which was completed in January 2007. The OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions.

In August 2007, the FDA granted us 510(k) clearance for the use of the Diamondback 360° as a therapy in patients with PAD. We commenced a limited commercial introduction of the Diamondback 360° in the United States in September 2007. This limited commercial introduction intentionally limited the size of our sales force and the number of customers each member of the sales force served in order to focus on obtaining quality and timely product feedback on initial product usages.

We market the Diamondback 360° in the United States through a direct sales force and commenced a full commercial launch in the quarter ended March 31, 2008. We plan to expend significant capital to increase the size of our sales and marketing efforts to expand our customer base as we implement full commercialization of the Diamondback 360°. We manufacture the Diamondback 360° internally at our facilities.

As of September 30, 2008, we had an accumulated deficit of $132.0 million. We expect our losses to continue as we continue our commercialization activities, develop additional product enhancements and make further regulatory submissions. To date, we have financed our operations primarily through the private placement of equity securities.

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Since our inception, we have experienced substantial operating losses and negative cash flows from operations. We had cash and cash equivalents of $14.7 million at September 30, 2008. During the year ended June 30, 2008 and three months ended September 30, 2008, net cash used in operations amounted to $31.9 million and $12.0 million, respectively. In February 2008, we were notified that recent conditions in the global credit markets have caused insufficient demand for auction rate securities, resulting in failed auctions for $23.0 million of our auction rate securities held at June 30, 2008 and September 30, 2008. These securities are currently not liquid, as we have an inability to sell the securities due to continued failed auctions. As a result, we recorded an other-than-temporary impairment loss of $1.3 million relating to these securities in our statement of operations for the year ended June 30, 2008. On March 28, 2008, we obtained a margin loan from UBS Financial Services, Inc., the entity through which we originally purchased our auction rate securities, for up to $12.0 million, which was secured by the $23.0 million par value of our auction rate securities. The outstanding balance on this loan at June 30, 2008 was $11.9 million. On August 21, 2008, we replaced this loan with a margin loan from UBS Bank USA, which increased maximum borrowings available to $23.0 million. This maximum borrowing amount is not set forth in the written agreement for the loan and may be adjusted from time to time by UBS Bank in its sole discretion. The margin loan has a floating interest rate equal to 30-day LIBOR, plus 1.0%. The loan is due on demand and UBS Bank will require us to repay it in full from the proceeds received from a public equity

offering where net proceeds exceed $50.0 million. In addition, if at any time any of our auction rate securities may be sold, exchanged, redeemed, transferred or otherwise conveyed for no less than their par value, then we must immediately effect such a transfer and the proceeds must be used to pay down outstanding borrowings under this loan. The margin requirements are determined by UBS Bank but are not included in the written loan agreement

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and are therefore subject to change. From August 21, 2008, the date this loan was initially funded, through the date of this Form 10, the margin requirements included maximum borrowings, including interest, of $23.0 million. If these margin requirements are not maintained, UBS Bank may require us to make a loan payment in an amount necessary to comply with the applicable margin requirements or demand repayment of the entire outstanding balance. We have maintained the margin requirements under the loans from both UBS entities. The outstanding balance on this loan at September 30, 2008 was $22.9 million.

In addition, on September 12, 2008, we entered into a loan and security agreement with Silicon Valley Bank with maximum available borrowings of $13.5 million. The agreement includes a $3.0 million term loan, a $5.0 million accounts receivable line of credit, and two term loans for an aggregate of $5.5 million that are guaranteed by certain of our affiliates. See Liquidity and Capital Resources for further information regarding this loan.

Our ability to continue as a going concern ultimately depends on our ability to either complete the merger with Replidyne or raise additional debt or equity capital prior to or during the quarter ending September 30, 2009. If the merger is not consummated or we are unable to raise additional debt or equity financing on terms acceptable to us, there will continue to be substantial doubt about our ability to continue as a going concern.

During fiscal year 2009, we plan to continue to expand our sales and marketing efforts, conduct research and development of product improvements and increase our manufacturing capacity to support anticipated future growth.

Financial Overview

Revenues. We expect to derive substantially all of our revenues for the foreseeable future from the sale of the Diamondback 360°. The system consists of a disposable, single-use, low-profile catheter that travels over our proprietary ViperWire guidewire and an external control unit that powers the system. Initial hospital orders usually include ten single-use catheters and guidewires, along with a control unit. Reorders for single-use catheters and guidewires occur as hospitals utilize the single-use catheters.

We apply Emerging Issues Task Force Bulletin (EITF) No. 00-21, *Revenue Arrangements with Multiple Deliverables,* the primary impact of which is to treat the Diamondback 360° as a single unit of accounting for initial customer orders until such time as we have sufficient sales history to satisfy the criteria for separate units of accounting. As such, revenues are deferred until the title and risk of loss of all Diamondback 360° components pass to the customer. Many initial shipments to customers included a loaner control unit, which we provided, until the new control unit received clearance from the FDA and was subsequently available for sale. The loaner control units were company-owned property and we maintained legal title to these units. The loaner control units were held in inventory at the time they were loaned to the various accounts under our limited commercial launch. The net inventory value of the loaner control units was $20,246 at June 30, 2007. At June 30, 2008, the loaner control units were fully reserved, as we had received FDA clearance on the new control unit and began shipping our new control unit during the quarter ended December 31, 2007. However, we could not meet the production demands of the new control units and, as a result, we continued to ship loaner control units during the quarter ended December 31, 2007. As of June 30, 2008, we had deferred revenue of $116,000, reflecting all disposable component shipments to customers pending receipt of a customer purchase order and shipment of a new control unit. We are currently meeting production demands for the new control units and all deferred revenue was recognized during the quarter ended September 30, 2008.

Cost of Goods Sold. We assemble the single-use catheter with components purchased from third-party suppliers, as well as with components manufactured in-house. The control unit and guidewires are purchased from third-party suppliers. Our cost of goods sold consists primarily of direct labor, manufacturing overhead, purchased raw materials and manufactured components. With the anticipated benefits of future cost reduction initiatives and increased volume and related economies of scale, we anticipate that gross margin percentages on single-use catheters that we assemble will be higher than those achieved on the control unit and guidewires that we purchase from third parties.

Selling, General and Administrative Expenses. Selling, general and administrative expenses include compensation for executive, sales, marketing, finance, information technology, human resources and administrative personnel, including stock-based compensation. Other significant expenses include travel and marketing costs, professional fees, and patent prosecution expenses.

Research and Development. Research and development expenses include costs associated with the design, development, testing, enhancement and regulatory approval of our products. Research and development expenses

include employee compensation including stock-based compensation, supplies and materials, consulting expenses, travel and facilities overhead. We also incur significant expenses to operate our clinical trials, including trial design, third-party fees, clinical site reimbursement, data management and travel expenses. All research and development expenses are expensed as incurred.

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Interest Income. Interest income is attributed to interest earned on deposits in investments that consist of money market funds, U.S. government securities, commercial paper and auction rate securities.

Interest Expense. Interest expense results from outstanding debt balances and the change in value of convertible preferred stock warrants and the issuance of convertible promissory notes in 2006. Convertible preferred stock warrants are classified as a liability under Financial Accounting Standards Board (FASB) Statement of Accounting Standards (SFAS) No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* and are subject to remeasurement at each balance sheet date with any change in value recognized as a component of interest expense. Immediately prior to the effective time of the merger with Replidyne, the convertible preferred stock warrants will convert into common stock warrants, thereby eliminating the preferred stock warrant liability.

Accretion of Redeemable Convertible Preferred Stock. Accretion of redeemable convertible preferred stock reflects the change in the current estimated fair market value of the preferred stock on a quarterly basis, as determined by management and the board of directors. Accretion is recorded as an increase to redeemable convertible preferred stock in the consolidated balance sheet and an increase to the loss attributable to common shareholders in the consolidated statement of operations. The redeemable convertible preferred stock will be converted into common stock immediately prior to the effective time of the merger with Replidyne. As such, the preferred stockholders will forfeit their liquidation preferences and we will no longer record accretion.

Net Operating Loss Carryforwards. We have established valuation allowances to fully offset our deferred tax assets due to the uncertainty about our ability to generate the future taxable income necessary to realize these deferred assets, particularly in light of our historical losses. The future use of net operating loss carryforwards is dependent on our attaining profitable operations and will be limited in any one year under Internal Revenue Code Section 382 due to significant ownership changes (as defined in Section 382) resulting from our equity financings. At June 30, 2008, we had net operating loss carryforwards for federal and state income tax reporting purposes of approximately $69.0 million, which will expire at various dates through fiscal 2028.

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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect amounts reported in those statements. Our estimates, assumptions and judgments, including those related to revenue recognition, excess and obsolete inventory, stock-based compensation, preferred stock and preferred stock warrants are updated as appropriate, which, in most cases, is at least quarterly. We use authoritative pronouncements, our technical accounting knowledge, cumulative business experience, judgment and other factors in the selection and application of our accounting policies. While we believe that the estimates, assumptions and judgments that we use in preparing our consolidated financial statements are appropriate, these estimates, assumptions and judgments are subject to factors and uncertainties regarding their outcome. Therefore, actual results may materially differ from these estimates.

Our significant accounting policies are described in Note 1 to our consolidated financial statements included elsewhere in this Form 10. Some of those significant accounting policies require us to make subjective or complex judgments or estimates. An accounting estimate is considered to be critical if it meets both of the following criteria: (1) the estimate requires assumptions about matters that are highly uncertain at the time the accounting estimate is made, and (2) different estimates that reasonably could have been used, or changes in the estimate that are reasonably likely to occur from period to period, would have a material impact on the presentation of our financial condition, results of operations, or cash flows. We believe that the following are our critical accounting policies and estimates:

Revenue Recognition. We recognize revenue in accordance with SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* and EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) shipment of all components has occurred or delivery of all components has occurred if the terms specify that title and risk of loss pass when products reach their destination; (3) the sales price is fixed or determinable; and (4) collectability is reasonably assured. We have no additional post-shipment or other contractual obligations or performance requirements and do

not provide any credits or other pricing adjustments affecting revenue recognition once these criteria have been met. The customer has no right of return on any component once the above criteria have been met. Payment terms are generally set at 30 days.

We derive our revenue through the sale of the Diamondback 360°, which includes single-use catheters, guidewires and control units used in the atherectomy procedure. Initial orders from all new customers require the customer to purchase the entire Diamondback 360° system, which includes multiple single-use catheters and guidewires and one control unit. Due to delays in the final FDA clearance of the new control unit and early production constraints of the new control unit, we were not able to deliver all components of the initial order. For these initial orders, we shipped and billed only for the single-use catheters and guidewires. In addition, we sent an older version of our control unit as a loaner unit with the customer s

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expectation that we would deliver and bill for a new control unit once it became available. As we had not delivered each of the individual components to all customers, we had deferred the revenue for the entire amount billed for single-use catheters and guidewires shipped to the customers that had not received the new control unit. Those billings totaled $116,000 at June 30, 2008, which amount had been deferred pending receipt of a customer purchase order and shipment of a new control unit. After the initial order, customers are not required to purchase any additional disposable products from us. Once we had delivered the new control unit to a customer, we recognized revenue that was previously deferred and revenue for subsequent reorders of single-use catheters, guidewires and additional new control units when the criteria of SAB No. 104 were met. We are currently meeting production demands for the new control units and all deferred revenue was recognized during the quarter ended September 30, 2008.

Investments. We classify all investments as available-for-sale. Investments are recorded at fair value and unrealized gains and losses are recorded as a separate component of shareholders deficiency until realized. Realized gains and losses are accounted for on the specific identification method. We have historically placed our investments primarily in auction rate securities, U.S. government securities, and commercial paper. These investments, a portion of which had original maturities beyond one year, were classified as short-term based on their liquid nature. The securities that had stated maturities beyond one year had certain economic characteristics of short-term investments due to a rate-setting mechanism and the ability to sell them through a Dutch auction process that occurred at pre-determined intervals, primarily every 28 days. For the year ended June 30, 2008 and three months ended September 30, 2008, the amount of gross realized gains and losses related to sales of investments were insignificant.

In February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $23.0 million of our auction rate securities held at June 30, 2008 and September 30, 2008. Currently, these affected securities are not liquid and will not become liquid until a future auction for these investments is successful, they are redeemed by the issuer, they mature, or they are repurchased by UBS. As a result, at June 30, 2008 and September 30, 2008, we have classified the fair value of the auction rate securities as a long-term asset. Starting in February 2008, interest rates on all auction rate securities were reset to temporary predetermined penalty or maximum rates. These maximum rates are generally limited to a maximum amount payable over a 12 month period equal to a rate based on the trailing 12-month average of 90-day treasury bills, plus 120 basis points. These maximum allowable rates range from 2.7% to 4.0% of par value per year. We have collected all interest due on our auction rate securities and have no reason to believe that we will not collect all interest due in the future. We do not expect to receive the principal associated with our auction rate securities until the earlier of a successful auction, their redemption by the issuer or their maturity. On March 28, 2008, we obtained a margin loan from UBS Financial Services, Inc., the entity through which we originally purchased our auction rate securities, for up to $12.0 million, which was secured by the $23.0 million par value of our auction rate securities. The outstanding balance on this loan at June 30, 2008 was $11.9 million. On August 21, 2008, we replaced this loan with a margin loan from UBS Bank USA, which increased maximum borrowings available to $23.0 million. This maximum borrowing amount is not set forth in the written agreement for the loan and may be adjusted from time to time by UBS Bank in its sole discretion. The margin loan has a floating interest rate equal to 30-day LIBOR, plus 1.0%. The loan is due on demand and UBS Bank will require us to repay it in full from the proceeds received from a public equity offering where net proceeds exceed $50.0 million. In addition, if at any time any of our auction rate securities may be sold, exchanged, redeemed, transferred or otherwise conveyed for no less than their par value, then we must immediately effect such a transfer and the proceeds must be used to pay down outstanding borrowings under this loan. The margin requirements are determined by UBS Bank but are not included in the written loan agreement and are therefore subject to change. From August 21, 2008, the date this loan was initially funded, through the date of this Form 10, the margin requirements included maximum borrowings, including interest, of $23.0 million. If these margin requirements are not maintained, UBS Bank may require us to make a loan payment in an amount necessary to comply with the applicable margin requirements or demand repayment of the entire outstanding balance. We have maintained the margin requirements under the loans from both UBS entities. The outstanding balance on this loan at September 30, 2008 was $22.9 million.

In accordance with EITF 03-01 and FSP FAS 115-1 and 124-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments,* we review several factors to determine whether a loss is

other-than-temporary. These factors include but are not limited to: (1) the length of time a security is in an unrealized loss position, (2) the extent to which fair value is less than cost, (3) the financial condition and near term prospects of the issuer, and (4) our intent and ability to hold the security for a period of time sufficient to allow for any unanticipated recovery in fair value.

We recorded an other-than-temporary impairment loss of $1.3 million relating to our auction rate securities in our statement of operations for the year ended June 30, 2008 and recorded an unrealized loss of $0.3 million relating to our auction rate securities in other comprehensive income (loss) for the three months ended September 30, 2008. We determined the fair value of our auction rate securities and quantified the other-than-temporary impairment loss and the unrealized loss with the assistance of ValueKnowledge LLC, an independent third party valuation firm, which utilized various valuation methods and considered, among other factors, estimates of present value of the auction rate securities based upon expected cash flows, the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value, the likelihood of a return of liquidity to the market for these securities and the potential to sell the securities in secondary markets.

At June 30, 2008, we concluded that no weight should be given to the value indicated by the secondary markets for student loan-backed auction rate securities similar to those we hold because these markets have very low transaction volumes and consist primarily of private transactions with minimal disclosure, transactions may not be representative of the actions of typically-motivated buyers and sellers and we do not currently intend to sell in the secondary

markets. However, we did consider the secondary markets for certain mortgage-backed securities to estimate the market yields attributable to CSI s auction rate securities, but determined that these secondary markets do not provide a sufficient basis of comparison for the auction rate securities that we hold and, accordingly, attributed no weight to the values of these mortgage-backed securities indicated by the secondary markets.

At June 30, 2008, we attributed a weight of 66.7% to estimates of present value of the auction rate securities based upon expected cash flows and a weight of 33.3% to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or willingness of third parties to provide financing in the market against the par value of those securities. The attribution of these weights required the exercise of valuation judgment. A measure of liquidity is available from borrowing, which led to the 33.3% weight attributed to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or the willingness of third parties to provide financing in the market against the par value of those securities. However, borrowing does not eliminate exposure to the risk of holding the securities, so the weight of 66.7% attributed to the present value of the auction rate securities based upon expected cash flows reflects the expectation that the securities are likely to be held for an uncertain period. We focused on these methodologies because no certainty exists regarding how the auction rate securities will be eventually converted to cash and these methodologies represent the most likely possible outcomes. To derive estimates of the present value of the auction rate securities based upon expected cash flows, we used the securities expected annual interest payments, ranging from 2.7% to 4.0% of par value, representing estimated maximum annual rates under the governing documents of the auction rate securities; annual market interest rates, ranging from 4.5% to 5.8%, based on observed traded, state sponsored, taxable certificates rated AAA or lower and issued between June 15 and June 30, 2008; and a range of expected terms to liquidity.

At June 30, 2008, our weighting of the valuation methods indicates an implied term to liquidity of approximately 3.5 years. The implied term to liquidity of approximately 3.5 years is a result of considering a range in possible timing of the various scenarios that would allow a holder of the auction rate securities to convert the auction rate securities to cash ranging from zero to ten years, with the highest probability assigned to the range of zero to five years. Several sources were consulted but no individual source of information was relied upon to arrive at our estimate of the range of possible timing to convert the auction rate securities to cash or the implied term to liquidity of approximately 3.5 years. The primary reason for the fair value being less than cost related to a lack of liquidity of the securities, rather than the financial condition and near term prospects of the issuer.

At September 30, 2008, we concluded that no weight should be given to the value indicated by the secondary markets for student loan backed auction rate securities similar to those we hold because these markets have very low transaction volumes and consist primarily of private transactions with minimal disclosure and transactions may not be representative of the actions of typically-motivated buyers and sellers and we do not currently intend to sell in the secondary markets. However, we did consider the secondary markets for certain mortgage-backed securities to estimate the market yields attributable to our auction rate securities, but determined that these secondary markets do not provide a sufficient basis of comparison for the auction rate securities that we hold and, accordingly, attributed no weight to the values of these mortgage-backed securities indicated by the secondary markets.

At September 30, 2008, we concluded that no weight should be given to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value based on low issuer call activity, so we attributed a weight of 100.0% to estimates of present value of the auction rate securities based upon expected cash flows. The attribution of weights to the valuation factors required the exercise of valuation judgment. The selection of a weight of 100.0% attributed to the present value of the auction rate securities based upon expected cash flows reflects the expectation, in absence of the Auction Rate Securities Rights Prospectus discussed below, that no certainty exists regarding how the auction rate securities will be eventually converted to cash and this methodology represents the possible outcome. To derive estimates of the present value of the auction rate securities based upon expected cash flows, we used the securities expected annual interest payments, ranging from 2.1% to 5.4% of par value, representing estimated maximum annual rates under the governing documents of the auction rate securities; annual market interest rates, ranging from 3.9% to 5.4%, based on observed traded, state sponsored, taxable certificates rated AAA or lower and issued between September 29 and September 30, 2008; certain mortgage-backed securities and indices; and a range of expected terms to liquidity.

Our weighting of the valuation methods as of September 30, 2008 indicates an implied term to liquidity of approximately five years in absence of the Auction Rate Securities Rights Prospectus discussed below. The implied term to liquidity of approximately five years is a result of considering a range in possible timing of the various scenarios that would allow a holder of the auction rate securities to convert the auction rate securities to cash ranging from zero to ten years, with the highest probability assigned to five years. UBS issued a comprehensive settlement, which was confirmed by an Auction Rate Securities Rights Prospectus issued by UBS on October 7, 2008, in which there is a possibility of redemption by UBS at par value for the auction rate securities held by us between June 30, 2010 and July 2, 2012. Under the comprehensive settlement, UBS has committed to purchase a total of $8.3 billion of auction rate securities at par value from most private clients during the two-year period beginning January 1, 2009. Private clients and charities holding less than $1.0 million in household assets at UBS were able to avail themselves of this relief beginning October 31, 2008. From mid-September 2008, UBS began to provide loans at no cost to its clients for the par value of their auction rate security holdings. In addition, UBS has also committed to provide liquidity solutions to institutional investors and has agreed to purchase all or any of a remaining $10.3 billion in auction rate securities at par value from its institutional clients beginning June 10, 2010. These auction rate security rights are not transferable, tradable or marginable. We have not considered the liquidity potentially generated by UBS s comprehensive settlement or the UBS loan in our valuation of the 19 auction rate certificates held by us because the settlement rights were not enforceable at September 30, 2008. The repurchase arrangement and lending arrangement may represent separate contracts, securities or other assets that have not been considered in the valuation of the auction rate securities.

Our auction rate securities include AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program. These auction rate securities continue to be AAA rated auction rate securities subsequent to the failed auctions that began in February 2008.

In addition to the valuation procedures described above, we considered (i) our current inability to hold these securities for a period of time sufficient to allow for an unanticipated recovery in fair value based on our current liquidity, history of operating losses, and management s estimates of required cash for continued product development and sales and marketing expenses, and (ii) failed auctions and the anticipation of continued failed auctions for all of our auction rate securities.

Based on the factors described above, we recorded the entire amount of impairment loss identified for the year ended June 30, 2008 of $1.3 million as other-than-temporary and recorded the decrease in fair value of $0.3 million as an unrealized loss for the three months ended September 30, 2008. We did not identify or record any additional realized or unrealized gains or losses for the year ended June 30, 2008 or the three months ended September 30, 2008. We will continue to monitor and evaluate the value of our investments each reporting period for further possible impairment or unrealized loss. Although we currently do not intend to do so, we may consider selling our auction rate securities in the secondary markets in the future, which may require a sale at a substantial discount to the stated principal value of these securities.

Excess and Obsolete Inventory. We have inventories that are principally comprised of capitalized direct labor and manufacturing overhead, raw materials and components, and finished goods. Due to the technological nature of our products, there is a risk of obsolescence to changes in our technology and the market, which is impacted by exogenous technological developments and events. Accordingly, we write down our inventories as we become aware of any situation where the carrying amount exceeds the estimated realizable value based on assumptions about future demands and market conditions. The evaluation includes analyses of inventory levels, expected product lives, product at risk of expiration, sales levels by product and projections of future sales demand.

Stock-Based Compensation. Effective July 1, 2006, we adopted SFAS No. 123(R), *Share-Based Payment*, as interpreted by SAB No. 107, using the prospective application method, to account for stock-based compensation expense associated with the issuance of stock options to employees and directors on or after July 1, 2006. The unvested compensation costs at July 1, 2006, which relate to grants of options that occurred prior to the date of adoption of SFAS No. 123(R), will continue to be accounted for under Accounting Principles Board (APB) No. 25, *Accounting for Stock Issued to Employees*. SFAS No. 123(R) requires us to recognize stock-based compensation expense in an amount equal to the fair value of share-based payments computed at the date of grant. The fair value of all employee and director stock options is expensed in the consolidated statements of operations over the related

vesting period of the options. We calculated the fair value on the date of grant using a Black-Scholes option pricing model.

To determine the inputs for the Black-Scholes option pricing model, we are required to develop several assumptions, which are highly subjective. These assumptions include:

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our common stock s volatility;

the length of our options lives, which is based on future exercises and cancellations;

the number of shares of common stock pursuant to which options which will ultimately be forfeited;

the risk-free rate of return; and

future dividends.

We use comparable public company data to determine volatility, as our common stock has not yet been publicly traded. We use a weighted average calculation to estimate the time our options will be outstanding as prescribed by Staff Accounting Bulletin No. 107, *Share-Based Payment*. We estimate the number of options that are expected to be forfeited based on our historical experience. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for the estimated life of the option. We use our judgment and expectations in setting future dividend rates, which is currently expected to be zero.

The absence of an active market for our common stock also requires our management and board of directors to estimate the fair value of our common stock for purposes of granting options and for determining stock-based compensation expense. In response to these requirements, our management and board of directors estimate the fair market value of common stock at each date at which options are granted based upon stock valuations and other qualitative factors. We have conducted stock valuations using two different valuation methods: the option pricing method and the probability weighted expected return method, or PWERM. The option pricing method assumes a liquidation of a company and treats common and preferred stock as call options on the enterprise value. The option pricing method is often used when the possible outcomes for a liquidity event are deemed to have equal likelihood and when valuing securities with a high degree of uncertainty regarding potential future values. We used the option pricing method for valuations of our common stock as of July 19, 2006, December 31, 2006, June 29, 2007 and September 30, 2007, as we deemed all liquidity events to have equal likelihood at those dates. All of these valuations were conducted retrospectively. We began using the PWERM in contemporaneous valuations of our common stock as of December 31, 2007, March 31, 2008 and June 30, 2008, and September 30, 2008, as of which time we had commenced significant efforts in connection with our initial public offering process and the probability of a public offering or other specific liquidation event, including the merger with Replidyne, had increased. Accordingly, management and the board of directors determined that the PWERM would be more appropriate than the option pricing method. For the PWERM, we estimated the likely return to stockholders based upon our becoming a public company through the merger with Replidyne or an initial public offering, being acquired or remaining a private company, and employed comparable public company, merger and acquisition transaction, and discounted cash flow analysis. These values were adjusted and weighted based on probability of occurrence. As of September 30, 2008, we assumed a 70% probability of completing the merger with Replidyne, a 10% probability of completing an initial public offering, a 15% probability of being acquired, and a 5% probability of remaining a private company.

Both the option pricing method and the PWERM have taken into consideration the following factors:

Financing Activity: Between July 19, 2006 and October 3, 2006, we sold $27.0 million in Series A convertible preferred stock at $5.71 per share; between May 16, 2007 and September 19, 2007, we sold $18.6 million in Series A-1 convertible preferred stock at $8.50 per share; and between November 13, 2007 and December 17, 2007, we sold $20.0 million in Series B convertible preferred stock at $9.25 per share. New and existing investors participated in the convertible preferred stock offerings, while certain existing investors declined the opportunity to participate. As of each valuation date, management and the board of directors considered the differences between the valuation of the common stock and the most recent price of our preferred stock and determined that such differences were reasonable and accurately reflected the anticipated time until a liquidity event.

Preferred Stock Rights and Preferences: The holders of preferred stock are entitled to receive cash dividends at the rate of 8% of the original purchase price, which dividends accrue, whether or not earned or declared, and whether or not we have legally available funds. Holders of preferred stock have the right to require us to redeem in cash 30% of the original amount on the fifth year anniversary of the purchase agreement for the applicable series of preferred stock, 30% after the sixth year and 40% after the seventh year. The price we would pay for the redeemed shares would be the greater of (i) the price per share paid for the preferred stock, plus all accrued and unpaid dividends, or (ii) the fair market value of the preferred stock at the time of redemption as determined by a professional appraiser. The holders of the preferred stock have the right to convert, at their option, their shares into common stock on a share for share basis. The holders of preferred stock also have the right to designate, and have designated, two individuals to our board of directors. Finally, in the event of our liquidation or winding up, the holders of preferred stock are entitled to receive an amount equal to (i) the price paid for the preferred shares, plus (ii) all dividends accrued and unpaid before any

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payments are made to holders of stock junior to the preferred stock. Our remaining net assets, if any, would be distributed to the holders of preferred and common stock based on their ownership amounts assuming the conversion of the preferred stock, except the total amount to be distributed to the preferred stock is subject to certain return on investment limitations. The aggregate liquidation preferences of our preferred stock at the dates listed below are as follows:

Date	Aggregate Liquidation Preference
September 30, 2006	$25.4 million
December 31, 2006	$27.9 million
March 31, 2007	$28.4 million
June 30, 2007	$37.3 million
September 30, 2007	$48.3 million
December 31, 2007	$69.3 million
March 31, 2008	$70.6 million
June 30, 2008	$72.0 million
September 30, 2008	$73.3 million

Growth of Executive Management Team: Management and the board of directors considered the development and growth of our executive management team, including the hiring of our Vice President of Sales and Vice President of Business Development to build our sales organization, our Vice President of Marketing to build our sales and marketing function, and our Chief Executive Officer.

OASIS Clinical Trial: The progress of our OASIS clinical trial, which began enrollment in January 2006 and was completed in January 2007.

FDA Process: In May 2007, we applied for 510(k) clearance from the FDA for the Diamondback 360° system. We received 510(k) clearance for use of the Diamondback 360° with a hollow crown as a therapy for patients with PAD in August 2007, and we received 510(k) clearances in October 2007 for the updated control unit used with the Diamondback 360° and in November 2007 for the Diamondback 360° with a solid crown.

Commercial Launch: Upon receiving FDA 510(k) clearance, we began shipping product to customers under our limited commercial launch plan. During the quarter ended March 31, 2008, we began a full commercial launch of the Diamondback 360°.

Merger and Acquisition Process: During the period from July 2007 through September 2007, we engaged investment bankers to explore potential merger and acquisition opportunities. CSI began its discussions with Replidyne in August 2008.

Offering Process: Beginning in the quarter ended June 30, 2007, we began discussions with investment bankers concerning our initial public offering process, and the organizational meeting for our initial public offering occurred in October 2007. We filed a registration statement on January 22, 2008 and filed several amendments. As a result of the volatile equity markets, as of September 30, 2008 it was probable that we would not complete the initial public offering process during the quarter ending December 31, 2008. Therefore, previously capitalized offering costs of approximately $1.7 million were expensed during the quarter ended September 30, 2008. On November 4, 2008, we withdrew the registration statement in conjunction with the announcement of the execution of the merger agreement with Replidyne.

Revenues: We recognized $22.2 million and $11.6 million in revenues for the year ended June 30, 2008 and three months ended September 30, 2008, respectively.

Our management and board of directors also considered the valuations of comparable public companies, our cash and working capital amounts, and additional objective and subjective factors relating to our business. For each valuation, our management and board of directors considered all of the factors that they considered to be relevant at the time and did not rely exclusively on any particular factors. Certain factors described with respect to each valuation represented progress in the development of our business, which reduced risk and improved the probability that we would achieve our business plan. In addition, the order in which we have described these factors in this Form 10 does not represent the relative importance or weight given to any of the factors.

The following highlights key milestones that contributed to the valuation of our common stock in each of our valuations:

Valuation as of July 19, 2006

This valuation estimated that the fair market value of our common stock as of July 19, 2006 was $2.43 per share, taking into consideration the sale of Series A convertible preferred stock at $5.71 per share and the hiring of our Vice President of Sales and Vice President of Business Development to begin the process of building a sales organization in the period from July 2006 through September 2006.

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Valuation as of December 31, 2006

This valuation estimated that the fair market value of our common stock as of December 31, 2006 was $2.79 per share, taking into consideration the sale of Series A convertible preferred stock at $5.71 per share, changes in the value of comparable public companies, the substantial completion of enrollment for the OASIS clinical trial, and the hiring of our Vice President of Marketing to continue building our sales and marketing function.

Valuation as of June 29, 2007

This valuation estimated that the fair market value of our common stock as of June 29, 2007 was $5.95 per share, taking into consideration the sale of Series A-1 convertible preferred stock at $8.50 per share, the completion of the OASIS clinical trial, the hiring of our Chief Executive Officer, our application for FDA 510(k) clearance for the Diamondback 360°, and the commencement of discussions with investment bankers regarding the initial public offering process.

Valuation as of September 30, 2007

This valuation estimated that the fair market value of our common stock as of September 30, 2007 was $7.36 per share, taking into consideration the sale of Series A-1 convertible preferred stock at $8.50 per share, expectation of the sale of Series B convertible preferred stock at $9.25 per share, receipt of FDA 510(k) clearance for the Diamondback 360°, continued discussions with investment bankers regarding the initial public offering process, the engagement of investment bankers to explore potential merger and acquisition opportunities, and the limited commercial launch of the Diamondback 360°.

Valuation as of December 31, 2007

This valuation estimated that the fair market value of our common stock as of December 31, 2007 was $8.44 per share, taking into consideration the sale of Series B convertible preferred stock at $9.25 per share, receipt of FDA 510(k) clearances for the updated control unit for the Diamondback 360° and for the Diamondback 360° with a solid crown, revenues of $4.6 million in revenue for the quarter ended December 31, 2007, and the holding of preparatory meetings as part of the initial public offering process.

Valuation as of March 31, 2008

This valuation estimated that the fair market value of our common stock as of March 31, 2008 was $10.27 per share, taking into consideration the sale of Series B convertible preferred stock at $9.25 per share during the quarter ending December 31, 2007, initiation of the full commercial launch of the Diamondback 360°, revenues of $12.3 million for the nine months ended March 31, 2008, and substantial completion of some of the milestones in the initial public offering process.

Valuation as of June 30, 2008

This valuation estimated that the fair market value of our common stock as of June 30, 2008 was $10.22 per share, taking into consideration revenues of $22.2 million for the year ended June 30, 2008 and substantial completion of additional milestones in the initial public offering process. This valuation also considered uncertain conditions in the public markets, which resulted in a slightly lower valuation of our common stock than the March 31, 2008 valuation.

Valuation as of September 30, 2008

This valuation estimated that the fair market value of our common stock as of September 30, 2008 was $10.25 per share, taking into consideration revenues of $11.6 million for the three months ended September 30, 2008, along with the estimated valuations associated with various liquidation scenarios considered under the PWERM method including the proposed merger with Replidyne.

Our management and board of directors set the exercise prices for option grants based upon their best estimate of the fair market value of our common stock at the time they made such grants, taking into account all information available at those times. In some cases, management and the board of directors made retrospective assessments of the valuation of our common stock at later dates and determined that the fair market value of our common stock at the times the grants were made was different than the exercise prices established for those grants. In cases in which the fair market value was higher than the exercise price, we recognized stock-based compensation expense for the excess of the fair market value of the common stock over the exercise price.

The following table sets forth the exercise prices of options granted during fiscal year 2008 and three months ended September 30, 2008, and the fair market value of our common stock, as determined by our management and board of

directors, on the dates of the option grants:

Date of Option Grant	Number of Shares	Exercise Price	Fair Market Value Per Share Assigned by Management and Board of Directors
August 7, 2007	402,500	5.11	5.95
October 9, 2007	331,083	5.11	7.36
November 13, 2007	154,917	7.36	7.90
December 12, 2007	775,000	7.86	8.44
December 31, 2007	1,056,234	7.86	8.44
February 14, 2008	172,213	9.04	9.36

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We also have granted restricted stock awards with vesting terms ranging from 12 to 36 months. The following table sets forth the number of shares of restricted stock awarded and the fair market value of our common stock, as determined by our management and board of directors, on the dates of the restricted stock award grants:

Date of Restricted Stock Award Grant	Number of Shares	Fair Market Value per Share Assigned by Management and Board of Directors
December 12, 2007	204,338	$ 8.44
February 14, 2008	307,200	$ 9.36
April 14, 2008	75,000	$ 10.27
April 22, 2008	253,600	$ 10.27
July 22, 2008	161,823	$ 10.22

Preferred Stock. Effective in fiscal 2007, with the sale of our Series A and A-1 convertible preferred stock, we began recording the current estimated fair value of our convertible preferred stock on a quarterly basis based on the fair market value of that stock as determined by our management and board of directors. In accordance with Accounting Series Release No. 268, *Presentation in Financial Statements of Redeemable Preferred Stocks* and EITF Abstracts, Topic D-98, *Classification and Measurement of Redeemable Securities*, we record changes in the current fair value of our redeemable convertible preferred stock in the consolidated statements of changes in shareholders (deficiency) equity and comprehensive (loss) income and consolidated statements of operations as accretion of redeemable convertible preferred stock.

In connection with the preparation of our financial statements, our management and board of directors established what they believe to be the fair value of our Series A convertible preferred stock, Series A-1 convertible preferred stock and Series B convertible preferred stock. This determination was based on concurrent significant stock transactions with third parties and a variety of factors, including our business milestones achieved and future financial projections, our position in the industry relative to our competitors, external factors impacting the value of our stock in the marketplace, the stock volatility of comparable companies in our industry, general economic trends and the application of various valuation methodologies. The following table shows the fair market value of one share of our Series A convertible preferred stock, Series A-1 convertible preferred stock and Series B convertible preferred stock at the dates noted during the fiscal year ended June 30, 2008 and three months ended September 30, 2008:

Date	Series A Convertible Preferred Stock	Series A-1 Convertible Preferred Stock	Series B Convertible Preferred Stock
September 30, 2007	9.20	9.20	
December 31, 2007	9.25	9.25	9.25
March 31, 2008	10.81	10.81	10.81
June 30, 2008	10.81	10.81	10.81
September 30, 2008	10.81	10.81	10.81

Preferred Stock Warrants. Freestanding warrants and other similar instruments related to shares that are redeemable are accounted for in accordance with SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, and its related interpretations. Under SFAS No. 150, the freestanding warrant that is related to our redeemable convertible preferred stock is classified as a liability on the balance sheet as of June 30, 2008 and September 30, 2008. The warrant is subject to remeasurement at each balance sheet date and any change in fair value is recognized as a component of interest expense. Fair value is measured using the Black-Scholes option pricing model. We will continue to adjust the liability for changes in fair value until the earlier of the exercise or expiration of the warrant or the completion of a liquidation event, including the completion of an initial public

offering with gross cash proceeds to us of at least $40.0 million, at which time all preferred stock warrants will be converted into warrants to purchase common stock and, accordingly, the liability will be reclassified to equity.

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Results of Operations

The following table sets forth, for the periods indicated, our results of operations expressed as dollar amounts (in thousands), and, for certain line items, the changes between the specified periods expressed as percent increases or decreases:

	Years Ended June 30,			Years Ended June 30,			Three Months Ended September 30,		
	2006	2007	Percent Change	2007	2008	Percent Change	2007	2008	Percent Change
Revenues	$	$		$	$ 22,177	100.0%	$	$ 11,646	100.0%
Cost of goods sold					8,927	100.0	539	3,881	620.0
Gross profit					13,250	100.0	(539)	7,765	1,540.6
Expenses:									
Selling, general and administrative	1,735	6,691	285.6%	6,691	35,326	428.0	3,552	16,424	362.4
Research and development	3,168	8,446	166.6	8,446	16,068	90.2	3,328	4,955	48.9
Total expenses	4,903	15,137	208.7	15,137	51,394	239.5	6,880	21,379	210.7
Loss from operations	(4,903)	(15,137)	208.7	(15,137)	(38,144)	152.0	(7,419)	(13,614)	83.5
Other income (expense):									
Interest expense	(48)	(1,340)	2,691.7	(1,340)	(923)	31.1	(300)	(227)	24.3
Interest income	56	881	1,473.2	881	1,167	32.5	278	142	48.9
Impairment on investments					(1,267)				
Total other income (expense)	8	(459)	5,837.5	(459)	(1,023)	122.9	(22)	(85)	286.4
Net loss	(4,895)	(15,596)	218.6	(15,596)	(39,167)	151.1	(7,441)	(13,699)	84.1
Accretion of redeemable convertible preferred stock		(16,835)		(16,835)	(19,422)	15.4	(4,853)		
Net loss available to common shareholders	$ (4,895)	$ (32,431)	562.5%	$ (32,431)	$ (58,589)	80.7%	$ (12,294)	$ (13,699)	11.4%

Comparison of the Three Months Ended September 30, 2007 with the Three Months Ended September 30, 2008

Revenues. We generated revenues of $11.6 million during the three months ended September 30, 2008 attributable to sales of the Diamondback 360°. Since September 2007, we have expanded our sales and marketing efforts and have shipped more than 10,000 single-use catheters through September 30, 2008. We expect our revenue to increase as we continue to expand our sales and marketing teams to increase penetration of the U.S. PAD market and introduce new and improved products.

We have applied EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*, the primary impact of which was to treat the Diamondback 360° as a single unit of accounting for initial customer orders. As such, revenues were deferred until the title and risk of loss of each Diamondback 360° component, consisting of catheters, guidewires, and a control unit, were transferred to the customer based on the shipping terms. Many initial shipments to customers also included a loaner control unit, which we provided, until the new control unit received clearance from the FDA and was subsequently available for sale. The loaner control units were company-owned property and we maintained legal title to these units. Accordingly, we had deferred revenue of $1.4 million as of September 30, 2007, reflecting all component shipments to customers pending receipt of a customer purchase order and shipment of a new control unit. We had deferred revenue of $116,000 as of June 30, 2008, all of which was recognized during the quarter ended September 30, 2008.

Cost of Goods Sold. Cost of goods sold increased by $3.4 million, from $539,000 for the three months ended September 30, 2007 to $3.9 million for the three months ended September 30, 2008. These amounts represent the cost of materials, labor and overhead for single-use catheters, guidewires and control units, and the increase reflects our increased sales. Cost of goods sold for the three months ended September 30, 2007 and 2008 includes $27,000 and $176,000, respectively, for stock-based compensation. We expect that cost of goods sold as a percentage of revenues will continue to decrease as we implement cost reduction initiatives and benefit from increased volume and related economies of scale.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased by $12.8 million, from $3.6 million for the three months ended September 30, 2007 to $16.4 million for the three months ended September 30, 2008. The primary reasons for the increase included the continued building of our sales and marketing team, contributing $9.6 million, and significant consulting and professional services, contributing $2.5 million, which includes $1.7 million in previously capitalized offering costs. In addition, stock-based compensation increased from $277,000 for the three months ended September 30, 2007 to $1.4 million for the three months ended September 30, 2008. We expect our selling, general and administrative expenses to increase significantly due primarily to the costs associated with expanding our sales and marketing organization to further commercialize our products.

Research and Development Expenses. Our research and development expenses increased by $1.6 million, from $3.3 million for the three months ended September 30, 2007 to $5.0 million for the three months ended September 30, 2008. Research and development spending increased as we continued projects to improve our product, such as the development of a new control unit, shaft designs and crown designs, and continued human feasibility trials in the coronary market. In addition, stock-based compensation increased from $73,000 for the three months ended September 30, 2007 to $112,000 for the three months ended September 30, 2008. We expect our research and development expenses to increase as we attempt to expand our product portfolio within the market for the treatment of peripheral arteries and leverage our core technology into the coronary market.

Interest Income. Interest income decreased by $136,000, from $278,000 for the three months ended September 30, 2007 to $142,000 for the three months ended September 30, 2008. The decrease was primarily due to lower average cash and cash equivalents and investment balances. Average cash and cash equivalent and investment balances were $21.6 million and $10.0 million for the three months ended September 30, 2007 and 2008, respectively.

Interest Expense. Interest expense decreased by $73,000, from $300,000 for the three months ended September 30, 2007 to $227,000 for the three months ended September 30, 2008. Interest expense during the three months ended September 30, 2007 was due to the change in the fair value of convertible preferred stock warrants. Interest expense during the three months ended September 30, 2008 was due to outstanding debt balances.

Accretion of Redeemable Convertible Preferred Stock. There was no accretion of redeemable convertible preferred stock for the three months ended September 30, 2008, as compared to accretion of redeemable convertible preferred stock of $4.9 million for the three months ended September 30, 2007. Accretion of redeemable convertible preferred stock reflects the change in estimated fair value of preferred stock at the balance sheet dates, and there was no change in the estimated fair value as of September 30, 2008 compared to June 30, 2008.

Comparison of the Fiscal Year Ended June 30, 2007 with the Fiscal Year Ended June 30, 2008

Revenues. We generated revenues of $22.2 million during the year ended June 30, 2008 attributable to sales of the Diamondback 360° to customers following FDA clearance in August 2007. We commenced a limited commercial introduction of the Diamondback 360° in the United States in September 2007, followed by a full commercial launch in the quarter ended March 31, 2008. We shipped more than 6,800 single-use catheters through June 30, 2008.

We have applied EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*, the primary impact of which was to treat the Diamondback 360° as a single unit of accounting for initial customer orders. As such, revenues are deferred until the title and risk of loss of each Diamondback 360° component, consisting of catheters, guidewires, and a control unit, are transferred to the customer based on the shipping terms. Many initial shipments to customers also included a loaner control unit, which we provided, until the new control unit received clearance from the FDA and was subsequently available for sale. The loaner control units were company-owned property and we maintained legal title to these units. Accordingly, we had deferred revenue of $116,000 as of June 30, 2008, reflecting all component shipments to customers pending receipt of a customer purchase order and shipment of a new control unit. All deferred revenue was recognized during the quarter ended September 30, 2008.

Cost of Goods Sold. For the year ended June 30, 2008, cost of goods sold was $8.9 million. This amount represents the cost of materials, labor and overhead for single-use catheters, guidewires and control units shipped subsequent to obtaining FDA clearance for the Diamondback 360° in August 2007. Cost of goods sold for the year ended June 30, 2008 includes $232,000 for stock based compensation.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased by $28.6 million, from $6.7 million for the year ended June 30, 2007 to $35.3 million for the year ended June 30, 2008. The primary reasons for the increase included the building of our sales and marketing team, contributing $18.6 million, and significant consulting and professional services, contributing $2.1 million. In addition, stock based compensation increased from $327,000 for the year ended June 30, 2007 to $6.9 million for the year ended June 30, 2008.

Research and Development Expenses. Our research and development expenses increased by $7.7 million, from $8.4 million for the year ended June 30, 2007 to $16.1 million for the year ended June 30, 2008. Research and development spending increased as we initiated projects to improve our product, such as the development of a new control unit, shaft designs and crown designs, and began human feasibility trials in the coronary market. In addition, stock based compensation increased from $63,000 for the year ended June 30, 2007 to $297,000 for the year ended June 30, 2008.

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Interest Income. Interest income increased by $286,000, from $881,000 for the year ended June 30, 2007 to $1.2 million for the year ended June 30, 2008. The increase was primarily due to higher average cash and cash equivalents and investment balances and higher rates of return. Average cash and cash equivalent and investment balances were $18.5 million and $20.4 million for the years ended June 30, 2007 and 2008, respectively.

Interest Expense. Interest expense decreased by $417,000, from $1.3 million for the year ended June 30, 2007 to $923,000 for the year ended June 30, 2008. The decrease was due to the smaller increase in the fair value of convertible preferred stock warrants from fiscal 2007 to fiscal 2008.

Impairment of investments. Due to the recent conditions in the global credit markets that have prevented us from liquidating our holdings of auction rate securities, we recorded an other-than-temporary impairment loss of $1.3 million relating to these auction rate securities in our statement of operations for the year ended June 30, 2008 and recorded an unrealized loss of $0.3 million relating to our auction rate securities in other comprehensive income (loss) for the three months ended September 30, 2008. We determined the fair value of our auction rate securities and quantified the other-than-temporary impairment loss and the unrealized loss with the assistance of ValueKnowledge LLC, an independent third party valuation firm, which utilized various valuation methods and considered, among other factors, estimates of present value of the auction rate securities based upon expected cash flows, the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value, the likelihood of a return of liquidity to the market for these securities and the potential to sell the securities in secondary markets.

At June 30, 2008, we concluded that no weight should be given to the value indicated by the secondary markets for student loan-backed auction rate securities similar to those we hold because these markets have very low transaction volumes and consist primarily of private transactions with minimal disclosure, transactions may not be representative of the actions of typically-motivated buyers and sellers and we do not currently intend to sell in the secondary markets. However, we did consider the secondary markets for certain mortgage-backed securities to estimate the market yields attributable to our auction rate securities, but determined that these secondary markets do not provide a sufficient basis of comparison for the auction rate securities that we hold and, accordingly, attributed no weight to the values of these mortgage-backed securities indicated by the secondary markets.

At June 30, 2008, we attributed a weight of 66.7% to estimates of present value of the auction rate securities based upon expected cash flows and a weight of 33.3% to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or willingness of third parties to provide financing in the market against the par value of those securities. The attribution of these weights required the exercise of valuation judgment. A measure of liquidity is available from borrowing, which led to the 33.3% weight attributed to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or the willingness of third parties to provide financing in the market against the par value of those securities. However, borrowing does not eliminate exposure to the risk of holding the securities, so the weight of 66.7% attributed to the present value of the auction rate securities based upon expected cash flows reflects the expectation that the securities are likely to be held for an uncertain period. We focused on these methodologies because no certainty exists regarding how the auction rate securities will be eventually converted to cash and these methodologies represent the most likely possible outcomes. To derive estimates of the present value of the auction rate securities based upon expected cash flows, we used the securities expected annual interest payments, ranging from 2.7% to 4.0% of par value, representing estimated maximum annual rates under the governing documents of the auction rate securities; annual market interest rates, ranging from 4.5% to 5.8%, based on observed traded, state sponsored, taxable certificates rated AAA or lower and issued between June 15 and June 30, 2008; and a range of expected terms to liquidity.

At June 30, 2008, our weighting of the valuation methods indicates an implied term to liquidity of approximately 3.5 years. The implied term to liquidity of approximately 3.5 years is a result of considering a range in possible timing of the various scenarios that would allow a holder of the auction rate securities to convert the auction rate securities to cash ranging from zero to ten years, with the highest probability assigned to the range of zero to five years. Several sources were consulted but no individual source of information was relied upon to arrive at our estimate of the range of possible timing to convert the auction rate securities to cash or the implied term to liquidity of approximately 3.5 years. The primary reason for the fair value being less than cost related to a lack of liquidity of the securities,

rather than the financial condition and near term prospects of the issuer.

At September 30, 2008, we concluded that no weight should be given to the value indicated by the secondary markets for student loan backed auction rate securities similar to those we hold because these markets have very low transaction volumes and consist primarily of private transactions with minimal disclosure and transactions may not be representative of the actions of typically-motivated buyers and sellers and we do not currently intend to sell in the secondary markets. However, we did consider the secondary markets for certain mortgage-backed securities to estimate the market yields attributable to our auction rate securities, but determined that these secondary markets do not provide a sufficient basis of comparison for the auction rate securities that we hold and, accordingly, attributed no weight to the values of these mortgage-backed securities indicated by the secondary markets.

At September 30, 2008, we concluded that no weight should be given to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value based on low issuer call activity, so we attributed a weight of 100.0% to estimates of present value of the auction rate securities based upon expected cash flows. The attribution of weights to the valuation factors required the exercise of valuation judgment. The selection of a weight of 100.0% attributed to the present value of the auction rate securities based upon expected cash flows reflects the expectation, in absence of the Auction Rate Securities Rights Prospectus discussed below, that no certainty exists regarding how the auction rate securities will be eventually converted to cash and this methodology represents the possible outcome. To derive estimates of the present value of the auction rate securities based upon expected cash flows, we used the securities expected annual interest payments, ranging from 2.1% to 5.4% of par value, representing estimated maximum annual rates under the governing documents of the auction rate securities; annual market interest rates, ranging from 3.9% to 5.4%, based on observed traded, state sponsored, taxable certificates rated AAA or lower and issued between September 29 and September 30, 2008; certain mortgage-backed securities and indices; and a range of expected terms to liquidity.

Our weighting of the valuation methods as of September 30, 2008 indicates an implied term to liquidity of approximately five years in absence of the Auction Rate Securities Rights Prospectus discussed below. The implied term to liquidity of approximately five years is a result of considering a range in possible timing of the various scenarios that would allow a holder of the auction rate securities to convert the auction rate securities to cash ranging from zero to ten years, with the highest probability assigned to five years. UBS issued a comprehensive settlement, which was confirmed by an Auction Rate Securities Rights Prospectus issued by UBS on October 7, 2008, in which there is a possibility of redemption by UBS at par value for the auction rate securities held by us between June 30, 2010 and July 2, 2012. Under the comprehensive settlement, UBS has committed to purchase a total of $8.3 billion of auction rate securities at par value from most private clients during the two-year period beginning January 1, 2009. Private clients and charities holding less than $1.0 million in household assets at UBS were able to avail themselves of this relief beginning October 31, 2008. From mid-September 2008, UBS began to provide loans at no cost to its clients for the par value of their auction rate security holdings. In addition, UBS has also committed to provide liquidity solutions to institutional investors and has agreed to purchase all or any of a remaining $10.3 billion in auction rate securities at par value from its institutional clients beginning June 10, 2010. These auction rate security rights are not transferable, tradable or marginable. We have not considered the liquidity potentially generated by UBS s comprehensive settlement or the UBS loan in our valuation of the 19 auction rate certificates held by us because the settlement rights were not enforceable at September 30, 2008. The repurchase arrangement and lending arrangement may represent separate contracts, securities or other assets that have not been considered in the valuation of the auction rate securities.

Our auction rate securities include AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program. These auction rate securities continue to be AAA rated auction rate securities subsequent to the failed auctions that began in February 2008.

In addition to the valuation procedures described above, we considered (i) our current inability to hold these securities for a period of time sufficient to allow for an unanticipated recovery in fair value based on our current liquidity, history of operating losses, and management s estimates of required cash for continued product development and sales and marketing expenses, and (ii) failed auctions and the anticipation of continued failed auctions for all of our auction rate securities.

Based on the factors described above, we recorded the entire amount of impairment loss identified for the year ended June 30, 2008 of $1.3 million as other-than-temporary and recorded the decrease in fair value of $0.3 million as an unrealized loss for the three months ended September 30, 2008. We did not identify or record any additional realized or unrealized gains or losses for the year ended June 30, 2008 or the three months ended September 30, 2008. We will continue to monitor and evaluate the value of our investments each reporting period for further possible impairment or unrealized loss. Although we currently do not intend to do so, we may consider selling our auction rate securities in the

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secondary markets in the future, which may require a sale at a substantial discount to the stated principal value of these securities.

Accretion of Redeemable Convertible Preferred Stock. Accretion of redeemable convertible preferred stock was $16.8 million for the year ended June 30, 2007, as compared to $19.4 million for the year ended June 30, 2008. Accretion of redeemable convertible preferred stock reflects the change in estimated fair value of preferred stock at the balance sheet dates.

Comparison of the Fiscal Year Ended June 30, 2006 with the Fiscal Year Ended June 30, 2007

Revenues. We did not generate any revenues during the fiscal years ended June 30, 2006 or 2007.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased by $5.0 million, from $1.7 million in fiscal 2006 to $6.7 million in fiscal 2007. The primary reasons for the increase included the addition of four officers to our executive management team, contributing $1.1 million, the development of our sales and marketing team, contributing $2.6 million, and consulting services, contributing $300,000. We recorded stock-based compensation of $327,000 during the fiscal year ended June 30, 2007, while none was recorded in 2006. The balance of the increase was spread among our general and administrative accounts and reflected the overall growth in the business.

Research and Development Expenses. Our research and development expenses increased by $5.2 million, from $3.2 million in fiscal 2006 to $8.4 million in fiscal 2007. Both clinical and regulatory spending increased substantially as we completed European and U.S. clinical trials and submitted our 510(k) clearance application to the FDA. In addition, we incurred significant research and development costs for projects expected to improve our product, such as the development of a new control unit and shaft designs. We recorded stock-based compensation of $63,000 during the fiscal year ended June 30, 2007.

Interest Income. Interest income increased by $825,000, from $56,000 in fiscal 2006 to $881,000 in fiscal 2007. The increase was due to higher average cash, cash equivalents and short-term investment balances. Average cash, cash equivalent and short-term investment balances were $1.6 million and $18.5 million during fiscal 2006 and 2007, respectively.

Interest Expense. Interest expense increased by $1.3 million, from $48,000 for the fiscal year ended June 30, 2006 to $1.3 million for the fiscal year ended June 30, 2007. The increase was due to the change in the estimated fair value of convertible preferred stock warrants.

Accretion of Redeemable Convertible Preferred Stock. Accretion of redeemable convertible preferred stock was $16.8 million for the fiscal year ended June 30, 2007. Accretion of redeemable convertible preferred stock reflects the change in estimated fair value of preferred stock at the balance sheet dates.

Liquidity and Capital Resources

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We had cash and cash equivalents of $14.7 million at September 30, 2008. During the years ended June 30, 2008 and three months ended September 30, 2008, net cash used in operations amounted to $31.9 million and $12.0 million, respectively. As of September 30, 2008, we had an accumulated deficit of $132.0 million. We have historically funded our operating losses primarily from the issuance of common and preferred stock and convertible promissory notes. We have incurred negative cash flows and net losses since inception. In addition, in February 2008, we were notified that recent conditions in the global credit markets have caused insufficient demand for auction rate securities, resulting in failed auctions for $23.0 million of our auction rate securities held at June 30, 2008 and September 30, 2008. These securities are currently not liquid, as we have an inability to sell the securities due to continued failed auctions. On March 28, 2008, we obtained a margin loan from UBS Financial Services, Inc., the entity through which we originally purchased our auction rate securities, for up to $12.0 million, which was secured by the $23.0 million par value of our auction rate securities. The outstanding balance on this loan at June 30, 2008 was $11.9 million. On August 21, 2008, we replaced this loan with a margin loan from UBS Bank USA, which increased maximum borrowings available to $23.0 million. This maximum borrowing amount is not set forth in the written agreement for the loan and may be adjusted from time to time by UBS Bank in its sole discretion The margin loan has a floating interest rate equal to 30-day LIBOR, plus 1.0%. The loan is due on demand and UBS Bank will require us to repay it in full from the

proceeds received from a public equity offering where net proceeds exceed $50.0 million. In addition, if at any time any of our auction rate securities may be sold, exchanged, redeemed, transferred or otherwise conveyed for no less than their par value, then we must immediately effect such a transfer and the proceeds must be used to pay down outstanding borrowings under this loan. The margin requirements are determined by UBS Bank but are not included in the

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written loan agreement and are therefore subject to change. From August 21, 2008, the date this loan was initially funded, through the date of this Form 10, the margin requirements included maximum borrowings, including interest, of $23.0 million. If these margin requirements are not maintained, UBS Bank may require us to make a loan payment in an amount necessary to comply with the applicable margin requirements or demand repayment of the entire outstanding balance. We have maintained the margin requirements under the loans from both UBS entities. The outstanding balance on this loan at September 30, 2008 was $22.9 million.

In addition, on September 12, 2008, we entered into a loan and security agreement with Silicon Valley Bank with maximum available borrowings of $13.5 million. The agreement includes a $3.0 million term loan, a $5.0 million accounts receivable line of credit, and two term loans for an aggregate of $5.5 million that are guaranteed by certain of our affiliates. The terms of each of these loans is as follows:

The $3.0 million term loan has a fixed interest rate of 10.5% and a final payment amount equal to 3.0% of the loan amount due at maturity. This term loan has a 36 month maturity, with repayment terms that include interest only payments during the first six months followed by 30 equal principal and interest payments. This term loan also includes an acceleration provision that requires us to pay the entire outstanding balance, plus a penalty ranging from 1.0% to 6.0% of the principal amount, upon prepayment or the occurrence and continuance of an event of default. As part of the term loan agreement, we granted Silicon Valley Bank a warrant to purchase 13,000 shares of Series B redeemable convertible preferred stock at an exercise price of $9.25 per share. This warrant is immediately exercisable and has a term of ten years, and was assigned an accounting value of $75,000. The balance outstanding on the term loan at September 30, 2008 was $3.0 million.

The accounts receivable line of credit has a two year maturity and a floating interest rate equal to the prime rate, plus 2.0%, with an interest rate floor of 7.0%. Interest on borrowings is due monthly and the principal balance is due at maturity. Borrowings on the line of credit are based on 80% of eligible domestic receivables, which is defined as receivables aged less than 90 days from the invoice date along with specific exclusions for contra-accounts, concentrations, and government receivables. Our accounts receivable receipts will be deposited into a lockbox account in the name of Silicon Valley Bank. The accounts receivable line of credit is subject to non-use fees, annual fees and cancellation fees. There was no balance outstanding on the line of credit at September 30, 2008.

One of the guaranteed term loans is for $3.0 million and the other guaranteed term loan is for $2.5 million, each with a one year maturity. Each of the guaranteed term loans has a floating interest rate equal to the prime rate, plus 2.25%, with an interest rate floor of 7.0% (effective rate of 7.0% at September 30, 2008). Interest on borrowings is due monthly and the principal balance is due at maturity. One of our directors and two entities affiliated with two of our directors agreed to act as guarantors of these term loans. In consideration for the guarantees, we issued the guarantors warrants to purchase an aggregate of 458,333 shares of our common stock at an exercise price of $6.00 per share. The balance outstanding on the guaranteed term loans at September 30, 2008 was $5.5 million (excluding debt discount of $1.8 million).

The guaranteed term loans and common stock warrants were allocated using the relative fair value method. Under this method, we estimated the fair value of the term loans without the guarantees and calculated the fair value of the common stock warrants using the Black-Scholes method. The relative fair value of the loans and warrants were applied to the loan proceeds of $5.5 million, resulting in an assigned value of $3.7 million for the loans and $1.8 million for the warrants. The assigned value of the warrants of $1.8 million is treated as a debt discount and amortized over the one year maturity of the loan.

Borrowings from Silicon Valley Bank are secured by all of our assets, other than our auction rate securities and intellectual property, and the investor guarantees. The borrowings are subject to prepayment penalties and financial covenants, including our maintaining a minimum liquidity ratio and our achievement of minimum monthly net revenue goals. Any non-compliance by us under the terms of our debt arrangements could result in an event of default

under the Silicon Valley Bank loan, which, if not cured, could result in the acceleration of this debt.

Based on current operating levels, combined with limited capital resources, financing our operations will require that we either complete the merger with Replidyne or raise additional equity or debt capital prior to or during the quarter ending September 30, 2009. If we fail to complete the merger with Replidyne or raise sufficient equity or debt capital, management would implement cost reduction measures, including workforce reductions, as well as reductions in overhead costs and capital expenditures. These factors raise substantial doubt about our ability to continue as a going concern. Our independent registered public accountants have included an explanatory paragraph in their report for our fiscal year ended June 30, 2008 with respect to our ability to continue as a going concern.

The reported changes in cash and cash equivalents and investments for the years ended June 30, 2006, 2007 and 2008 and for the three months September 30, 2007 and 2008 are summarized below.

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Cash and Cash Equivalents. Cash and cash equivalents increased by $11.4 million, from $3.3 million at September 30, 2007 to $14.7 million at September 30, 2008. Cash and cash equivalents decreased by $0.3 million, from $7.9 million at June 30, 2007 to $7.6 million at June 30, 2008.

Investments. Short-term investments decreased by $18.5 million, from $18.5 million at September 30, 2007 to $0 at September 30, 2008. Short-term investments decreased by $11.6 million, from $11.6 million at June 30, 2007 to $0 at June 30, 2008.

Our investments include AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program, or FFELP. The federal government insures loans in the FFELP so that lenders are reimbursed at least 97% of the loan s outstanding principal and accrued interest if a borrower defaults. Approximately 99.2% of the par value of our auction rate securities is supported by student loan assets that are guaranteed by the federal government under the FFELP.

In February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $23.0 million of our auction rate securities held at June 30, 2008 and September 30, 2008. Currently, these affected securities are not liquid and will not become liquid until a future auction for these investments is successful, they are redeemed by the issuer, they mature, or they are repurchased by UBS. As a result, at June 30, 2008 and September 30, 2008, we have classified the fair value of our auction rate securities as a long-term asset. We have recorded an other-than-temporary impairment loss of $1.3 million relating to these auction rate securities in our statement of operations for the year ended June 30, 2008 and recorded an unrealized loss of $0.3 million relating to our auction rate securities in other comprehensive income (loss) for the three months ended September 30, 2008. We determined the fair value of our auction rate securities and quantified the other-than-temporary impairment loss and the unrealized loss with the assistance of ValueKnowledge LLC, an independent third party valuation firm, which utilized various valuation methods and considered, among other factors, estimates of present value of the auction rate securities based upon expected cash flows, the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value, the likelihood of a return of liquidity to the market for these securities and the potential to sell the securities in secondary markets.

At June 30, 2008, we concluded that no weight should be given to the value indicated by the secondary markets for student loan-backed auction rate securities similar to those we hold because these markets have very low transaction volumes and consist primarily of private transactions with minimal disclosure, transactions may not be representative of the actions of typically-motivated buyers and sellers and we do not currently intend to sell in the secondary markets. However, we did consider the secondary markets for certain mortgage-backed securities but determined that these secondary markets do not provide a sufficient basis of comparison for the auction rate securities that we hold and, accordingly, attributed no weight to the values of these mortgage-backed securities to estimate the market yields attributable to our auction rate securities, indicated by the secondary markets.

At June 30, 2008, we attributed a weight of 66.7% to estimates of present value of the auction rate securities based upon expected cash flows and a weight of 33.3% to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or willingness of third parties to provide financing in the market against the par value of those securities. The attribution of these weights required the exercise of valuation judgment. A measure of liquidity is available from borrowing, which led to the 33.3% weight attributed to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or the willingness of third parties to provide financing in the market against the par value of those securities. However, borrowing does not eliminate exposure to the risk of holding the securities, so the weight of 66.7% attributed to the present value of the auction rate securities based upon expected cash flows reflects the expectation that the securities are likely to be held for an uncertain period. We focused on these methodologies because no certainty exists regarding how the auction rate securities will be eventually converted to cash and these methodologies represent the most likely possible outcomes. To derive estimates of the present value of the auction rate securities based upon expected cash flows, we used the securities expected annual interest payments, ranging from 2.7% to 4.0% of par value, representing estimated maximum annual rates under the governing documents of the auction rate securities; annual market interest rates, ranging from 4.5% to 5.8%, based on observed traded, state sponsored, taxable certificates rated AAA or lower and issued between June 15 and June 30, 2008; and a range of expected terms to liquidity.

At June 30, 2008, our weighting of the valuation methods indicates an implied term to liquidity of approximately 3.5 years. The implied term to liquidity of approximately 3.5 years is a result of considering a range in possible timing of the various scenarios that would allow a holder of the auction rate securities to convert the auction rate securities to cash ranging from zero to ten years, with the highest probability assigned to the range of zero to five years. Several sources were consulted but no individual source of information was relied upon to arrive at our estimate of the range of possible timing to convert the auction rate securities to cash or the implied term to liquidity of approximately 3.5 years. The primary reason for the fair value being less than cost related to a lack of liquidity of the securities, rather than the financial condition and near term prospects of the issuer.

At September 30, 2008, we concluded that no weight should be given to the value indicated by the secondary markets for student loan backed auction rate securities similar to those we hold because these markets have very low transaction volumes and consist primarily of private transactions with minimal disclosure and transactions may not be representative of the actions of typically-motivated buyers and sellers and we do not currently intend to sell in the secondary markets. However, we did consider the secondary markets for certain mortgage-backed securities to estimate the market yields attributable to our auction rate securities, but determined that these secondary markets do not provide a sufficient basis of comparison for the auction rate securities that we hold and, accordingly, attributed no weight to the values of these mortgage-backed securities indicated by the secondary markets.

At September 30, 2008, we concluded that no weight should be given to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value based on low issuer call activity, so we attributed a weight of 100.0% to estimates of present value of the auction rate securities based upon expected cash flows. The attribution of weights to the valuation factors required the exercise of valuation judgment. The selection of a weight of 100.0% attributed to the present value of the auction rate securities based upon expected cash flows reflects the expectation, in absence of the Auction Rate Securities Rights Prospectus discussed below, that no certainty exists regarding how the auction rate securities will be eventually converted to cash and this methodology represents the possible outcome. To derive estimates of the present value of the auction rate securities based upon expected cash flows, we used the securities expected annual interest payments, ranging from 2.1% to 5.4% of par value, representing estimated maximum annual rates under the governing documents of the auction rate securities; annual market interest rates, ranging from 3.9% to 5.4%, based on observed traded, state sponsored, taxable certificates rated AAA or lower and issued between September 29 and September 30, 2008; certain mortgage-backed securities and indices; and a range of expected terms to liquidity.

Our weighting of the valuation methods as of September 30, 2008 indicates an implied term to liquidity of approximately five years in absence of the Auction Rate Securities Rights Prospectus discussed below. The implied term to liquidity of approximately five years is a result of considering a range in possible timing of the various scenarios that would allow a holder of the auction rate securities to convert the auction rate securities to cash ranging from zero to ten years, with the highest probability assigned to five years. UBS issued a comprehensive settlement, which was confirmed by an Auction Rate Securities Rights Prospectus issued by UBS on October 7, 2008, in which there is a possibility of redemption by UBS at par value for the auction rate securities held by us between June 30, 2010 and July 2, 2012. Under the comprehensive settlement, UBS has committed to purchase a total of $8.3 billion of auction rate securities at par value from most private clients during the two-year period beginning January 1, 2009. Private clients and charities holding less than $1.0 million in household assets at UBS were able to avail themselves of this relief beginning October 31, 2008. From mid-September 2008, UBS began to provide loans at no cost to its clients for the par value of their auction rate security holdings. In addition, UBS has also committed to provide liquidity solutions to institutional investors and has agreed to purchase all or any of a remaining $10.3 billion in auction rate securities at par value from its institutional clients beginning June 10, 2010. These auction rate security rights are not transferable, tradable or marginable. We have not considered the liquidity potentially generated by UBS s comprehensive settlement or the UBS loan in our valuation of the 19 auction rate certificates held by us because the settlement rights were not enforceable at September 30, 2008. The repurchase arrangement and lending arrangement may represent separate contracts, securities or other assets that have not been considered in the valuation of the auction rate securities.

Our auction rate securities include AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program. These auction rate securities continue to be AAA rated auction rate securities subsequent to the failed auctions that began in

February 2008.

In addition to the valuation procedures described above, we considered (i) our current inability to hold these securities for a period of time sufficient to allow for an unanticipated recovery in fair value based on our current liquidity, history of operating losses, and management s estimates of required cash for continued product development and sales and marketing expenses, and (ii) failed auctions and the anticipation of

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continued failed auctions for all of our auction rate securities.

Based on the factors described above, we recorded the entire amount of impairment loss identified for the year ended June 30, 2008 of $1.3 million as other-than-temporary and recorded the decrease in fair value of $0.3 million as an unrealized loss for the three months ended September 30, 2008. We did not identify or record any additional realized or unrealized losses for the year ended June 30, 2008 or the three months ended September 30, 2008. We will continue to monitor and evaluate the value of our investments each reporting period for further possible impairment or unrealized loss. Although we currently do not intend to do so, we may consider selling our auction rate securities in the secondary markets in the future, which may require a sale at a substantial discount to the stated principal value of these securities.

For additional discussion of liquidity issues relating to our auction rate securities, see Quantitative and Qualitative Disclosures About Market Risk.

Operating Activities. Net cash used in operating activities was $5.0 million, $12.3 million and $31.9 million in fiscal 2006, 2007 and 2008, respectively, and $8.0 million and $12.0 million for the three months ended September 30, 2007 and 2008, respectively. For fiscal 2006, 2007, and 2008, we had a net loss of $4.9 million, $15.6 million, and $39.2 million, respectively, and for the three months ended September 30, 2007 and 2008, we had a net loss of $7.4 million and $13.7 million, respectively. Changes in working capital accounts also contributed to the net cash used in fiscal 2006, 2007, and 2008 and the three months ended September 30, 2007 and 2008.

Investing Activities. Net cash used in investing activities was $228,000, $11.9 million and $12.4 million in fiscal 2006, 2007 and 2008, respectively, and $7.0 million and $382,000 for the three months ended September 30, 2007 and 2008, respectively. For the years ended June 30, 2007 and 2008 and three months ended September 30, 2007, we purchased investments in the amount of $23.2 million, $31.3 million and $12.7 million, respectively. For the year ended June 30, 2008, we purchased and sold investments in the amount of $11.8 million, $20.0 million and $5.9 million, respectively. The balance of cash used in investing activities primarily related to the purchase of property and equipment. Purchases of property and equipment used cash of $235,000, $465,000 and $721,000 in fiscal 2006, 2007 and 2008, respectively, and $207,000 and $201,000 in the three months ended September 30, 2007 and 2008, respectively.

Financing Activities. Net cash provided by financing activities was $5.0 million, $30.5 million and $44.0 million in fiscal 2006, 2007 and 2008, respectively, and $10.4 million and $19.6 million in the three months ended September 30, 2007 and 2008, respectively. Cash provided by financing activities during these periods included:

- net proceeds from the sale of common stock of $2.3 million in fiscal 2006;
- proceeds from the issuance of convertible promissory notes of $3.1 million in fiscal 2006;
- net proceeds from the issuance of convertible preferred stock of $30.3 million in each of fiscal 2007 and 2008 and $10.3 million in the three months ended September 30, 2007;
- issuance of convertible preferred stock warrants of $1.8 million in fiscal 2007;
- proceeds from a long-term debt of $16.4 million and $19.6 million during the year ended June 30, 2008 and three months ended September 30, 2008, respectively; and
- exercise of stock options and warrants of $1.9 million during the year ended June 30, 2008.

Cash used in financing activities in these periods included:

- repayment of a note payable to a stockholder of $350,000 in fiscal 2006;
- payment of redeemable convertible preferred stock offering costs of $1.8 million in the year ended June 30, 2007; and
- payment on a loan payable of $4.5 million during the year ended June 30, 2008.

Our future capital requirements will depend on many factors, including our sales growth, market acceptance of our existing and future products, the amount and timing of our research and development expenditures, the timing of our introduction of new products, the expansion of our sales and marketing efforts and working capital needs. We expect our long-term liquidity needs to consist primarily of working capital and capital expenditure requirements. Based on current operating levels, combined with limited capital resources, financing our operations will require that we either complete the merger with Replidyne raise additional equity or debt capital prior to or during the quarter ending September 30, 2009. If the merger is not consummated or we are unable to raise additional debt or equity financing on terms acceptable to us, there will continue to be substantial doubt about our ability to continue as a going concern. If we are unable to obtain additional financing or successfully market our products on a timely basis, we would need to slow our product development, sales, and marketing efforts and may be unable to continue our operations.

Contractual Cash Obligations. Our contractual obligations and commercial commitments as of June 30, 2008 are summarized below:

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	Payments Due by Period				
Contractual Obligations	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
			(in thousands)		
Operating leases(1)	$ 2,088	$ 464	$ 946	$ 678	$ 0
Purchase commitments(2)	5,328	5,328			
Total	$ 7,416	$ 5,792	$ 946	$ 678	$ 0

(1) The amounts reflected in the table above for operating leases represent future minimum payments under a non-cancellable operating lease for our office and production facility along with equipment.

(2) This amount reflects open purchase orders.

On September 12, 2008, we entered into a loan and security agreement with Silicon Valley Bank with maximum available borrowings of $13.5 million. The agreement includes a $3.0 million term loan, a $5.0 million accounts receivable line of credit, and two term loans for an aggregate of $5.5 million that are guaranteed by certain of our affiliates. As of September 30, 2008, the balance outstanding under the Silicon Valley Bank debt totaled $8.5 million. Repayment terms of these borrowings include $6.1 million due in less than one year, and $2.4 million due in one to three years.

Related Party Transactions

For a description of our related party transactions, see the discussion under the heading Certain Relationships and Related Transactions, and Director Independence.

Off-Balance Sheet Arrangements

Since inception, we have not engaged in any off-balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. This standard clarifies the principle that fair value should be based on the assumptions that market participants would use when pricing an asset or liability. Additionally, it establishes a fair value hierarchy that prioritizes the information used to develop these assumptions. On February 12, 2008, the FASB issued FASB Staff Position, or FSP, FAS 157-2, *Effective Date of FASB Statement No. 157*, or FSP FAS 157-2. FSP FAS 157-2 defers the implementation of SFAS No. 157 for certain

nonfinancial assets and nonfinancial liabilities. The portion of SFAS No. 157 that has been deferred by FSP FAS 157-2 will be effective for us beginning in the first quarter of fiscal year 2010. SFAS No. 157 was adopted for financial assets and liabilities on July 1, 2008, and did not have a material impact on our financial position or consolidated results of operations during the three months ended September 30, 2008.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*. This standard provides companies with an option to report selected financial assets and liabilities at fair value and establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities. SFAS No. 159

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was adopted on July 1, 2008, and did not have a material impact on our financial position or consolidated results of operations during the three months ended September 30, 2008.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), *Business Combinations*, and SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51*. The revised standards continue the movement toward the greater use of fair values in financial reporting. SFAS No. 141(R) will significantly change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods, including the accounting for contingent consideration. SFAS No. 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS No. 141(R) and SFAS No. 160 are effective for fiscal years beginning on or after December 15, 2008, with SFAS No. 141(R) to be applied prospectively while SFAS No. 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements of SFAS No. 160 shall be applied prospectively. Early adoption is prohibited for both standards. We are currently evaluating the impact of these statements but expect that the adoption of SFAS No. 141(R) will have a material impact on how we will identify, negotiate and value any future acquisitions and a material impact on how an acquisition will affect our consolidated financial statements, and that SFAS No. 160 will not have a material impact on our financial position or consolidated results of operations.

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented.

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 or availability. To achieve these objectives, our investment policy, as amended in April 2008, allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including money market funds and U.S. government securities. Our cash and cash equivalents as of September 30, 2008 include liquid money market accounts. Due to the short-term nature of these investments, we believe that there is no material exposure to interest rate risk.

Our investments include AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program, or FFELP. The federal government insures loans in the FFELP so that lenders are reimbursed at least 97% of the loan s outstanding principal and accrued interest if a borrower defaults. Approximately 99.2% of the par value of our auction rate securities is supported by student loan assets that are guaranteed by the federal government under the FFELP.

Our auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals, primarily every 28 days, through auctions. The recent conditions in the global credit markets have prevented us from liquidating our holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed by the issuer or they mature.

In February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $23.0 million of our auction rate securities held at June 30, 2008 and September 30, 2008. Currently, these affected securities are not liquid and will not become liquid until a future auction for these investments is successful, they are redeemed by the issuer, they mature, or they are repurchased by UBS. As a result, at June 30, 2008 and September 30, 2008, we have classified the fair value of the auction rate securities as a long-term asset. Starting in February 2008, interest rates on all auction rate securities were reset to temporary predetermined penalty or maximum rates. These maximum rates are limited to a maximum amount payable over a 12 month period generally equal to a rate based on the trailing 12-month average of 90-day treasury bills, plus 120 basis points. These maximum allowable rates range from 2.7% to 4.0% of par value per year. We have collected all interest due on our auction rate securities and have no reason to believe that we will not collect all interest due in the future. We do not expect to receive the principal associated with our auction rate securities until the earlier of a successful auction, their

redemption by the issuer or their maturity. On March 28, 2008, we obtained a margin loan from UBS Financial Services, Inc., the entity through which we originally purchased our auction rate securities, for up to $12.0 million, which was secured by the $23.0 million par value of our auction rate securities. The outstanding balance on this loan at June 30, 2008 was $11.9 million. On August 21, 2008, we replaced this loan with a margin loan from UBS Bank USA, which increased maximum borrowings available to $23.0 million. This maximum borrowing amount is not set forth in the written agreement for the loan and may be adjusted from time to time by UBS Bank in its sole discretion The margin loan has a floating interest rate equal to 30-day LIBOR,

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plus 1.0%. The loan is due on demand and UBS Bank will require us to repay it in full from the proceeds received from a public equity offering where net proceeds exceed $50.0 million. In addition, if at any time any of our auction rate securities may be sold, exchanged, redeemed, transferred or otherwise conveyed for no less than their par value, then we must immediately effect such a transfer and the proceeds must be used to pay down outstanding borrowings under this loan. The margin requirements are determined by UBS Bank but are not included in the written loan agreement and are therefore subject to change. From August 21, 2008, the date this loan was initially funded, through the date of this Form 10, the margin requirements included maximum borrowings, including interest, of $23.0 million. If these margin requirements are not maintained, UBS Bank may require us to make a loan payment in an amount necessary to comply with the applicable margin requirements or demand repayment of the entire outstanding balance. We have maintained the margin requirements under the loans from both UBS entities. The outstanding balance on this loan at September 30, 2008 was $22.9 million.

We have recorded an other-than-temporary impairment loss of $1.3 million relating to our auction rate securities in our statement of operations for the year ended June 30, 2008 and recorded an unrealized loss of $0.3 million relating to our auction rate securities in other comprehensive income (loss) for the three months ended September 30, 2008. We determined the fair value of our auction rate securities and quantified the other-than-temporary impairment loss with the assistance of ValueKnowledge LLC, an independent third party valuation firm, which utilized various valuation methods and considered, among other factors, estimates of present value of the auction rate securities based upon expected cash flows, the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value, the likelihood of a return of liquidity to the market for these securities and the potential to sell the securities in secondary markets.

At June 30, 2008, we concluded that no weight should be given to the value indicated by the secondary markets for student loan-backed auction rate securities similar to those we hold because these markets have very low transaction volumes and consist primarily of private transactions with minimal disclosure, transactions may not be representative of the actions of typically-motivated buyers and sellers and we do not currently intend to sell in the secondary markets. However, we did consider the secondary markets for certain mortgage-backed securities to estimate the market yields attributable to our auction rate securities, but determined that these secondary markets do not provide a sufficient basis of comparison for the auction rate securities that we hold and, accordingly, attributed no weight to the values of these mortgage-backed securities indicated by the secondary markets.

At June 30, 2008, we attributed a weight of 66.7% to estimates of present value of the auction rate securities based upon expected cash flows and a weight of 33.3% to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or willingness of third parties to provide financing in the market against the par value of those securities. The attribution of these weights required the exercise of valuation judgment. A measure of liquidity is available from borrowing, which led to the 33.3% weight attributed to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or the willingness of third parties to provide financing in the market against the par value of those securities. However, borrowing does not eliminate exposure to the risk of holding the securities, so the weight of 66.7% attributed to the present value of the auction rate securities based upon expected cash flows reflects the expectation that the securities are likely to be held for an uncertain period. We focused on these methodologies because no certainty exists regarding how the auction rate securities will be eventually converted to cash and these methodologies represent the most likely possible outcomes. To derive estimates of the present value of the auction rate securities based upon expected cash flows, we used the securities expected annual interest payments, ranging from 2.7% to 4.0% of par value, representing estimated maximum annual rates under the governing documents of the auction rate securities; annual market interest rates, ranging from 4.5% to 5.8%, based on observed traded, state sponsored, taxable certificates rated AAA or lower and issued between June 15 and June 30, 2008; and a range of expected terms to liquidity.

At June 30, 2008, our weighting of the valuation methods indicates an implied term to liquidity of approximately 3.5 years. The implied term to liquidity of approximately 3.5 years is a result of considering a range in possible timing of the various scenarios that would allow a holder of the auction rate securities to convert the auction rate securities to cash ranging from zero to ten years, with the highest probability assigned to the range of zero to five years. Several sources were consulted but no individual source of information was relied upon to arrive at our estimate of the range

of possible timing to convert the auction rate securities to cash or the implied term to liquidity of approximately 3.5 years. The primary reason for the fair value being less than cost related to a lack of liquidity of the securities, rather than the financial condition and near term prospects of the issuer.

At September 30, 2008, we concluded that no weight should be given to the value indicated by the secondary markets for student loan backed auction rate securities similar to those we hold because these markets have very low transaction volumes and consist primarily of private transactions with minimal disclosure and transactions may not be representative of the actions of typically-motivated buyers and sellers and we do not currently intend to sell in the secondary markets. However, we did consider the secondary markets for certain mortgage-backed securities to estimate the market yields attributable to our auction rate securities, but determined that these secondary markets do not provide a sufficient basis of comparison for the auction rate securities that we hold and, accordingly, attributed no weight to the values of these mortgage-backed securities indicated by the secondary markets.

At September 30, 2008, we concluded that no weight should be given to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value based on low issuer call activity, so we attributed a weight of 100.0% to estimates of present value of the auction rate securities based upon expected cash flows. The attribution of weights to the valuation factors required the exercise of valuation judgment. The selection of a weight of 100.0% attributed to the present value of the auction rate securities based upon expected cash flows reflects the expectation, in absence of the Auction Rate Securities Rights Prospectus discussed below, that no certainty exists regarding how the auction rate securities will be eventually converted to cash and this methodology represents the possible outcome. To derive estimates of the present value of the auction rate securities based upon expected cash flows, we used the securities expected annual interest payments, ranging from 2.1% to 5.4% of par value, representing estimated maximum annual rates under the governing documents of the auction rate securities; annual market interest rates, ranging from 3.9% to 5.4%, based on observed traded, state sponsored, taxable certificates rated AAA or lower and issued between September 29 and September 30, 2008; certain mortgage-backed securities and indices; and a range of expected terms to liquidity.

Our weighting of the valuation methods as of September 30, 2008 indicates an implied term to liquidity of approximately five years in absence of the Auction Rate Securities Rights Prospectus discussed below. The implied term to liquidity of approximately five years is a result of considering a range in possible timing of the various scenarios that would allow a holder of the auction rate securities to convert the auction rate securities to cash ranging from zero to ten years, with the highest probability assigned to five years. UBS issued a comprehensive settlement, which was confirmed by an Auction Rate Securities Rights Prospectus issued by UBS on October 7, 2008, in which there is a possibility of redemption by UBS at par value for the auction rate securities held by us between June 30, 2010 and July 2, 2012. Under the comprehensive settlement, UBS has committed to purchase a total of $8.3 billion of auction rate securities at par value from most private clients during the two-year period beginning January 1, 2009. Private clients and charities holding less than $1.0 million in household assets at UBS were able to avail themselves of this relief beginning October 31, 2008. From mid-September 2008, UBS began to provide loans at no cost to its clients for the par value of their auction rate security holdings. In addition, UBS has also committed to provide liquidity solutions to institutional investors and has agreed to purchase all or any of a remaining $10.3 billion in auction rate securities at par value from its institutional clients beginning June 10, 2010. These auction rate security rights are not transferable, tradable or marginable. We have not considered the liquidity potentially generated by UBS s comprehensive settlement or the UBS loan in our valuation of the 19 auction rate certificates held by us because the settlement rights were not enforceable at September 30, 2008. The repurchase arrangement and lending arrangement may represent separate contracts, securities or other assets that have not been considered in the valuation of the auction rate securities.

Our auction rate securities include AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program. These auction rate securities continue to be AAA rated auction rate securities subsequent to the failed auctions that began in February 2008.

In addition to the valuation procedures described above, we considered (i) our current inability to hold these securities for a period of time sufficient to allow for an unanticipated recovery in fair value based on our current liquidity, history of operating losses, and management s estimates of required cash for continued product development and sales and marketing expenses, and (ii) failed auctions and the anticipation of continued failed auctions for all of

our auction rate securities.

Based on the factors described above, we recorded the entire amount of impairment loss identified for the year ended June 30, 2008 of $1.3 million as other-than-temporary and recorded the decrease in fair value of $0.3 million as an unrealized loss for the three months ended September 30, 2008. We did not identify or record any additional realized or unrealized gains or losses for the year ended June 30, 2008 or the three months ended September 30, 2008. We will continue to monitor and evaluate the value of our investments each reporting period for further possible impairment or unrealized loss. Although we currently do not intend to do so, we may consider selling our auction rate securities in the

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secondary markets in the future, which may require a sale at a substantial discount to the stated principal value of these securities.

In the event that we need to access the funds of our auction rate securities that have experienced insufficient demand at auctions, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful, they are redeemed by the issuer, they mature, or they are repurchased by UBS. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them to maturity.

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ITEM 3. PROPERTIES

Our principal executive offices are located in a 47,000 square foot facility located in St. Paul, Minnesota. We have leased this facility through November 2012 with an option to renew through November 2017. This facility accommodates our research and development, sales, marketing, manufacturing, finance and administrative activities. We believe that our current premises are substantially adequate for our current and anticipated future needs through the next 12 months and that sufficient facilities are available for any limited expansion we would need to make in that time.

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ITEM 4. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information regarding the beneficial ownership of our common stock and preferred stock as of October 31, 2008 for:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock or preferred stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The percentage ownership information shown in the table is based upon 7,724,137 shares of common stock and 9,088,136 shares of preferred stock outstanding as of October 31, 2008.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock or preferred stock. We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, the rules include shares of common stock and preferred stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before December 30, 2008, which is 60 days after October 31, 2008. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Unless otherwise noted below, the address for each person or entity listed in the table is c/o Cardiovascular Systems, Inc., 651 Campus Drive, Saint Paul, Minnesota 55112-3495.

	Common Stock		Preferred Stock	
Beneficial Owner	**Number of Shares Beneficially Owned**	**Percentage of Shares Beneficially Owned(1)**	**Number of Shares Beneficially Owned**	**Percentage of Shares Beneficially Owned(2)**
Named Executive Officers and Directors				
David L. Martin(3)	532,667	6.5%		*
Laurence L. Betterley(4)	75,000	1.0%		*
James E. Flaherty(5)	144,333	1.8%		*
Michael J. Kallok, Ph.D.(6)	688,715	8.2%		*
John Borrell(7)	151,469	1.9%	11,764	*
Paul Tyska(8)	114,982	1.5%		*
Robert J. Thatcher(9)	147,378	1.9%	12,000	*
John H. Friedman(10)	70,000	*		*
Geoffrey O. Hartzler, M.D.(11)	380,472	4.8%		*
Roger J. Howe, Ph.D.(12)	327,275	4.1%		*
Brent G. Blackey(13)	41,135	*	10,900	*
Glen D. Nelson, M.D.(14)	618,112	7.5%	245,968	2.7%
Gary M. Petrucci(15)	910,957	11.0%	41,245	*
Christy Wyskiel(16)	70,000	*		*
	4,375,215	39.4%	325,670	3.6%

All Directors and Executive Officers as a Group (16 individuals)				
5% Shareholders				
Easton Capital Investment Group(17)	1,644,059	17.5%	1,400,000	15.1%
ITX International Equity Corp.(18)	778,186	9.2%	771,404	8.4%
Maverick Capital, Ltd.(19)	2,640,882	25.5%	2,343,501	25.1%
Mitsui & Co. Venture Partners II, L.P.(20)	896,449	10.4%	888,666	9.7%
Whitebox Hedged High Yield Partners, LP (21)	948,748	10.9%	939,517	10.3%

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* Less than 1% of the outstanding shares.

(1) Based on 7,724,137 shares of common stock outstanding as of October 31, 2008. Unless otherwise indicated, each person or entity listed has sole investment and voting power with respect to the shares listed.

(2) Based on an aggregate of 9,088,136 shares of preferred stock outstanding as of October 31, 2008, consisting of 4,737,561 shares of Series A convertible preferred stock, 2,188,425 shares of Series A-1 convertible preferred stock and 2,162,150 shares of Series B convertible preferred stock. Unless otherwise indicated, each person or entity listed has sole investment and voting power with respect to the shares listed.

(3) Consists of 76,000 shares of our common stock and options to acquire a total of 456,667 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Mr. Martin.

(4) Consists of 75,000 shares of restricted stock that are subject to a risk of forfeiture.

(5) Consists of 45,500 shares of our common stock and options to acquire a total of 98,833 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Mr. Flaherty.

(6) Consists of 5,500 shares of our common stock and options to acquire a total of 683,215 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by

Dr. Kallok.

(7) Consists of 23,000 shares of our common stock, 11,764 shares of our Series A-1 convertible preferred stock currently convertible into 12,135 shares of our common stock, and options to acquire a total of 116,334 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Mr. Borrell.

(8) Consists of 9,982 shares of our common stock held by Mr. Tyska and options to acquire a total of 105,000 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Mr. Tyska.

(9) Consists of 12,000 shares of our Series A-1 convertible preferred stock currently convertible into

12,378 shares of our common stock held by Mr. Thatcher and options to acquire a total of 135,000 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Mr. Thatcher.

(10) Consists of options to acquire a total of 70,000 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Mr. Friedman. These options are held for the benefit of entities affiliated with Easton Capital Investment Group.

(11) Consists of 180,663 shares of our common stock and options to acquire a total of 199,809 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Dr. Hartzler.

(12) Consists of 41,500 shares of our common stock and warrants to acquire a total of 13,000 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Sonora Web LLLP, of which Dr. Howe is the general partner, and options to acquire a total of 272,775 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Dr. Howe.

(13) Consists of 5,900 shares of our Series A-1 convertible preferred stock currently convertible into 6,086 shares of our common stock, 5,000 shares of our Series B convertible preferred stock currently convertible into 5,049 shares of our common stock, and options to acquire a total of

30,000 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Mr. Blackey.

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(14) Consists of (i) 149,167 shares of our common stock, 131,349 shares of our Series A convertible preferred stock currently convertible into 132,042 shares of our common stock, 41,913 shares of our Series A-1 convertible preferred stock currently convertible into 43,235 shares of our common stock, 54,054 shares of our Series B convertible preferred stock currently convertible into 54,585 shares of our common stock, warrants to acquire a total of 85,333 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008, and currently exercisable warrants to acquire a total of 18,652 shares of our Series A convertible preferred stock currently convertible into 18,750 shares of our common stock

held by GDN Holdings, LLC; and (ii) options to acquire a total of 135,000 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Dr. Nelson.

(15) Consists of (i) 50,000 shares held by Applecrest Partners LTD Partnership, of which Mr. Petrucci is the General Partner, and (ii) 355,699 shares of our common stock, 36,124 shares of our Series A convertible preferred stock currently convertible into 36,314 shares of our common stock, options to acquire a total of 476,161 shares and warrants to acquire a total of 23,750 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008, and currently exercisable warrants to acquire a total of 5,130 shares of our Series A

convertible preferred stock currently convertible into 5,157 shares of our common stock held by Mr. Petrucci.

(16) Consists of options to acquire a total of 70,000 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Ms. Wyskiel. These options are held for the benefit of Maverick Fund II, Ltd., Maverick Fund, L.D.C. and Maverick Fund USA, Ltd.

(17) Consists of (i) 612,960 shares of our Series A convertible preferred stock currently convertible into 616,197 shares of our common stock, currently exercisable warrants to acquire a total of 166,667 shares of our common stock and currently exercisable warrants to purchase 87,040 shares of our Series A convertible

preferred stock currently convertible into 87,499 shares of our common stock, held by Easton Hunt Capital Partners, L.P., (ii) 612,960 shares of Series A convertible preferred stock currently convertible into 616,197 shares of our common stock, and currently exercisable warrants to purchase 87,040 shares of our Series A convertible preferred stock currently convertible into 87,499 shares of our common stock, held by Easton Capital Partners, LP, and (iii) options to acquire a total of 70,000 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Mr. Friedman, one of our directors. Investment decisions of Easton Hunt Capital Partners, L.P. are made by EHC GP, LP through its general partner, EHC, Inc.

Mr. Friedman is the President and Chief Executive Officer of EHC, Inc. Investment decisions of Easton Capital Partners, LP are made by its general partner, ECP GP, LLC, through its manager, ECP GP, Inc. Mr. Friedman is the President and Chief Executive Officer of EHC, Inc. and ECP GP, Inc. Mr. Friedman shares voting and investing power over the shares owned by Easton Hunt Capital Partners, L.P. and Easton Capital Partners, LP. Mr. Friedman disclaims beneficial ownership of the shares held by entities affiliated with Easton Capital Investment Group, except to the extent of his pecuniary interest therein. The address for the entities affiliated with Easton Capital Investment Group is 767 Third Avenue, 7th Floor, New York, New York 10017.

(18) Consists of 350,263 shares of our Series A convertible

preferred stock currently convertible into 352,112 shares of our common stock, 47,079 shares of our Series A-1 convertible preferred stock currently convertible into 48,564 shares of our common stock, 324,325 shares of our Series B convertible preferred stock currently convertible into 327,511 shares of our common stock and currently exercisable warrants to purchase 49,737 shares of our Series A convertible preferred stock currently convertible into 49,999 shares of our common stock, held by ITX International Equity Corp. Mr. Takehito Jimbo is the President, Chief Executive Officer and a member of the board of directors of ITX International Equity Corp. and may be deemed to have sole voting and dispositive power with respect to the shares held by ITX

International Equity Corp. The address of ITX International Equity Corp. is c/o ITX International Holdings, Inc., 700 E. El Camino Real, Suite 200, Mountain View, California 94040.

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(19) Consists of (i) 770,212 shares of Series A convertible preferred stock currently convertible into 774,280 shares of our common stock, 103,524 shares of Series A-1 convertible preferred stock currently convertible into 106,790 shares of our common stock, 47,545 shares of Series B convertible preferred stock currently convertible into 48,012 shares of our common stock, currently exercisable warrants to acquire a total of 91,623 shares of our common stock, and currently exercisable warrants to purchase 109,370 shares of our Series A convertible preferred stock currently convertible into 109,947 shares of our common stock, held by Maverick Fund, L.D.C., (ii) 310,952 shares of Series A convertible preferred stock

currently convertible into 312,594 shares of our common stock, 41,795 shares of Series A-1 convertible preferred stock currently convertible into 43,113 shares of our common stock, 19,195 shares of Series B convertible preferred stock currently convertible into 19,383 shares of our common stock, currently exercisable warrants to acquire a total of 36,990 shares of our common stock, and currently exercisable warrants to purchase 44,155 shares of our Series A convertible preferred stock currently convertible into 44,388 shares of our common stock, held by Maverick Fund USA, Ltd., (iii) 670,149 shares of Series A convertible preferred stock currently convertible into 673,688 shares of our common stock, 90,075 shares of Series A-1 convertible

preferred stock currently convertible into 92,917 shares of our common stock, 41,368 shares of Series B convertible preferred stock currently convertible into 41,774 shares of our common stock, currently exercisable warrants to acquire a total of 79,720 shares of our common stock, and currently exercisable warrants to purchase 95,161 shares of our Series A convertible preferred stock currently convertible into 95,663 shares of our common stock, held by Maverick Fund II, Ltd., and (iv) options to acquire a total of 70,000 shares of our common stock currently exercisable or exercisable within 60 days after October 31, 2008 held by Ms. Wyskiel, one of our directors. These options are held for the benefit of Maverick Fund II, Ltd., Maverick Fund, L.D.C. and

Maverick Fund USA, Ltd. Maverick Capital, Ltd. is an investment adviser registered under Section 203 of the Investment Advisers Act of 1940 and, as such, may be deemed to have beneficial ownership of the shares held by Maverick Fund II, Ltd., Maverick Fund, L.D.C. and Maverick Fund USA, Ltd. through the investment discretion it exercises over these accounts. Maverick Capital Management, LLC is the general partner of Maverick Capital, Ltd. Lee S. Ainslie III is the manager of Maverick Capital Management, LLC who possesses sole investment discretion pursuant to Maverick Capital Management, LLC s regulations. The address for the entities affiliated with Maverick Capital, Ltd. is 300 Crescent Court, 18th Floor, Dallas, Texas 75201.

(20) Consists of 675,148 shares of our Series A convertible

preferred stock currently convertible into 678,713 shares of our common stock, 117,647 shares of our Series A-1 convertible preferred stock currently convertible into 121,359 shares of our common stock, and currently exercisable warrants to purchase 95,871 shares of our Series A convertible preferred stock currently convertible into 96,377 shares of our common stock held by Mitsui & Co. Venture Partners II, L.P. Koichi Ando, President and Chief Executive Officer of Mitsui & Co. Venture Partners, Inc., the general partner of Mitsui & Co. Venture Partners II L.P., may be deemed to have voting and investment power over the shares held by Mitsui & Co. Venture Partners II L.P. The address of Mitsui & Co. Venture Partners II, L.P. is 200 Park Avenue, New York, New York 10166.

(21)

Consists of 939,517 shares of our Series B convertible preferred stock currently convertible into 948,748 shares of our common stock held by Whitebox Hedged High Yield Partners, LP. Andrew J. Redleaf is the managing member of the general partner and has voting and investment power over the shares held by Whitebox Hedged High Yield Partners, LP. The address of Whitebox Hedged High Yield Partners, LP is 3033 Excelsior Blvd., Suite 300, Minneapolis, Minnesota 55416.

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ITEM 5. DIRECTORS AND EXECUTIVE OFFICERS

Executive Officers and Directors

The name, age and position of each of our directors and executive officers as of October 31, 2008 are as follows:

Name	Age	Position
Glen D. Nelson, M.D.(3)	71	Chairman
David L. Martin	44	President, Chief Executive Officer and Director
Laurence L. Betterley	54	Chief Financial Officer
James E. Flaherty	55	Chief Administrative Officer and Secretary
Michael J. Kallok, Ph.D.	60	Chief Scientific Officer, Director
John Borrell	41	Vice President of Sales
Brian Doughty	45	Vice President of Marketing
Robert J. Thatcher	54	Executive Vice President
Paul Tyska	50	Vice President of Business Development
Paul Koehn	45	Vice President of Manufacturing
Brent G. Blackey(1)	49	Director
John H. Friedman(2)	55	Director
Geoffrey O. Hartzler, M.D.(1)(3)	61	Director
Roger J. Howe, Ph.D.(2)	65	Director
Gary M. Petrucci(2)	67	Director
Christy Wyskiel(1)	36	Director

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Nominating and Governance Committee.

David L. Martin, President, Chief Executive Officer and Director. Mr. Martin has been our President and Chief Executive Officer since February 2007, and a director since August 2006. Mr. Martin also served as our Interim Chief Financial Officer from January 2008 to April 2008. Prior to joining us, Mr. Martin was Chief Operating Officer of FoxHollow Technologies, Inc. from January 2004 to February 2006, Executive Vice President of Sales and Marketing of FoxHollow Technologies, Inc. from January 2003 to January 2004, Vice President of Global Sales and International Operations at CardioVention Inc. from October 2001 to May 2002, Vice President of Global Sales for RITA Medical Systems, Inc. from March 2000 to October 2001 and Director of U.S. Sales, Cardiac Surgery for Guidant Corporation from September 1999 to March 2000. Mr. Martin has also held sales and sales management positions for The Procter & Gamble Company and Boston Scientific Corporation. Mr. Martin currently serves as a director of AccessClosure, Inc. and Apieron Inc., two privately-held medical device companies.

Laurence L. Betterley, Chief Financial Officer. Mr. Betterley joined us in April 2008 as our Chief Financial Officer. Previously, Mr. Betterley was Chief Financial Officer at Cima NanoTech, Inc. from May 2007 to April 2008, Senior Vice President and Chief Financial Officer of PLATO Learning, Inc. from June 2004 to January 2007, Senior Vice President and Chief Financial Officer of Diametrics Medical, Inc. from 1996 to 2003, and Chief Financial Officer of Cray Research Inc. from 1994 to 1996.

James E. Flaherty, Chief Administrative Officer and Secretary. Mr. Flaherty has been our Chief Administrative Officer since January 14, 2008. Mr. Flaherty was our Chief Financial Officer from March 2003 to January 14, 2008. As Chief Administrative Officer, Mr. Flaherty reports directly to our Chief Executive Officer and has responsibility for information technology, facilities, legal matters, financial analysis of business development opportunities and business operations. Mr. Flaherty assisted with our initial public offering process, including financial matters, and assisted with the transition of our new Chief Financial Officer. As our Chief Financial Officer, Mr. Flaherty had primary responsibility for the preparation of historical financial statements, but he no longer has any such responsibility. Prior to joining us, Mr. Flaherty served as an independent financial consultant from 2001 to 2003 and Chief Financial Officer of Zomax Incorporated from 1997 to 2001. Mr. Flaherty served as Chief Financial Officer of Racotek, Inc. from 1990 to 1996, of Time Management Corporation from 1986 to 1990, and of Nugget Oil Corp. from 1980 to 1985. Mr. Flaherty was an accountant at Coopers & Lybrand from 1975 to 1980. On June 9, 2005, the Securities and Exchange Commission filed a civil injunctive action charging Zomax Incorporated with violations of federal securities law by filing a materially misstated Form 10-Q for the period ended June 30, 2000. The SEC further charged that in a conference call with analysts, certain of Zomax s executive officers,

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including Mr. Flaherty, misrepresented or omitted to state material facts regarding Zomax s prospects of meeting quarterly revenue and earnings targets, in violation of federal securities law. Without admitting or denying the SEC s charges, Mr. Flaherty consented to the entry of a court order enjoining him from any violation of certain provisions of federal securities law. In addition, Mr. Flaherty agreed to disgorge $16,770 plus prejudgment interest and pay a $75,000 civil penalty.

Michael J. Kallok, Ph.D., Chief Scientific Officer and Director. Dr. Kallok has been our Chief Scientific Officer since February 2007 and a director since December 2002. Dr. Kallok was our Chief Executive Officer from December 2002 to February 2007. Dr. Kallok previously held positions at Medtronic Inc., Angeion Corporation, Myocor, Inc. and Boston Scientific Corporation. Dr. Kallok is also founder and president of his own consulting business, Medical Device Consulting, Inc.

John Borrell, Vice President of Sales. Mr. Borrell joined us in July 2006 as Vice President of Sales and Marketing. When Mr. Doughty was named Vice President of Marketing in August 2007, Mr. Borrell became our Vice President of Sales. Previously, he was employed as Director of Sales of FoxHollow Technologies, Inc. from October 2003 to April 2006. Mr. Borrell has more than 15 years of sales and sales management experience and has held various positions with Novoste Corporation (now NOVT Corporation), Medtronic Vascular, Inc., Heartport, Inc. and Johnson & Johnson.

Brian Doughty, Vice President of Marketing. Mr. Doughty joined us in December 2006 as Director of Marketing and was named Vice President of Marketing in August 2007. Prior to joining us, Mr. Doughty was Director of Marketing at EKOS Corporation from February 2005 to December 2006, National Sales Initiatives Manager of FoxHollow Technologies, Inc. from September 2004 to February 2005, National Sales Operations Director at Medtronic from August 2000 to September 2004, and Sales Team Leader for Johnson and Johnson from December 1998 to August 2000. Mr. Doughty has also held sales and sales management positions for Ameritech Information Systems.

Robert J. Thatcher, Executive Vice President. Mr. Thatcher joined us as Senior Vice President of Sales and Marketing in October 2005 and became our Vice President of Operations in September 2006. Mr. Thatcher became our Executive Vice President in August 2007. Previously, Mr. Thatcher was Senior Vice President of TriVirix Inc. from October 2003 to October 2005. Mr. Thatcher has more than 29 years of medical device experience in both large and start-up companies. Mr. Thatcher has held various sales management, marketing management and general management positions at Medtronic, Inc., Schneider USA, Inc. (a former division of Pfizer Inc.), Boston Scientific Corporation and several startup companies.

Paul Tyska, Vice President of Business Development. Mr. Tyska joined us in August 2006 as Vice President of Business Development. Previously, Mr. Tyska was employed at FoxHollow Technologies, Inc. since July 2003 where he most recently served as National Sales Director from February 2006 to August 2006. Mr. Tyska has held various positions with Guidant Corporation, CardioThoracic Systems, Inc., W. L. Gore & Associates and ATI Medical Inc.

Paul Koehn, Vice President of Manufacturing. Mr. Koehn joined us in March 2007 as Director of Manufacturing and was promoted to Vice President of Manufacturing in October 2007. Previously, Mr. Koehn was Vice President of Operations for Sewall Gear Manufacturing from 2000 to March 2007 and before joining Sewall Gear, Mr. Koehn held various quality and manufacturing management roles with Dana Corporation.

Glen D. Nelson, M.D. Dr. Nelson has been a member of our board of directors since 2003 and our Chairman since August 2007. Dr. Nelson was a member of the board of directors of Medtronic, Inc. from 1980 until 2002. Dr. Nelson joined Medtronic as Executive Vice President in 1986, and he was elected Vice Chairman in 1988, a position held until his retirement in 2002. Before joining Medtronic, Dr. Nelson practiced surgery from 1969 to 1986. Dr. Nelson was Chairman of the Board and Chief Executive Officer of American MedCenters, Inc. from 1984 to 1986. Dr. Nelson also was Chairman, President and Chief Executive Officer of the Park Nicollet Medical Center, a large multi-specialty group practice in Minneapolis, from 1975 to 1986. Dr. Nelson is on the board of directors of DexCom, Inc. and The Travelers Companies, Inc., both publicly-held companies, and also serves as a director for ten private companies.

Brent G. Blackey. Mr. Blackey has been a member of our board of directors since 2007. Since 2004, Mr. Blackey has served as the President and Chief Operating Officer for Holiday Companies. Between 2002 and 2004 Mr. Blackey

was a Senior Partner at the accounting firm of Ernst & Young LLP. Prior to 2002, Mr. Blackey served most recently as a Senior Partner at the accounting firm of Arthur Anderson LLP. Mr. Blackey serves on the board of directors of Datalink Corporation, and also serves on the Board of Overseers for the University of Minnesota, Carlson School of Management.

John H. Friedman. Mr. Friedman has been a member of our board of directors since 2006. Mr. Friedman is the Managing Partner of the Easton Capital Investment Group, a private equity firm. Prior to founding Easton Capital,

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Mr. Friedman was the founder and Managing General Partner of Security Pacific Capital Investors, a $200-million private equity fund geared towards expansion financings and recapitalizations, from 1989 to 1992. Prior to joining Security Pacific, Mr. Friedman was a Managing Director and Partner at E.M. Warburg, Pincus & Co., Inc. from 1981 to 1989. Mr. Friedman has also served as a Managing Director of Atrium Capital Corp., an investment firm. Mr. Friedman currently serves on the board of directors of Trellis Bioscience, Inc., Xoft, Inc., Sanarus Inc., Genetix Pharmaceuticals, Inc., PlaySpan Inc. and Experimed Bioscience, Inc., all of which are privately-held companies. Mr. Friedman is also Co-Chairman of the Cold Spring Harbor President s Council.

Geoffrey O. Hartzler, M.D. Dr. Hartzler has been a member of our board of directors since 2002. Dr. Hartzler commenced practice as a cardiologist in 1974, serving from 1980 to 1995 as a Consulting Cardiologist with the Mid America Heart Institute of St. Luke s Hospital in Kansas City, Missouri. Dr. Hartzler has co-founded three medical product companies including Ventritex Inc. Most recently he served as Chairman of the Board of IntraLuminal Therapeutics, Inc. from 1997 to 2004 and Vice Chairman from 2004 to 2006. Dr. Hartzler has also served as a consultant or director to over a dozen business entities, some of which are medical device companies.

Roger J. Howe, Ph.D. Dr. Howe has been a member of our board of directors since 2002. Over the past 22 years, Dr. Howe has founded four successful start-up ventures in the technology, information systems and medical products business sectors. Most recently, Dr. Howe served as Chairman of the Board and Chief Financial Officer of Reliant Technologies, Inc., a medical laser company, from 2001 to 2005. From 1996 to 2001, Dr. Howe served as Chief Executive Officer of Metrix Communications, Inc., a business-to-business software development company that he founded. Dr. Howe currently serves on the boards of directors of Stemedica Cell Technologies, Inc., BioPharma Scientific, Inc., America s Back & Neck Clinic, Inc. and Reliant Pictures Corporation, all of which are privately-held companies.

Gary M. Petrucci. Mr. Petrucci has been a member of our board of directors since 1992. Since August 2006, Mr. Petrucci has been Senior Vice President Investments at UBS Financial Services, Inc. Previously, Mr. Petrucci was an Investment Executive with Piper Jaffray & Co. from 1968 until Piper Jaffray s retail brokerage unit was sold to UBS Financial Services in August 2006. Mr. Petrucci served on the board of directors of Piper Jaffray & Co. from 1981 to 1995. Mr. Petrucci achieved the Fred Sirianni Award 14 times since the award began 25 years ago honoring the top producing Investment Executive at Piper Jaffray. In January 2005, this award was renamed in his honor. Mr. Petrucci received the 2002 Outstanding Alumni award from St. Cloud State University. Mr. Petrucci is serving as a member on the boards of directors of America s Back & Neck Clinic, Inc., National Urology Board, Stemedica Cell Technologies, Inc. and the University of Minnesota Landscape Arboretum.

Christy Wyskiel. Ms. Wyskiel has been a member of our board of directors since 2006. Since 2004, Ms. Wyskiel has served as a Managing Director in the healthcare group of Maverick Capital, Ltd., where she has worked since 2002. Maverick Capital, Ltd. currently manages more than $11 billion in assets. Prior to joining Maverick, Ms. Wyskiel served as an Equity Analyst at T. Rowe Price Associates, Inc. where she focused on the medical device industry. Ms. Wyskiel also served as a Healthcare Associate and Analyst in the investment banking department of Cowen and Company, LLC.

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ITEM 6. EXECUTIVE COMPENSATION

COMPENSATION DISCUSSION AND ANALYSIS

In the following Compensation Discussion and Analysis, we describe the material elements of the compensation awarded to, earned by or paid to our Chief Executive Officer, the two individuals who served as our Chief Financial Officer in fiscal 2008, and the other three most highly compensated executive officers as determined in accordance with SEC rules, who are collectively referred to as the named executive officers. This discussion focuses primarily on the fiscal 2008 information contained in the tables and related footnotes and narrative discussion but also describes compensation actions taken during other periods to the extent it enhances the understanding of our executive compensation disclosure for fiscal 2008. For example, although our fiscal year ends on June 30 of each year, our compensation programs have been established on a calendar year basis and, therefore, the discussion below includes information regarding periods before and after the fiscal year. We expect that the compensation program for executive officers of the combined company following the merger with Replidyne will be established on a fiscal year basis. Pursuant to the merger agreement with Replidyne, it is contemplated that the employment of all of Replidyne s current executive officers will be terminated immediately prior to the completion of the merger, and our then current officers will be appointed as the officers of the combined company and will be subject to the same compensation programs as they were as officers of us prior to the merger.

Compensation Objectives and Philosophy

The primary objectives of our compensation programs are to:

attract and retain talented and dedicated executives to manage and lead our company;

align the interests of our executives and shareholders by implementing cash incentive and equity programs designed to reward the achievement of corporate and individual objectives that promote growth in our business; and

motivate individuals to work as a team for the success of the company by fairly recognizing the contributions of each individual, including their experience, abilities and performance, to our collective success.

To achieve these objectives, our compensation committee recommends executive compensation packages to our board of directors that are generally based on a mix of salary, cash incentive payments and equity awards. Our compensation committee has not adopted any formal guidelines for allocating total compensation between equity and cash compensation, but attempts to recommend equity and cash amounts that are competitive with the amounts paid by other growth stage medical device companies. We believe that performance and equity-based compensation are important components of the total executive compensation package for maximizing shareholder value while, at the same time, attracting, motivating and retaining high-quality executives.

Setting Executive Compensation

The compensation committee makes recommendations to the board of directors regarding the elements of executive compensation, including the level of each element, the mix among the elements and total compensation based upon the objectives and philosophies set forth above. The compensation committee considers a number of factors, including:

each executive s position within the company and the level of responsibility;

the skills and experience required by an executive s position;

the executive s individual experience and qualifications;

the competitive environment for comparable executive talent having similar experience, skills and responsibilities;

company performance compared to specific objectives;

the executive s current and historical compensation levels;

the executive s length of service to our company;

compensation equity and consistency across all executive positions; and

the executive s existing holdings and rights to acquire equity.

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As a means of assessing the competitive market for executive talent, we have consulted with Lyons, Benenson & Company, a third-party compensation consulting firm, on competitive compensation for companies of comparable size and stage of development. Lyons compared executive compensation data of the following companies: ATS Medical, Inc.; Conceptus, Inc.; Cytokinetics, Incorporated; Emisphere Technologies, Inc.; FoxHollow Technologies, Inc.; Geron Corporation; Hansen Medical, Inc.; Lexicon Pharmaceuticals, Inc.; Misonix, Inc.; Nastech Pharmaceutical Company Inc.; Sonus Pharmaceuticals, Inc.; Tanox, Inc.; TanS1 Inc.; Vascular Solutions, Inc.; and XTENT, Inc. The compensation committee did not consider the compensation paid by any of the individual companies in Lyons survey, but instead reviewed the overall results of the survey when considering its recommendations for the compensation of our executive officers. Although the compensation committee seeks to recommend executive compensation at levels it believes to be competitive, this is only one factor in the committee s overall compensation recommendations and is not used as a stand-alone benchmarking tool. We will continue to seek information and guidance from a compensation consultant from time to time in the future.

Executive Compensation Components for Fiscal Year 2008

The principal elements of our executive compensation program for fiscal 2008 were:

base salary;

annual cash incentive compensation;

equity-based compensation, primarily in the form of stock options; and

employment benefits and limited perquisites.

In allocating compensation across these elements, the compensation committee does not follow any strict policy or guidelines. However, consistent with the general compensation objectives and philosophies outlined above, the compensation committee seeks to place a meaningful percentage of an executive s compensation at risk based on creating long-term shareholder value. For example, the compensation committee sets each executive s annual incentive compensation at a level designed to motivate the executive to achieve goals consistent with our long term business objectives, typically by establishing annual incentive opportunities ranging from 40% to 100% of the executive s base salary. The compensation committee believes this allocation of cash compensation between base salary and annual incentive compensation strikes the appropriate balance between guaranteeing executives an income adequate to satisfy living expenses and providing an incentive for the achievement of our goals. Equity-based compensation is also compensation at risk, since the equity increases in value only if we are successful in achieving our business goals, and serves to provide an incentive over a longer term. The compensation committee s judgment of the appropriate mix of compensation elements is also influenced by information they have reviewed as to the allocations made by other medical products companies at a similar stage of development and the experience of our compensation committee members. The fiscal 2008 compensation for our Chief Financial Officer was determined in the context of negotiating the terms under which he would join us as a new employee in April 2008, but our other named executive officers joined us prior to fiscal 2008.

Base Salary

Base salary is an important element of our executive compensation program as it provides executives with a fixed, regular, non-contingent earnings stream to support annual living and other expenses. As a component of total compensation, we generally set base salaries at levels believed to attract and retain an experienced management team that will successfully grow our business and create shareholder value. We also utilize base salaries to reward individual performance and contributions to our overall business objectives, but seek to do so in a manner that does not detract from the executives incentive to realize additional compensation through our performance-based compensation programs, stock options and restricted stock awards.

Our employment agreement with David Martin provides that his annual base salary for calendar 2007 would be $370,000 and that his base salary for subsequent years shall be determined by the board of directors. We offered this amount as part of a package of compensation for Mr. Martin sufficient to induce him to join us. The compensation package for Mr. Martin is designed to provide annual cash compensation, including both base salary and potential cash incentive earnings, sufficient to meet his current needs, although less than the annual cash compensation

Mr. Martin received at his previous employer and, we believe, less than Mr. Martin likely could have obtained with other, more established employers. The equity portion of Mr. Martin s compensation package, as described below, was designed to provide sufficient potential growth in value to induce Mr. Martin to join us despite the lower cash compensation.

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We paid each of John Borrell and Paul Tyska at an annual base salary rate of $200,000 during calendar 2008, the same base salaries they received in calendar 2007. The base salaries for each of Mr. Borrell and Mr. Tyska were negotiated as part of a compensation packages offered to induce them to join us. Mr. Borrell joined us in July 2006 as Vice President of Sales and Marketing and Mr. Tyska joined as Vice President of Business Development in August 2006. In each case the base salary was set at an amount that we believed to be generally consistent with the base salaries paid by other growth stage medical device companies for similar positions, but substantially less than the total cash compensation each of Mr. Borrell and Mr. Tyska received with their previous employers and, we believe, less than each of Mr. Borrell and Mr. Tyska likely could have obtained with other, more established employers. In order to induce Mr. Borrell and Mr. Tyska to accept positions with us despite lower base salaries, we agreed that each would also have the opportunity to earn performance-based incentive compensation, as described below, as well as equity awards. We believed that it was appropriate to make a significant portion of Mr. Borrell s cash compensation (a higher percentage than most other executives) subject to the achievement of performance objectives because of the particularly important role the Vice President of Sales and Marketing would play in the commercial introduction of our first product.

Each of Michael J. Kallok and James E. Flaherty has served as an officer prior to fiscal 2007 and their base salary rates are set by the compensation committee each year.

Our named executive officers received base salary at the calendar 2007 rates for the first and second quarters of fiscal 2008, and effective January 1, 2008, the base salaries for most of our named executive officers were increased for calendar 2008, which includes the third and fourth quarters of fiscal 2008. The base salary rates for each of our named executive officers, other than our Chief Financial Officer, in effect at the end of calendar 2007 and for calendar 2008, and the percentage changes from calendar 2007 to 2008, are set forth below.

	Annual Base Salary Rates		
Name	**Calendar 2007**	**Calendar 2008**	**% Change**
David L. Martin	$370,000	$395,000	6.8%
James E. Flaherty	200,000	218,000	9.0
Michael J. Kallok, Ph.D.	250,000	255,000	2.0
John Borrell	200,000	200,000	0
Paul Tyska	200,000	200,000	0

With respect to each increase, the compensation committee considered the range of compensation it believed to be paid by companies in our industry at a similar stage of development for the same position, the responsibility of the position as compared to other positions within our management team, the tenure of the employee with us, and cost-of-living adjustments. The compensation committee did not attempt to assign values to particular elements of performance or the other factors considered and considered all of these factors generally in making its judgment regarding base salaries. We did not raise the base salaries of John Borrell or Paul Tyska for calendar 2008 because we provide them with additional incentive compensation in the form of monthly sales commissions, as discussed below.

Laurence Betterley commenced employment as our Chief Financial Officer on April 14, 2008. Pursuant to the terms of his employment agreement, Mr. Betterley receives an annual base salary of $225,000. This base salary was negotiated with Mr. Betterley as part of the compensation package offered to induce him to join us. The base salary was set at an amount that we believed to be generally consistent with the base salaries paid by other growth stage medical device companies for similar positions.

Our compensation committee will review our Chief Executive Officer s salary annually at the end of each calendar year. The committee may recommend adjustments to the Chief Executive Officer s base salary based upon the committee s review of his current base salary, incentive cash compensation and equity-based compensation, as well as his performance and comparative market data.

Our compensation committee reviews other executives salaries throughout the year, with input from the Chief Executive Officer. The committee may recommend adjustments to each other named executive officer s base salary based upon the Chief Executive Officer s recommendation and the reviewed executive s responsibilities, experience

and performance, as well as comparative market data.

In utilizing comparative data, the compensation committee seeks to recommend salaries for each executive at a level that is appropriate after giving consideration to experience for the relevant position and the executive s performance. We review performance for both our company (based upon achievement of strategic initiatives) and each individual executive. Based upon these factors, the committee may recommend adjustments to base salaries to better align individual compensation with comparative market compensation, to provide merit-based increases based upon individual or company achievement, or to account for changes in roles and responsibilities.

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Annual Cash Incentive Compensation

Before Mr. Martin joined us as Chief Executive Officer we generally paid annual bonus compensation to our executive officers based on the executive s performance during the calendar year, the position and level of responsibility of the executive and the performance of our company, with particular focus on the executive s contribution to that performance. Because we had no revenues, the elements of company performance considered typically included progress in product development and clinical testing and achievement of financing goals. Payments were made based on the evaluation by our board and compensation committee of a broad range of information relating to individual and company performance rather than the achievement of specific goals. All of our executive officers were eligible to receive these discretionary annual bonuses, including James E. Flaherty, Michael J. Kallok, John Borrell and Paul Tyska. For the first two quarters of fiscal 2007, the bonus amounts for Messrs. Flaherty and Kallok were determined entirely at the discretion of the board and compensation committee, while the bonus amounts for Messrs. Borrell and Tyska were based upon provisions contained in their employment agreements providing that each executive is entitled to receive incentive pay equal to a designated percentage of his base salary, payable quarterly and based on performance objectives. Under the terms of his employment agreement, Mr. Borrell is eligible to receive a cash bonus up to $200,000 per year based upon quarterly objectives to be determined. Mr. Tyska s employment agreement provides that he is eligible to participate in a bonus program that is targeted to pay out $100,000 per year based on achieving results based upon agreed-upon objectives.

Shortly after Mr. Martin joined us in February 2007 and upon his recommendation, the compensation committee established an incentive program for calendar 2007, which included the third and fourth quarters of fiscal 2007 and the first two quarters of fiscal 2008, designed to reward named executive officers with quarterly payments for achieving specific individual goals related to financial growth, product development and commercialization and operational improvement.

Under the terms of the incentive program, the compensation committee set an annual target bonus amount for each officer expressed as a percentage of that officer s base salary. The percentage assigned to each officer was dependent in part on the position and responsibilities of the officer, and in the case of new hires in fiscal 2007, consistent with prior commitments made to such new hires. For each officer other than the Chief Executive Officer, the compensation committee delegated to the Chief Executive Officer the authority to set individual quarterly objectives that had to be achieved to earn the bonus. Each officer that achieved the quarterly objectives was entitled to receive partial payment of the annual target amount, typically 25% each quarter. We believe that quarterly objectives provide an incentive to maintain the rapid pace of growth of our business at its current stage.

The objectives reflected specific tasks for which the individual executive was responsible that were consistent with our overall fiscal year operating plan established by our board of directors. The specific objectives established for each of our named executive officers for the quarters ended September 30, 2007 and December 31, 2007 are set forth below:

Michael J. Kallok, Ph.D.

Objectives

Receive 510(k) clearance from the FDA for the Diamondback 360°

Support sales and marketing field activities

James E. Flaherty

Objectives

Adequate progress on our financing plan

Prepare a new financial model

Complete Series A-1 and B preferred stock financings

John Borrell

Objectives

Achieve specified average selling price and customer reorder rates

Company revenues of at least $800,000

Achieve specified hiring goals

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Paul Tyska

Objectives

Make adequate progress in strategic projects

Use of the Diamondback 360(o) by certain key opinion leaders

At the end of calendar 2007, Mr. Martin and the compensation committee concluded that each of the executive officers listed above had substantially satisfied all of the objectives and we paid the full target bonus amount to each officer for these periods, except for Mr. Borrell, who began to receive sales commissions in lieu of the quarterly incentive compensation following our limited commercial launch in September 2007. The compensation committee did not assign values to individual objectives or otherwise quantify the bonus amount payable with respect to any particular objective or group of objectives.

Generally, the objectives required performance at levels intended to positively impact shareholder value and reflect moderately aggressive to aggressive goals that are attainable, but require strong performance. Our Chief Executive Officer and compensation committee retain the discretion to increase or decrease a named executive officer s quarterly or annual bonus payout to recognize either inferior or superior individual performance in cases where this performance is not fully represented by the achievement or non-achievement of the pre-established objectives. For example, our compensation committee reserves the right to award an officer 100% of his or her annual target bonus even if that officer had not achieved any quarterly objectives. Neither the Chief Executive Officer nor the compensation committee exercised discretion to award any bonus with respect to fiscal 2008 in circumstances where applicable performance objectives had not been substantially met.

The compensation committee evaluated whether the Chief Executive Officer had earned his calendar 2007 annual target bonus amount only at the end of the calendar year based on our overall progress relative to our business plan. The compensation committee did not establish specific individual objectives for Mr. Martin under the incentive program for calendar 2007 because the committee concluded that defining appropriate objectives would be difficult given that Mr. Martin was new in his position. The committee decided that our overall results would be a more effective indicator of Mr. Martin s success as Chief Executive Officer than any specific quarterly objectives that might be established for Mr. Martin. Accordingly, shortly after Mr. Martin joined us, the compensation committee agreed, consistent with Mr. Martin s employment agreement, that Mr. Martin would have the opportunity to earn incentive pay of up to 25% of his base salary at the end of calendar 2007, provided his performance was satisfactory to the compensation committee. In December 2007, the compensation committee concluded that Mr. Martin had performed well during calendar 2007 and awarded him a bonus of $92,500, 100% of his target bonus for calendar 2007, which included the first and second quarters of fiscal 2008.

The following sets forth for each of our named executive officers the target incentive compensation as a percentage of base salary and total incentive plan payments earned in calendar 2007:

Name	Target Incentive Compensation as % of Base Salary	Total Calendar 2007 Non-Equity Incentive Plan Payments
David L. Martin	25%	$ 92,500
James E. Flaherty(1)	40	77,000
Michael J. Kallok, Ph.D.	40	100,000
John Borrell(2)	100	150,000
Paul Tyska	50	100,000

(1) Mr. Flaherty s base salary was raised from $185,000 to $200,000 during calendar 2007. Accordingly, the actual incentive payment he received for calendar 2007 does not reflect 40% of his base salary in effect on December 31, 2007.

(2) Mr. Borrell received an additional $114,517 in sales commissions for the period commencing with our limited commercial launch in September 2007 and ending on December 31, 2007.

For David Martin, John Borrell and Paul Tyska the percentage of base salary that would be available as incentive compensation was negotiated as a term of their employment agreements at the time of their joining us. For James E. Flaherty and Michael J. Kallok, the compensation committee determined that 40% of base salary represented an appropriate short term cash incentive, based on the experience and judgment of the members of the compensation committee. In determining these percentages, the compensation committee s philosophy was to reduce fixed compensation costs in favor of variable compensation costs tied to performance, where possible.

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In February 2008, the board adopted a new incentive plan for calendar 2008, which includes the third and fourth quarters of fiscal 2008 and the first two quarters of fiscal 2009. This plan conditions the payment of incentive compensation to all participants, including Mr. Martin, upon our achievement of revenue and gross margin financial goals. None of our named executive officers is subject to individual goals under this plan. Under this plan, our named executive officers are eligible to receive annual cash incentive compensation with target bonus levels ranging from 50%, in the case of our President and Chief Executive Officer, to 40%, in the case of our other named executive officers, of their yearly base salaries. Participants are eligible to earn 50% to 150% of their target bonus amount depending upon our performance relative to the plan criteria; however, in the event of extraordinary revenue performance above the goals set by the board, all of the named executive officers would receive incentive payments greater than 150% of their targets based upon a formula established by the board, with no maximum payout set under the plan. The plan provides for two separate payments to the participants, the first based upon company performance in the first six months of calendar 2008 and the second based upon company performance in the entire calendar year. The plan criteria are the same for all of our named executive officers. This plan is designed to reward the executive officers for achieving and surpassing the financial goals set by the compensation committee and board of directors. We believe that the financial goals are aggressive but attainable if our performance is strong.

The annual threshold, target and maximum incentive compensation of our named executive officers under this new plan are set forth in the Grants of Plan-Based Awards in Fiscal Year 2008 table on page 81. The target percentages of annual base salary under this new plan are as follows:

Name	Target % of Annual Base Salary
David L. Martin	50%
Laurence L. Betterley(1)	40%
James E. Flaherty	40%
Michael J. Kallok, Ph.D.	40%
John Borrell	40%
Paul Tyska	40%

(1) Mr. Betterley s actual payment will be adjusted proportionally to reflect his start date of April 14, 2008.

In order for each officer to be eligible to receive a payment for the first six months of calendar 2008, we needed to achieve gross margins of at least 50% for that period. If we achieved this goal, then upon achievement of the revenue goals set forth below, each of the plan participants was eligible to receive the following percentages of their annual target bonus:

Revenue for the Period of January 1, 2008 June 30, 2008	% of Annual Target Bonus
$10 million	25%
$12 million	50%
Over $12 million	62.5%

Based upon our achievement of the gross margin goal and revenues in excess of $12 million for this six-month period, on August 29, 2008 we made payments under this plan to our named executive officers equal to 62.5% of their annual target incentive compensation. If we meet gross margin and revenue goals for the entire calendar year, we will make an additional payment to our named executive officers following the end of calendar 2008.

In addition to incentives under the new plan, Mr. Borrell receives a monthly sales commission of 0.666% of all sales and Mr. Tyska receives a monthly sales commission of 0.333% of all sales. We believe that paying sales commissions to these named executive officers each month of the first full year of our commercial launch provides them with significant incentives to maximize their efforts to increase our sales throughout the year.

Stock Option and Other Equity Awards

Consistent with our compensation philosophies related to performance-based compensation, long-term shareholder value creation and alignment of executive interests with those of shareholders, we make periodic grants of long-term compensation in the form of stock options or restricted stock to our named executive officers, to our other executive officers and across our organization generally.

For our named executive officers, we believe that stock options offer the best incentives and tax attributes (by deferring taxes until the holder is ready to exercise and sell) necessary to motivate and retain them to enhance overall enterprise value.

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Stock options provide named executive officers with the opportunity to purchase our common stock at a price fixed on the grant date regardless of future market price. A stock option becomes valuable only if our common stock price increases above the option exercise price and the holder of the option remains employed during the period required for the option shares to vest. This provides an incentive for an option holder to remain employed by us. In addition, stock options link a significant portion of an employee s compensation to shareholders interests by providing an incentive to achieve corporate goals and increase shareholder value.

Under our 2007 Equity Incentive Plan, we may also make grants of restricted stock awards, restricted stock units, performance share awards, performance unit awards and stock appreciation rights to officers and other employees. We adopted this plan to give us flexibility in the types of awards that we could grant to our executive officers and other employees.

In connection with the negotiations to hire Mr. Martin, our Chief Executive Officer, we agreed in principle that Mr. Martin would be granted options to purchase a number of shares which, when combined with shares subject to options that he had already received as a board member and consultant, would equal approximately 5.5% of our then outstanding common stock. Our compensation committee and board of directors believed, based on their collective experience with other medical device companies, that 5.5% was within the range of equity compensation amounts typically granted at the Chief Executive Officer level by companies of comparable size and stage of development. They also believed that equity compensation at 5.5% was a key element necessary to make the entire compensation package offered to Mr. Martin sufficiently attractive to induce him to join our company.

Our compensation committee consulted Lyons, Benenson & Company, a third-party compensation consulting firm, to determine competitive levels of stock option grants for officers in comparable positions with companies of comparable size and stage of development. Based on the guidance from Lyons and the experience of our compensation committee members, the compensation committee considered the relative ownership levels of each officer based upon levels prior to a public offering and estimated levels following a public offering and has identified target levels of option grants for each of our officers. Furthermore, the compensation committee considered each named executive officer s role and responsibilities, ability to influence long term value creation, retention and incentive factors and current stock and option holdings at the time of grant, as well as individual performance, which is a significant factor in the committee s decisions. We granted options in fiscal 2008 to each of our officers to bring the total number of shares subject to options held by each such officer, including shares subject to any previously granted options, closer to the levels identified by the compensation committee as appropriate for that position, while also taking into consideration performance of the officer and the limitations imposed by number of shares authorized for issuance under our stock option plans. The compensation committee did not consider specific performance objectives but generally concluded that each of our executive officers had performed well and deserved option grants intended to move their equity ownership closer to the compensation committee s targeted levels. The grants of stock options to purchase 775,000 shares made to our named executive officers in December 2008 vest in full on the third anniversary of the grant date, provided that we have completed an initial public offering or a change of control transaction before December 31, 2008. We included this vesting restriction on the grants of stock options in order to provide additional incentives to our named executive officers to complete an initial public offering or complete an alternate transaction that would provide shareholder liquidity. These options have been amended by our board of directors to provide for vesting of 50% of the options on the first anniversary, and 50% of the options on the second anniversary, of the closing of the merger with Replidyne.

Certain of our stock option and restricted stock agreements also provide that in the event of a change of control (the sale by us of substantially all of our assets and the consequent discontinuance of our business, or in the event of a merger, exchange or liquidation of us), the vesting of all options and shares of restricted stock will accelerate and the options will be immediately exercisable as of the effective date of the change of control. Excluding the options to purchase 775,000 shares of our common stock described in the previous paragraph, our named executive officers are also the holders of unvested options to purchase 808,332 shares of our common stock and 75,000 shares of unvested restricted stock that are subject to a stock option or restricted stock agreement that contains this provision. It is a condition to the closing of the merger with Replidyne that we obtain an acknowledgement in a form reasonably acceptable to Replidyne from the holders of these options and shares of restricted stock that the terms of the option or

restricted stock agreements related thereto do not provide that the vesting of such securities will accelerate, in whole or in part, in connection with or as a result of the consummation of the merger and the other transactions contemplated by the merger agreement.

From time to time we may make one-time grants of stock options or restricted stock to recognize promotion or consistent long-term contribution, or for specific incentive purposes. For example, in fiscal 2008 we made a grant of 348,725 vested stock options to Dr. Kallok to replace expired and unexercised options. Dr. Kallok would have been required to expend substantial funds to exercise these options and pay the associated tax liability, but he would not have been able to benefit from liquidity of the exercised shares to cover the exercise price or the tax liability. Dr. Kallok was instrumental in our company s development and we made this replacement grant for retention purposes and to reward Dr. Kallok for his service.

We also granted stock options to our named executive officers in connection with their initial employment. In connection with our negotiations with Mr. Betterley to join us as Chief Financial Officer, we provided Mr. Betterley with a grant of 75,000 shares of restricted stock under our 2007 Equity Incentive Plan, which shares vest ratably in three annual installments, beginning on April 14, 2009. We have made grants of restricted stock to various employees under our 2007 Equity Incentive Plan and Mr. Betterley was our first named executive officer to receive such a grant. We intend to grant restricted stock instead of, or in addition to, stock options to our executive officers in the future, because we can typically use fewer shares from our available pool in making restricted stock grants. We believe that restricted stock is as effective as stock options in motivating performance of employees.

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We have not made any grants of stock options or restricted stock to our named executive officers since the end of fiscal 2008.

Although we do not have any detailed stock retention or ownership guidelines, our board of directors and the compensation committee generally encourage our executives to have a financial stake in our company in order to align the interests of our shareholders and management, and view stock options as a means of furthering this goal. We will continue to evaluate whether to implement a stock ownership policy for our officers and directors.

Additional information regarding the stock option and restricted stock grants made to our named executive officers for fiscal 2008 is available in the Summary Compensation Table for Fiscal Year 2008 on page 79, and in the Outstanding Equity Awards at Fiscal Year-end for Fiscal Year 2008 Table on page 81.

Limited Perquisites; Other Benefits

It is generally our policy not to extend significant perquisites to our executives beyond those that are available to our employees generally, such as 401(k) plan, health, dental and life insurance benefits. We have given car allowances to certain named executives and moving allowances for executives who have relocated. We also pay for housing and related costs for our Chief Executive Officer.

Role of Our Compensation Committee

Our compensation committee was appointed by our board of directors, and consists entirely of directors who are outside directors for purposes of Section 162(m) and non-employee directors for purposes of Rule 16b-3 under the Exchange Act. Our compensation committee is comprised of Messrs. Petrucci, Howe and Friedman. The functions of our compensation committee include, among other things:

- recommending the annual compensation packages, including base salaries, incentive compensation, deferred compensation and stock-based compensation, for our executive officers;
- recommending cash incentive compensation plans and deferred compensation plans for our executive officers, including corporate performance objectives;
- administering our stock incentive plans, and subject to board approval in the case of executive officers, approving grants of stock, stock options and other equity awards under such plans;
- reviewing and making recommendations regarding the terms of employment agreements for our executive officers;
- reviewing and discussing the compensation discussion and analysis with management; and
- preparing the compensation committee report to be included in our annual proxy statement.

All compensation committee recommendations regarding compensation to be paid or awarded to our executive officers are subject to approval by a majority of the independent directors serving on our board of directors.

Our Chief Executive Officer may not be present during any board or compensation committee voting or deliberations with respect to his compensation. Our Chief Executive Officer may, however, be present during any other voting or deliberations regarding compensation of our other executive officers, but may not vote on such items of business. In fiscal 2008, our compensation committee met without the Chief Executive Officer present to review and determine the compensation of our Chief Executive Officer, with input from him and our third-party compensation consultant on his annual salary and cash incentive compensation for the year. For all other executive officers in fiscal 2008, the compensation committee met with our Chief Executive Officer to consider and determine executive compensation, based on recommendations by our Chief Executive Officer and our third-party compensation consultant.

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Summary Compensation Table for Fiscal Year 2008

The following table provides information regarding the compensation earned during the fiscal years ended June 30, 2008 and June 30, 2007 by our Chief Executive Officer, the two individuals who served as our Chief Financial Officer during fiscal 2008, and each of our other three most highly compensated executive officers. We refer to these persons as our named executive officers elsewhere in this Form 10.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards(1) ($)	Option Awards(1) ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
David L. Martin	2008	$377,629	$ 0	$	$ 314,552	$215,928	$94,427	$1,002,536
President and Chief Executive Officer(2)	2007	129,573	0		99,108	0	47,653	276,334
Laurence L. Betterley	2008	43,269	0	64,011		23,438	0	130,718
Chief Financial Officer(3)								
James E. Flaherty	2008	196,853	0		81,304	94,500	0	372,657
Chief Administrative Officer and former Chief Financial Officer(4)(5)	2007	166,658	39,562		26,179	37,000	0	269,399
Michael J. Kallok, Ph.D.	2008	242,769	0		1,686,016	113,750	0	2,042,535
Chief Scientific Officer and former Chief Executive Officer(5)(6)	2007	246,923	50,000		49,184	50,000	0	396,107
John Borrell	2008	200,000	0		75,773	331,493	7,800	615,066
Vice President of Sales(7)	2007	196,154	0		19,729	200,000	7,800	423,683
Paul Tyska	2008	200,000	0		54,270	158,429	7,800	420,499
Vice President Business Development(8)	2007	167,692	0		12,774	83,333	6,825	270,624

(1) The value of stock awards and options in this table represent the amounts recognized for financial statement reporting purposes for

fiscal 2008 in accordance with FAS 123(R), and thus may include amounts from awards granted in and prior to fiscal 2008. For a discussion of valuation assumptions and additional SFAS No. 123(R) disclosures, see Note 6 to our consolidated financial statements regarding stock compensation at page F-17 of this Form 10.

(2) Mr. Martin commenced employment on February 15, 2007.

The amount under Non-Equity Incentive Plan Compensation for Mr. Martin for 2008 consists of (i) incentive compensation of $92,500 paid to Mr. Martin at the end of calendar 2007 to satisfy our commitment to pay Mr. Martin 25% of his initial base salary of $370,000 under

his employment agreement dated December 19, 2006, which award was based upon his performance in the third and fourth quarters of fiscal 2007 and the first and second quarters of fiscal 2008, and (ii) incentive compensation of $123,428 paid for company performance through June 30, 2008 under our incentive plan for calendar 2008. Any additional amounts earned by Mr. Martin under the calendar 2008 incentive plan will be paid in fiscal 2009. Please also see the Grants of Plan-Based Awards in Fiscal Year 2008 table, which discloses the full potential amounts payable under this plan for calendar 2008.

The amounts under All Other Compensation for Mr. Martin (i) for 2008 consist of

payments for housing, furniture rental, cleaning and related expenses of $68,499, car and transportation expenses of $17,471, and reimbursement of $8,457 for transportation costs of visits to Minnesota by his family, and (ii) for 2007 consist of payments for housing, moving, furniture rental, cleaning and related expenses of $38,483, car and transportation expenses of $6,794, and reimbursement of $2,376 in legal fees incurred in connection with the negotiation of his employment agreement. We provided Mr. Martin with a moving allowance of $40,000 that he used for various of these expenses in fiscal 2007 and fiscal 2008, with approximately $7,327 remaining under

this allowance following fiscal 2008.

(3) Mr. Betterley commenced employment on April 14, 2008.

The amount under Non-Equity Incentive Plan Compensation for Mr. Betterley for 2008 consists of incentive compensation paid for company performance through June 30, 2008 under our incentive plan for calendar 2008. The amount accrued through June 30, 2008 will be paid to Mr. Betterley, along with any additional amounts earned by Mr. Betterley under the calendar 2008 incentive plan will be paid in fiscal 2009. Please also see the Grants of Plan-Based Awards in Fiscal Year 2008 table, which discloses the full potential amounts

payable under this plan for calendar 2008.

(4) Mr. Flaherty was our Chief Financial Officer until January 14, 2008, when he became our Chief Administrative Officer. Mr. Martin was appointed our Interim Chief Financial Officer pending the appointment of our new Chief Financial Officer in April 2008.

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The amount under Non-Equity Incentive Plan Compensation for Mr. Flaherty for 2008 consists of (i) incentive compensation of $40,000 paid to Mr. Flaherty for the first and second quarters of fiscal 2008 under our incentive program for calendar 2007, and (ii) incentive compensation of $54,500 paid for company performance through June 30, 2008 under our incentive plan for calendar 2008. Any additional amounts earned by Mr. Flaherty under the calendar 2008 incentive plan will be paid in fiscal 2009. Please also see the Grants of Plan-Based Awards in Fiscal Year 2008 table, which discloses the full potential amounts payable under this plan for calendar 2008.

(5)

Cash incentive compensation for each of Messrs. Flaherty and Kallok for performance in the first and second quarters of fiscal 2007 was based entirely upon the discretion of the board and the compensation committee, and the amounts paid are represented in the Bonus column. For performance in the third and fourth quarters of fiscal 2007, cash incentive compensation for these named executive officers was based upon specific performance objectives, and the amounts paid are represented in the Non-Equity Incentive Plan Compensation column.

(6) The amount under Non-Equity Incentive Plan Compensation for Dr. Kallok for 2008 consists of (i) incentive compensation of $50,000 paid to Dr. Kallok for

the first and second quarters of fiscal 2008 under our incentive program for calendar 2007, and (ii) incentive compensation of $63,750 paid for company performance through June 30, 2008 under our incentive plan for calendar 2008. Any additional amounts earned by Dr. Kallok under the calendar 2008 incentive plan will be paid in fiscal 2009. Please also see the Grants of Plan-Based Awards in Fiscal Year 2008 table, which discloses the full potential amounts payable under this plan for calendar 2008.

(7) Mr. Borrell commenced employment on July 1, 2006.

The amount under Non-Equity Incentive Plan Compensation for Mr. Borrell for 2008 consists of (i) incentive compensation of

$50,000 paid to Mr. Borrell for the first and second quarters of fiscal 2008 under our incentive program for calendar 2007, (ii) commissions of $231,493 earned in fiscal 2008, and (iii) incentive compensation of $50,000 paid for company performance through June 30, 2008 under our incentive plan for calendar 2008. Any additional amounts earned by Mr. Borrell under the calendar 2008 incentive plan will be paid in fiscal 2009. Please also see the Grants of Plan-Based Awards in Fiscal Year 2008 table, which discloses the full potential amounts payable under this plan for calendar 2008.

The amounts under All Other Compensation for Mr. Borrell consist of a car allowance of $650 per month.

(8) Mr. Tyska commenced employment on August 23, 2006.

The amount under Non-Equity Incentive Plan Compensation for Mr. Tyska for 2008 consists of (i) incentive compensation of $50,000 paid to Mr. Tyska for the first and second quarters of fiscal 2008 under our incentive program for calendar 2007, (ii) commissions of $58,429 earned in fiscal 2008, and (iii) incentive compensation of $50,000 paid for company performance through June 30, 2008 under our incentive plan for calendar 2008. Any additional amounts earned by Mr. Tyska under the calendar 2008 incentive plan will be paid in fiscal 2009. Please also see the Grants of Plan-Based Awards in Fiscal Year 2008 table, which discloses

the full potential amounts payable under this plan for calendar 2008.

The amounts under All Other Compensation for Mr. Tyska consist of a car allowance of $650 per month.

Grants of Plan-Based Awards in Fiscal Year 2008

All stock options granted to our named executive officers are incentive stock options, to the extent permissible under the Internal Revenue Code of 1986, as amended. The exercise price per share of each stock option granted to our named executive officers was equal to the fair market value of our common stock as determined in good faith by our board of directors on the date of the grant. The options listed in the table below were granted under our 2007 Equity Incentive Plan. See Employee Benefit Plans Current Equity Plans 2007 Equity Compensation Plan for a complete description of terms of the options grants.

The following table sets forth certain information regarding grants of plan-based awards to our named executive officers during the fiscal year ended June 30, 2008. We omitted columns related to equity incentive plan awards as none of our named executive officers earned any such awards during fiscal 2008.

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		Estimated Future Payouts Under Non-Equity Incentive Plan Awards(1)			All Other Stock Awards: Number of	All Other Option Awards: Number of		Grant Date
Name	**Grant Date**	**Threshold ($)**	**Target ($)**	**Maximum(2) ($)**	**Shares of Stock or Units**	**Securities Underlying Options**	**Exercise or Base Price of Option Awards(3)**	**Fair Market Value of Stock and Option Awards(4)**
David L. Martin	12/12/07					375,000	$7.86	$1,621,125
	2/13/08	$98,750	$197,500	$296,250				
Laurence L. Betterley(5)	4/14/08	$45,000	$ 90,000	$135,000	75,000			770,250
James E. Flaherty	8/07/07					35,000	$5.11	110,565
	12/12/07					50,000	$7.86	216,150
	2/13/08	$43,600	$ 87,200	$130,800				
Michael J. Kallok, Ph.D.	12/12/07					50,000	$7.86	216,150
	12/31/07					488,215	$7.86	1,630,150
	2/13/08	$51,000	$102,000	$153,000				
John Borrell(6)	8/07/07					35,000	$5.11	110,565
	12/12/07					100,000	$7.86	432,300
	2/13/08	$40,000	$ 80,000	$120,000				
Paul Tyska(7)	8/07/07					35,000	$5.11	110,565
	12/12/07					50,000	$7.86	216,150
	2/13/08	$40,000	$ 80,000	$120,000				

(1) Amounts in this column represent potential payments under our incentive plan for calendar 2008, which includes the third and fourth quarters of fiscal 2008

and the first and second quarters of fiscal 2009. Please see the Summary Compensation Table for the amounts accrued for payments under this plan to our named executive officers through June 30, 2008.

(2) The amounts in this column represent the maximum payments based upon revenue and gross margin goals established by our board of directors. In the event of extraordinary revenue performance above those goals, all of the named executive officers would receive incentive payments greater than these amounts based upon a formula established by the board, with no maximum payout set under the plan.

(3) See Note 6 to our consolidated

financial statements regarding stock compensation at page F-17 of this Form 10 for a discussion of the methodology for determining the exercise price.

(4) Reflects the grant date fair market value of stock and option awards granted in fiscal 2008, computed in accordance with SFAS No. 123(R). For a discussion of valuation assumptions, see Note 6 to our consolidated financial statements regarding stock compensation at page F-17 of this Form 10.

(5) Mr. Betterley s actual incentive compensation will be adjusted proportionally to reflect his start date of April 14, 2008. (6) Mr. Borrell will also be

paid a sales commission of 0.666% on all sales, to be paid monthly. There are no threshold, target or maximum amounts payable in connection with this sales commission. (7) Mr. Tyska will also be paid a sales commission of 0.333% on all sales, to be paid monthly. There are no threshold, target or maximum amounts payable in connection with this sales commission.

Outstanding Equity Awards at Fiscal Year-end for Fiscal Year 2008

The following table sets forth certain information regarding outstanding equity awards held by our named executive officers as of June 30, 2008.

	Option Awards				Stock Awards		
	Number of Securities Underlying Unexercised	Number of Securities Underlying Unexercised	Option	Option	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights

Name	Grant Date	Options Exercisable	Options Unexercisable	Exercise Price(1)	Expiration Date	Rights That Have Not Vested	That Have Not Vested
David L. Martin(2)(3)	7/17/06	45,000	65,000	$5.71	7/16/11		
	8/15/06	20,000	40,000	5.71	8/14/11		
	2/15/07	240,000	300,000	5.71	2/14/12		
	6/12/07	46,667	93,333	5.11	6/11/17		

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		Option Awards				Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price(1)	Option Expiration Date	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested
	12/12/07	0	375,000	7.86	12/11/17		
Laurence L. Betterley(4)	4/14/08					75,000	$766,601
James E. Flaherty(3)(5)	2/17/04	20,000	0	6.00	2/16/09		
	11/16/04	7,500	0	6.00	11/15/09		
	7/01/05	16,666	8,334	8.00	6/30/10		
	11/08/05	8,000	4,000	8.00	11/7/10		
	12/19/06	4,833	9,667	5.71	12/18/16		
	4/18/07	13,000	26,000	5.71	4/17/17		
	8/07/07	0	35,000	5.11	8/06/17		
	12/12/07	0	50,000	7.86	12/11/17		
Michael J. Kallok, Ph.D.(3)(6)	6/21/04	25,000	0	6.00	2/16/09		
	11/16/04	20,000	0	6.00	11/15/09		
	11/08/05	33,334	16,666	8.00	11/07/10		
	7/17/06	16,666	33,334	5.71	7/16/11		
	12/19/06	33,333	66,667	5.71	12/18/16		
	12/12/07	0	50,000	7.86	12/11/17		
	12/31/07	488,215	0	7.86	12/30/12		
John Borrell(3)(5)	7/17/06	44,000	88,000	5.71	6/30/11		
	12/19/06	2,667	5,333	5.71	12/18/16		
	4/18/07	11,333	22,667	5.71	4/17/17		
	8/07/07	0	35,000	5.11	8/06/17		
	12/12/07	0	100,000	7.86	12/11/17		

Paul Tyska(3)(5)	10/03/06	46,666	93,334	5.71	10/02/11
	8/07/07	0	35,000	5.11	8/06/17
	12/12/07	0	50,000	7.86	12/11/17

(1) See Note 6 to our consolidated financial statements regarding stock compensation at page F-17 of this Form 10 for a discussion of the methodology for determining the exercise price.

(2) The July 2006 options vest at the rate of 5,000 shares per month starting on August 17, 2006. The August 2006 and June 2007 options vest at the rate of one-third per year starting on the first anniversary of the grant date. The February 2007 options vest at the rate of 15,000 shares per month starting March 15, 2007. The December 2007 grant will vest in full on the third anniversary of the grant date provided that we have completed an initial public offering or a change of control transaction before December 31, 2008. The

December 2007 options have been amended by our board of directors to provide for vesting of 50% of the options on the first anniversary, and 50% of the options on the second anniversary, of the closing of the merger with Replidyne.

(3) Certain of CSI s stock option agreements provide that in the event of a change of control (the sale by CSI of substantially all of its assets and the consequent discontinuance of its business, or in the event of a merger, exchange or liquidation of CSI), the vesting of all options will accelerate and the options will be immediately exercisable as of the effective date of the change of control. It is a condition to the closing of the merger with Replidyne that CSI obtain an acknowledgement in a form reasonably acceptable to Replidyne from our officers and

directors and the holders of 80% of the remainder of these options that the terms of the option agreements related thereto do not provide that the vesting of such securities will accelerate, in whole or in part, in connection with or as a result of the consummation of the merger and the other transactions contemplated by the merger agreement.

(4) Restricted stock award vests at the rate of one-third per year starting on the first anniversary of the grant date.

(5) All option awards vest at the rate of one-third per year starting on the first anniversary of the grant date, except for the grants made on December 12, 2007, which vest in full on the third anniversary of the grant date provided that we have completed an initial public offering or a change of control transaction before December 31, 2008. The

December 2007 options have been amended by our board of directors to provide for vesting of 50% of the options on the first anniversary, and 50% of the options on the second anniversary, of the closing of the merger with Replidyne.

(6) All option awards received through December 2006 vest at the rate of one-third per year starting on the first anniversary of the grant date. The grant made on December 12, 2007 vests in full on the third anniversary of the grant date provided that we have completed an initial public offering or a change of control transaction before December 31, 2008.

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The December 31, 2007 grant vested immediately. The December 12, 2007 options have been amended by our board of directors to provide for vesting of 50% of the options on the first anniversary, and 50% of the options on the second anniversary, of the closing of the merger with Replidyne.

Option Exercises and Stock Vested for Fiscal Year 2008

The following table sets forth certain information regarding option exercises by our named executive officers during the fiscal year ended June 30, 2008. There was no stock vesting for any of our named executive officers during the fiscal year ended June 30, 2008.

	Option Awards	
Name	**Number of Shares Acquired on Exercise**	**Value Realized on Exercise(1)**
David L. Martin	70,000	$ 115,500
Laurence L. Betterley		
James E. Flaherty	40,000	94,284
Michael J. Kallok, Ph.D.		
John Borrell		
Paul Tyska		

(1) Reflects the aggregate dollar amount realized by the individual upon exercise of the options as determined by multiplying the

number of shares acquired on exercise by the difference between the fair market value of the shares on the date of exercise, as determined by our management and board of directors, and the exercise price of the options.

Potential Payments Upon Termination or Change of Control

The majority of our stock option agreements provide that in the event of a change of control (the sale by us of substantially all of our assets and the consequent discontinuance of our business, or in the event of a merger, exchange or liquidation of us), the vesting of all options will accelerate and the options will be immediately exercisable as of the effective date of the change of control. Our restricted stock agreements also provide for the acceleration of vesting as of the effective date of a change of control. We estimate the potential value of acceleration of options and restricted stock held by each of our named executive officers as of June 30, 2008 to be as follows:

Name	Value of Accelerated Options or Restricted Stock(1)
David L. Martin	$ 3,214,862
Laurence L. Betterley	766,601
James E. Flaherty	485,627
Michael J. Kallok, Ph.D.	606,663
John Borrell	939,083
Paul Tyska	718,549

(1) Reflects the excess of the fair market value of the shares underlying unvested options over the exercise price of such options, or the fair market value of the unvested restricted stock. Fair market value is based upon a per share

price of $10.22 as of June 30, 2008, as determined by our management and board of directors.

Under the terms of the employment agreement with Mr. Martin, we will pay Mr. Martin an amount equal to 12 months of his then current base salary and 12 months of our share of health insurance costs if Mr. Martin is terminated by us without cause, or if Mr. Martin terminates his employment for good reason, as defined in the agreement. Good reason is generally defined as the assignment of job responsibilities to Mr. Martin that are not comparable in status or responsibility to those job responsibilities set forth in the agreement, a reduction in Mr. Martin s base salary without his consent, or our failure to provide Mr. Martin the benefits promised under his employment agreement. As a condition to receiving his severance benefits, Mr. Martin is required to execute a release of claims agreement in favor of us.

Under the terms of the employment agreement with Mr. Betterley, we will pay Mr. Betterley an amount equal to 12 months of his then current base salary and 12 months of our share of health insurance costs if Mr. Betterley is terminated by us without cause, or if Mr. Betterley terminates his employment for good reason, as defined in the agreement. Good reason is generally defined as the assignment of job responsibilities to Mr. Betterley that are not comparable in status or responsibility to those job responsibilities set forth in the agreement, a reduction in Mr. Betterley s base salary without his consent, or our failure to provide Mr. Betterley the benefits promised under his employment agreement. As a condition to receiving his severance benefits, Mr. Betterley is required to execute a release of claims agreement in favor of us. Mr. Betterley must have been continuously employed by us for six months to be eligible to receive any severance benefits.

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Under the terms of the employment agreement with Dr. Kallok, we will pay Dr. Kallok an amount equal to 12 months of his then current base salary, 12 months of our share of health insurance costs and the greater of his prior year bonus or current bonus, as adjusted per terms of the agreement if Dr. Kallok is terminated by us without cause, or if Dr. Kallok terminates his employment for good reason, as defined in the agreement. Good reason is generally defined as the assignment of job responsibilities to Dr. Kallok that are not comparable in status or responsibility to those job responsibilities set forth in the agreement, a reduction in Dr. Kallok s base salary without his consent, or our failure to provide Dr. Kallok the benefits promised under his employment agreement. As a condition to receiving his severance benefits, Dr. Kallok is required to execute a release of claims agreement in favor of us.

We agreed to the payment of severance benefits in the employment agreements with Mr. Martin, Mr. Betterley and Dr. Kallok because they each requested these severance benefits and we believed it was necessary to provide such benefits in order to obtain the agreements with them. We believe that other medical device manufacturers provide substantially similar severance benefits to their senior officers and that providing severance benefits to our Chief Executive Officer and Chief Financial Officer is therefore consistent with market practices. We believe that such benefits are reasonable to protect the Chief Executive Officer and Chief Financial Officer against the risk of having no compensation while they seek alternative employment following a termination of their employment with us. The terms of the severance provisions for Mr. Martin and Mr. Betterley, on the one hand, and Dr. Kallok, on the other hand, vary in certain respects because Dr. Kallok s agreement was negotiated in May 2003 before we had formed a compensation committee and when the composition of the board was different than the current board, and Mr. Martin s agreement was negotiated in December 2006 and Mr. Betterley s agreement was negotiated in April 2008.

The following table shows as of June 30, 2008 the potential payments upon termination by us without cause or by the employee for good reason for Messrs. Martin and Kallok:

Name	12 Months Base Salary	12 Months Health Insurance Costs	Bonus	Total
David L. Martin	$395,000	$ 12,000	$ 0	$407,000
Michael J. Kallok, Ph.D.	255,000	12,000	100,000	367,000

Mr. Betterley joined us on April 14, 2008 and, therefore, was not employed by us for at least six months at June 30, 2008. Accordingly, he would have received no termination payments at that time.

Non-Competition Agreements

The employment agreements for David Martin, Laurence Betterley, Michael Kallok and James Flaherty contain non-competition provisions. The non-competition provisions prohibit these officers from providing services to any person or entity in connection with products that compete with those of the company. The geographic market covered by the agreements is that in which we compete at the time of the executive s termination. The non-competition restrictions are in effect during the period that each of these officers is employed by us and continue for one year following the termination of their employment with us.

Employee Benefit Plans

Current Equity Plans

2007 Equity Incentive Plan. Our board of directors adopted our 2007 Equity Incentive Plan, or the 2007 Plan, in October 2007 and approved certain amendments to the 2007 Plan in November 2007, and our shareholders approved the 2007 Plan in December 2007. The 2007 Plan became effective on the date of board approval. Incentive stock options may be granted pursuant to the 2007 Plan until October 2017 and other awards may be granted under the plan until the 2007 Plan is discontinued or terminated by the administrator.

Equity Awards. The 2007 Plan permits the granting of incentive stock options, nonqualified options, restricted stock awards, restricted stock units, performance share awards, performance unit awards and stock appreciation rights to employees, officers, consultants and directors.

Share Reserve. The aggregate number of shares of our common stock issuable pursuant to stock awards under the 2007 Plan prior to July 1, 2008 was 3,000,000 shares. The number of shares of our common stock reserved for

issuance will automatically increase on the first day of each fiscal year, beginning on July 1, 2008, and ending on July 1, 2017, by the lesser of (i) 1,500,000 shares, (ii) 5% of the outstanding shares of common stock on such date or (iii) a lesser amount determined by the board of directors. As of July 1, 2008, the number of shares reserved under the 2007 Plan was increased by

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379,397 shares. As of September 30, 2008, we had 2,158,364 options outstanding under our 2007 Plan at a weighted average exercise price of $7.92 per share and 949,098 shares of restricted stock outstanding subject to a risk of forfeiture.

Under the 2007 Plan, no person may be granted equity awards intended to qualify as performance-based compensation covering more than 100,000 shares of our common stock during any calendar year pursuant to stock options, stock appreciation rights, restricted stock awards or restricted stock unit awards.

If any awards granted under the 2007 Plan expire or terminate prior to exercise or otherwise lapse, or if any awards are settled in cash, the shares subject to such portion of the award are available for subsequent grants of awards. Further, shares of stock used to pay the exercise price under any award or used to satisfy any tax withholding obligation attributable to any award, whether withheld by us or tendered by the participant, will continue to be reserved and available for awards granted under the 2007 Plan.

The total number of shares and the exercise price per share of common stock that may be issued pursuant to outstanding awards under the 2007 Plan are subject to adjustment by the board of directors upon the occurrence of stock dividends, stock splits or other recapitalizations, or because of mergers, consolidations, reorganizations or similar transactions in which we receive no consideration. The board of directors may also provide for the protection of plan participants in the event of a merger, liquidation, reorganization, divestiture (including a spin-off) or similar transaction.

Administration. The 2007 Plan may be administered by the board of directors or a committee appointed by the board. Any committee appointed by the board to administer the 2007 Plan shall consist of at least two non-employee directors (as defined in Rule 16b-3, or any successor provision, of the General Rules and Regulations under the Securities Exchange Act of 1934). The plan administrator has broad powers to administer and interpret the 2007 Plan, including the authority to (i) establish rules for the administration of the 2007 Plan, (ii) select the participants in the 2007 Plan, (iii) determine the types of awards to be granted and the number of shares covered by such awards, and (iv) set the terms and conditions of such awards. All determinations and interpretations of the plan administrator are binding on all interested parties.

Our board of directors may terminate or amend the 2007 Plan, except that the terms of award agreements then outstanding may not be adversely affected without the consent of the participant. The board of directors may not amend the 2007 Plan to materially increase the total number of shares of our common stock available for issuance under the 2007 Plan, materially increase the benefits accruing to any individual, decrease the price at which options may be granted, or materially modify the requirements for eligibility to participate in the 2007 Plan without the approval of our shareholders if such approval is required to comply with the Internal Revenue Code of 1986, as amended, or the Code, or other applicable laws or regulations.

Stock Options. Options granted under the 2007 Plan may be either incentive stock options within the meaning of Code Section 422 or nonqualified stock options that do not qualify for special tax treatment under Code Section 422. No incentive stock option may be granted with a per share exercise price less than the fair market value of a share of the underlying common stock on the date the incentive stock option is granted. Unless otherwise determined by the plan administrator, the per share exercise price for nonqualified stock options granted under the 2007 Plan also will not be less than the fair market value of a share of our common stock on the date the nonqualified stock option is granted.

The period during which an option may be exercised and whether the option will be exercisable immediately, in stages, or otherwise is set by the administrator. An incentive stock option generally may not be exercisable more than ten years from the date of grant.

Participants generally must pay for shares upon exercise of options with cash, certified check or our common stock valued at the stock s then fair market value. Each incentive option granted under the 2007 Plan is nontransferable during the lifetime of the participant. A nonqualified stock option may, if permitted by the plan administrator, be transferred to certain family members, family limited partnerships and family trusts.

The plan administrator may, in its discretion, modify or impose additional restrictions on the term or exercisability of an option. The plan administrator may also determine the effect that a participant s termination of employment with us or a subsidiary may have on the exercisability of such option. The grants of stock options under the 2007 Plan are

subject to the plan administrator s discretion.

Tax Limitations on Stock Options. Nonqualified stock options granted under the 2007 Plan are not intended to and do not qualify for favorable tax treatment available to incentive stock options under Code Section 422. Generally, no income is taxable to the participant (and we are not entitled to any deduction) upon the grant of a nonqualified stock option. When a nonqualified stock option is exercised, the participant generally must recognize compensation taxable as ordinary income

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equal to the difference between the option price and the fair market value of the shares on the date of exercise. We normally will receive a deduction equal to the amount of compensation the participant is required to recognize as ordinary income and must comply with applicable tax withholding requirements.

Incentive stock options granted pursuant to the 2007 Plan are intended to qualify for favorable tax treatment to the participant under Code Section 422. Under Code Section 422, a participant realizes no taxable income when the incentive stock option is granted. If the participant has been an employee of ours or any subsidiary at all times from the date of grant until three months before the date of exercise, the participant will realize no taxable income when the option is exercised. If the participant does not dispose of shares acquired upon exercise for a period of two years from the granting of the incentive stock option and one year after receipt of the shares, the participant may sell the shares and report any gain as capital gain. We will not be entitled to a tax deduction in connection with either the grant or exercise of an incentive stock option, but may be required to comply with applicable withholding requirements. If the participant should dispose of the shares prior to the expiration of the two-year or one-year periods described above, the participant will be deemed to have received compensation taxable as ordinary income in the year of the early sale in an amount equal to the lesser of (i) the difference between the fair market value of our common stock on the date of exercise and the option price of the shares, or (ii) the difference between the sale price of the shares and the option price of shares. In the event of such an early sale, we will be entitled to a tax deduction equal to the amount recognized by the participant as ordinary income. The foregoing discussion ignores the impact of the alternative minimum tax, which may particularly be applicable to the year in which an incentive stock option is exercised.

Stock Appreciation Rights. A stock appreciation right may be granted independent of or in tandem with a previously or contemporaneously granted stock option, as determined by the plan administrator. Generally, upon the exercise of a stock appreciation right, the participant will receive cash, shares of common stock or some combination of cash and shares having a value equal to the excess of (i) the fair market value of a specified number of shares of our common stock, over (ii) a specified exercise price. If the stock appreciation right is granted in tandem with a stock option, the exercise of the stock appreciation right will generally cancel a corresponding portion of the option, and, conversely, the exercise of the stock option will cancel a corresponding portion of the stock appreciation right. The plan administrator will determine the term of the stock appreciation right and how it will become exercisable. A stock appreciation right may not be transferred by a participant except by will or the laws of descent and distribution.

Restricted Stock Awards and Restricted Stock Unit Awards. The plan administrator is also authorized to grant awards of restricted stock and restricted stock units. Each restricted stock award granted under the 2007 Plan shall be for a number of shares as determined by the plan administrator, and the plan administrator, in its discretion, may also establish continued employment, achievement of performance criteria, vesting or other conditions that must be satisfied for the restrictions on the transferability of the shares and the risks of forfeiture to lapse. Each restricted stock unit represents the right to receive cash or shares of our common stock, or any combination thereof, at a future date, subject to continued employment, achievement of performance criteria, vesting or other conditions as determined by the plan administrator.

If a restricted stock award or restricted stock unit award is intended to qualify as performance-based compensation under Code Section 162(m), the risks of forfeiture shall lapse based on the achievement of one or more performance objectives established in writing by the plan administrator in accordance with Code Section 162(m) and the applicable regulations. Such performance objectives shall consist of any one, or a combination of, (i) revenue, (ii) net income, (iii) earnings per share, (iv) return on equity, (v) return on assets, (vi) increase in revenue, (vii) increase in share price or earnings, (viii) return on investment, or (ix) increase in market share, in all cases including, if selected by the plan administrator, threshold, target and maximum levels.

Performance Share Awards and Performance Units Awards. The plan administrator is also authorized to grant performance share and performance unit awards. Performance share awards generally provide the participant with the opportunity to receive shares of our common stock and performance units generally provide recipients with the opportunity to receive cash awards, but only if certain performance criteria are achieved over specified performance periods. A performance share award or performance unit award may not be transferred by a participant except by will or the laws of descent and distribution.

Prior Equity Plans

2003 Stock Option Plan. Our board of directors adopted our 2003 Stock Option Plan, or 2003 Plan, in May 2003, and the shareholders approved the 2003 Plan in November 2003, in order to provide for the granting of stock options to our employees, directors and consultants. The 2003 Plan permits the granting of incentive stock options meeting the requirements of Section 422 of the Code, and also nonqualified options, which do not meet the requirements of Section 422. Under the 2003 Plan, 3,800,000 shares of common stock were reserved for issuance pursuant to options granted under the 2003 Plan and approved by the board of directors in February 2005 and August 2006 and shareholders in March 2005 and October 2006.

The 2003 Plan is administered by the board of directors. The 2003 Plan gives broad powers to the board of directors to administer and interpret the Plan, including the authority to select the individuals to be granted options and to prescribe the

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particular form and conditions of each option granted. If the board of directors so directs, the 2003 Plan may be administered by a stock option committee of three or more persons who would be appointed and serve at the pleasure of the board.

Incentive stock options are permitted to be granted pursuant to the 2003 Plan through May 20, 2013, ten years from the date our board of directors adopted the 2003 Plan. Nonqualified stock options may be granted pursuant to the 2003 Plan until the 2003 Plan is terminated by the board of directors. In the event of a sale of substantially all of our assets or in the event of a merger, exchange, consolidation, or liquidation, the board of directors is authorized to terminate the 2003 Plan. As of September 30, 2008 there were 3,504,500 options outstanding under the 2003 Plan with a weighted average exercise price of $5.76 per share, and no further shares will be issued under the 2003 Plan.

1991 Stock Option Plan. The 1991 Stock Option Plan, or 1991 Plan, was adopted by the board of directors in July 1991. Under the 1991 Plan, 750,000 shares of common stock were reserved for option grants. With the creation of the 2003 Plan, no additional options were granted under the 1991 Plan. As of September 30, 2008, there were options outstanding under the 1991 Plan to purchase an aggregate of 48,611 shares of common stock with a weighted average exercise price of $12.00 per share.

Options Granted Outside Stock Option Plans

In addition to the options granted under the 2007, 2003 and 1991 Plans, the board of directors has granted options outside of those plans. As of September 30, 2008, there were 130,000 such options outstanding with a weighted average exercise price of $5.06 per share.

401(k) Plan

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our executive officers are also eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Code. The plan provides that each participant may contribute any amount of his or her pre-tax compensation, up to the statutory limit, which is $15,500 for calendar year 2007. Participants that are 50 years or older can also make catch-up contributions, which in calendar year 2007 may be up to an additional $5,000 above the statutory limit. Under the 401(k) plan, each participant is fully vested in his or her deferred salary contributions. Participant contributions are held and invested by the plan s trustee. The plan also permits us to make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. In fiscal 2008, we made no contributions to the plan.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee. We have had a compensation committee for one year. Prior to establishing the compensation committee, our full board of directors made decisions relating to compensation of our executive officers.

Director Compensation

The non-employee members of our board of directors are reimbursed for travel, lodging and other reasonable expenses incurred in attending board or committee meetings. Upon initial election to the board of directors, each non-employee director has been granted an option to purchase 60,000 shares of our common stock. In subsequent years, each non-employee director has received an annual stock option grant to purchase a quantity of our common stock that is determined by our board of directors on an annual basis. For fiscal year 2008, each of our non-employee directors was granted options to purchase 30,000 shares of our common stock. The board has, in the past, granted additional options to our board chairman and each of our committee chairs for services in those capacities. In addition, certain directors received additional grants in fiscal 2008 as described in the footnotes below.

The following table provides summary information concerning the compensation of each non-employee director during the fiscal year ended June 30, 2008.

Name	Option Awards(1)(2)(3)

Brent G. Blackey(4)	$ 109,337
John H. Friedman(5)	137,051
Geoffrey O. Hartzler, M.D.(5)(6)	506,398
Roger J. Howe, Ph.D.(5)(7)	768,522

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Name	Option Awards(1)(2)(3)
Glen D. Nelson, M.D.(5)	125,002
Gary M. Petrucci(5)(8)	1,408,858
Christy Wyskiel(5)	137,051

(1) The value of options in this table represent the amounts recognized for financial statement reporting purposes for fiscal 2008 in accordance with FAS 123(R), and thus may include amounts from awards granted in and prior to fiscal 2008. For a discussion of valuation assumptions and additional SFAS No. 123(R) disclosures, see Note 6 to our consolidated financial statements regarding stock compensation at page F-17 of this Form 10.

(2) Certain of our stock option agreements provide that in the event of a change of control, (the sale by us of substantially all of our assets and the consequent discontinuance of our business, or in

the event of a merger, exchange or liquidation of us), the vesting of all options will accelerate and the options will be immediately exercisable as of the effective date of the change of control. It is a condition to the closing of the merger with Replidyne that we obtain an acknowledgement in a form reasonably acceptable to Replidyne from our officers and directors and the holders of 80% of the remainder of these options that the terms of the option agreements related thereto do not provide that the vesting of such securities will accelerate, in whole or in part, in connection with or as a result of the consummation of the merger and the other transactions contemplated by the merger agreement.

(3) The aggregate number of shares subject to outstanding option awards held by each of the directors listed in

the table above as of June 30, 2008 was as follows: Mr. Blackey 70,000 shares; Mr. Friedman 90,000 shares; Dr. Hartzler 199,809 shares; Dr. Howe 272,775 shares; Dr. Nelson 135,000 shares; Mr. Petrucci 476,161 shares; and Ms. Wyskiel 90,000 shares.

(4) In connection with his initial election to the board of directors, Mr. Blackey was granted a ten-year option to purchase 60,000 shares of our common stock at $5.11 per share on October 9, 2007, such option to vest one-third on each of the first three anniversaries of the date of grant. Mr. Blackey was also granted an immediately vested ten-year option to purchase 10,000 shares of our common stock at $5.11 in connection with his appointment as chairman of the audit committee. The grant date fair value of the option awards granted to Mr. Blackey, computed in accordance with

SFAS No. 123(R), was $312,130.

(5) As compensation for their continued board service, on October 9, 2007 and November 13, 2007 each of Messrs. Friedman, Howe and Petrucci was granted options to purchase 6,680 shares of our common stock at $5.11 per share and 23,320 shares of our common stock at $7.36 per share, respectively, and each of Messrs. Hartzler and Nelson and Ms. Wyskiel was granted options to purchase 6,681 shares of our common stock at $5.11 per share and 23,319 shares of our common stock at $7.36 per share, respectively. On November 13, 2007, Mr. Petrucci was granted an option to purchase an additional 15,000 shares at $7.36 per share in connection with his service as chairman of the board. The grant date fair value of the option award granted to each of Messrs. Friedman, Hartzler, Howe and Nelson and

Ms. Wyskiel, computed in accordance with SFAS No. 123(R), was $125,002. The grant date fair value of the option award granted to Mr. Petrucci, computed in accordance with SFAS No. 123(R), was $1,408,858. The options held by Mr. Friedman are held for the benefit of Easton Capital Partners, LP and Easton Hunt Capital Partners, L.P. The options held by Ms. Wyskiel are held for the benefit of Maverick Fund II, Ltd., Maverick Fund, L.D.C. and Maverick Fund USA, Ltd.

(6) On February 14, 2008, Dr. Hartzler was granted a five-year option to purchase 114,809 shares of our common stock at $9.04 per share to replace an expired and unexercised option. The grant date fair value of this option award, computed in accordance with SFAS No. 123(R), was $381,395.

(7) On December 31, 2007, Dr. Howe was granted a

five-year option to purchase 187,775 shares of our common stock at $7.86 per share to replace an expired and unexercised option. The grant date fair value of this option award, computed in accordance with SFAS No. 123(R), was $626,981.

(8) On December 31, 2007, Mr. Petrucci was granted a five-year option to purchase 366,161 shares of our common stock at $7.86 per share to replace an expired and unexercised option. The grant date fair value of this option award, computed in accordance with SFAS No. 123(R), was $1,222,612.

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ITEM 7. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The following is a summary of transactions since July 1, 2004 to which we have been a party in which the amount involved exceeded $120,000 and in which any of our executive officers, directors or beneficial holders of more than 5% of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the section of this Form 10 entitled Compensation Discussion and Analysis.

Issuance of Warrants to Loan Guarantors

On September 12, 2008, we entered into a loan and security agreement with Silicon Valley Bank. The agreement includes a $3.0 million term loan, a $5.0 million accounts receivable line of credit, and two term loans for an aggregate of $5.5 million that are guaranteed by certain of our affiliates. One of our directors and two entities affiliated with two of our directors agreed to act as guarantors of these term loans. Those guarantors are Glen Nelson, who is guaranteeing $1.0 million, funds managed by Maverick Capital, Ltd., which are guaranteeing $2.5 million, and Easton Capital Investment Group, which is guaranteeing $2.0 million. Our director Christy Wyskiel is a Managing Director of Maverick Capital, Ltd., and our director John Friedman is the Managing Partner of Easton Capital Investment Group. In consideration for guaranteeing the investor guaranty line of credit, we issued the guarantors warrants to purchase shares of our common stock at an exercise price of $6.00 per share in the following amounts: funds managed by Maverick Capital, Ltd., 208,333 shares; Easton Capital Investment Group, 166,667 shares; and Glen Nelson, 83,333 shares. These warrants are immediately exercisable and have terms of five years.

Preferred Stock Issuances

Issuance of Series B Convertible Preferred Stock

In December 2007 we issued an aggregate of 2,162,150 shares of our Series B convertible preferred stock at a price per share of $9.25, for an aggregate purchase price of approximately $20 million. We believe that the conversion price of the Series B convertible preferred stock into common stock at $9.25 per share represented or exceeded the fair value of our common stock at issuance. The table below sets forth the number of Series B convertible preferred shares sold to our 5% holders, directors, officers and entities associated with them. The terms of these purchases were the same as those made available to unaffiliated purchasers.

Name	Number of Shares of Series B Convertible Preferred Stock	Approximate Aggregate Purchase Price ($)
Brent G. Blackey	5,000	$ 46,250
GDN Holdings, LLC(1)	54,054	500,000
Paul Koehn	3,784	35,002
Maverick Capital, Ltd.(2)(3)	108,108	999,999
ITX International Equity Corp.	324,325	3,000,006
Whitebox Hedged High Yield Partners, LP	939,517	8,690,532

(1) Glen Nelson, one of our directors, is the sole owner of GDN Holdings, LLC.

(2)

Christy Wyskiel, one of our directors, is a Managing Director of Maverick Capital, Ltd.

(3) Consists of shares issued to Maverick Fund II, Ltd., Maverick Fund, L.D.C. and Maverick Fund USA, Ltd.

Issuance of Series A-1 Convertible Preferred Stock

From July through October 2007, we issued an aggregate of 2,188,425 shares of our Series A-1 convertible preferred stock at a price per share of $8.50, for an aggregate purchase price of approximately $18.6 million. The table below sets forth the number of Series A-1 convertible preferred shares sold to our 5% holders, directors, officers and entities associated with them. The terms of these purchases were the same as those made available to unaffiliated purchasers.

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Name	Number of Shares of Series A-1 Convertible Preferred Stock	Approximate Aggregate Purchase Price ($)
Brent G. Blackey	5,900	$ 50,150
John Borrell	11,764	99,994
GDN Holdings, LLC(1)	41,913	356,261
Maverick Capital, Ltd.(2)(3)	235,394	2,000,850
Mitsui & Co. Venture Partners II, L.P.(4)	117,645	1,000,000
Robert J. Thatcher	12,000	102,000
ITX International Equity Corp.	47,079	400,172

(1) Glen Nelson, one of our directors, is the sole owner of GDN Holdings, LLC.

(2) Christy Wyskiel, one of our directors, is a Managing Director of Maverick Capital, Ltd.

(3) Consists of shares issued to Maverick Fund II, Ltd., Maverick Fund, L.D.C. and Maverick Fund USA, Ltd.

(4) Mitsui & Co. Venture Partners II, L.P. is a 5% holder, as set forth in the section entitled Principal Shareholders.

Issuance of Series A Convertible Preferred Stock

From July through October 2006, we issued an aggregate of 4,728,547 shares of our Series A convertible preferred stock and warrants to purchase an aggregate of 671,453 shares of our Series A convertible preferred stock at a price per unit of $5.71, for an aggregate purchase price of approximately $27 million. The table below sets forth the number of Series A convertible preferred shares and Series A warrants sold to our 5% holders, directors, officers and entities associated with them. The terms of these purchases were the same as those made available to unaffiliated purchasers.

Name	Number of Shares of Series A Convertible Preferred Stock	Number of Series A Convertible Preferred Stock Warrant Shares	Approximate Aggregate Purchase Price ($)
Easton Capital Investment Group(1)(2)	1,225,920	174,080	$ 7,000,000
Maverick Capital, Ltd.(3)(4)	1,751,313	248,686	9,999,997
GDN Holdings LLC(5)	131,349	18,652	750,003
Gary M. Petrucci(6)	36,124	5,130	206,268
Mitsui & Co. Venture Partners II, L.P.(7)	675,148	95,871	3,855,095
ITX International Equity Corp.	350,263	49,737	2,000,002

(1) John Friedman, one of our directors, is the Managing Partner of the Easton Capital Investment Group. Mr. Friedman disclaims any beneficial ownership of the shares held by entities affiliated with Easton Capital Investment Group.

(2) Consists of shares issued to Easton Hunt Capital Partners, L.P. and Easton Capital Partners, LP.

(3) Christy Wyskiel, one of our directors, is

a Managing Director of Maverick Capital, Ltd.

(4) Consists of shares issued to Maverick Fund II, Ltd., Maverick Fund, L.D.C. and Maverick Fund USA, Ltd.

(5) Glen Nelson, one of our directors, is the sole owner of GDN Holdings, LLC.

(6) Mr. Petrucci acquired Series A convertible preferred stock pursuant to the conversion of an 8% convertible promissory note in the principal amount of $200,000 that was issued to him in connection with our bridge financing that occurred from February 2006 through July 2006.

(7) Mitsui & Co. Venture Partners II, L.P. is a 5% holder, as set forth in the section entitled Principal

Shareholders.

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Common Stock Issuances

2005 Private Placement

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