CARDIOVASCULAR SYSTEMS INC
Form S-1
January 22, 2008

Table of Contents

As filed with the Securities and Exchange Commission on January 22, 2008
Registration No. 333-

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

Form S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

CARDIOVASCULAR SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Minnesota	**3841**	**41-1698056**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification No.)*

651 Campus Drive
St. Paul, Minnesota 55112-3495
(651) 259-1600
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

David L. Martin
President, Chief Executive Officer and Interim Chief Financial Officer
Cardiovascular Systems, Inc.
651 Campus Drive
St. Paul, Minnesota 55112-3495
(651) 259-1600
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Robert K. Ranum, Esq.
Alexander Rosenstein, Esq.
Fredrikson & Byron, P.A.
200 South Sixth Street, Suite 4000
Minneapolis, Minnesota 55402
(612) 492-7000

Alan F. Denenberg, Esq.
Davis Polk & Wardwell
1600 El Camino Real
Menlo Park, California 94025
(650) 752-2000

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. o

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering. o

If this form is a post effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this form is a post effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[(1)(2)]	Amount of Registration Fee
Common stock, no par value per share	$ 86,250,000	$ 3,390

(1) Estimated solely for the purpose of computing the registration fee pursuant to Rule 457(o) under the Securities Act.
(2) Includes shares of common stock that the underwriters have an option to purchase to cover over-allotments, if any.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

Table of Contents

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. The prospectus is not an offer to sell securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS (Subject to Completion)
Issued January 22, 2008

Shares

Common Stock

Cardiovascular Systems, Inc. is offering shares of its common stock. This is our initial public offering and no public market currently exists for our shares. We anticipate that the initial public offering price will be between $ and $ per share.

We have applied to have our common stock approved for quotation on the Nasdaq Global Market under the symbol CSII.

Investing in our common stock involves risks. See Risk Factors beginning on page 7.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts	$	$
Proceeds, before expenses, to Cardiovascular Systems, Inc.	$	$

We have granted the underwriters the right to purchase up to an additional shares of common stock to cover over-allotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares to purchasers on , 2008.

Morgan Stanley **Citi**

William Blair & Company

, 2008

TABLE OF CONTENTS

Consent of PricewaterhouseCoopers, LLC

You should rely only on the information contained in this prospectus and any free-writing prospectus that we authorize to be distributed to you. We have not, and the underwriters have not, authorized any other person to provide you information different from or in addition to that contained in this prospectus or any related free-writing prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state where the offer or sale is not permitted. The information in this prospectus is complete and accurate only as of the date on the cover page of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

Until , 2008 (25 days after the date of this prospectus), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus.

Table of Contents

Market and Industry Data

Information and management estimates contained in this prospectus 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 prospectus 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 prospectus 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.

Table of Contents

PROSPECTUS SUMMARY

This summary highlights selected information contained in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all the information you should consider. You should carefully read the entire prospectus including Risk Factors beginning on page 7 and the financial statements and related notes before making an investment decision. References in this prospectus to CSI, our company, we, us our refer to Cardiovascular Systems, Inc. and its subsidiaries, except where the context makes clear that the reference is only to Cardiovascular Systems, Inc. itself and not its subsidiaries.

Our Business

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 is a common circulatory problem in which plaque deposits build up on the walls of vessels, reducing blood flow. The plaque deposits range from soft to calcified, with calcified plaque being difficult to treat with traditional interventional procedures. The Diamondback 360° is capable of treating a broad range of plaque types, including calcified vessel lesions, and addresses many of the limitations associated with existing treatment alternatives.

The Diamondback 360° removes both soft and calcified plaque in plaque-lined vessels through the orbital rotation of a diamond grit coated offset crown that is attached to a flexible drive shaft. 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 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 rotates faster and centrifugal force causes the crown to orbit, creating a lumen with a diameter that is approximately twice the diameter of the device. By giving physicians the ability to create different lumen diameters by changing 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. 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 were the first, and so far the only, company to conduct a prospective multi-center clinical trial with a prior investigational device exemption in support of a 510(k) clearance for an atherectomy device. We commenced a limited commercial introduction of the Diamondback 360° in the United States in September 2007. Through December 31, 2007, we shipped more than 1,700 single-use catheters to 57 hospitals and have generated revenues of approximately $4.6 million. 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 from the FDA to use the Diamondback 360° to treat patients with coronary artery disease.

Our Market

The American Medical Association reports that PAD affects approximately eight to 12 million people in the United States. According to 2007 statistics from the American Heart Association, PAD becomes more common with age and affects approximately 12% to 20% of the U.S. population over 65 years old. An aging population, coupled with an

increasing incidence of PAD risk factors, such as 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.

Table of Contents

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, published in the Journal of the American Medical Association in 2001, 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 in the artery and many patients have difficulty maintaining lifestyle changes. Additionally, many prescribed medications are contraindicated 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.

Traditional procedural intervention treatments for PAD include surgical procedures, angioplasty, stenting and atherectomy. Surgical procedures, such as bypass or amputation, are widely utilized, but may have procedure-related complications that range in severity and include mortality risk. Angioplasty and stenting procedures may result in complications such as damage to a vessel when a balloon is expanded or potential for stent fracture. Current atherectomy procedures also have significant drawbacks, including:

- difficulty treating calcified lesions, diffuse disease and lesions below the knee;
- potential safety concerns relating to damage of the arterial wall;
- the inability to create lumens larger than the catheter itself in a single insertion;
- the creation of rough, uneven lumens with deep grooves;
- 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;
- 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.

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. We believe that the

Diamondback 360° offers substantial benefits to patients, physicians, hospitals and third-party payors, including:

Strong Safety Profile. The differential sanding of the device reduces the risk of arterial perforation and damage to the arterial wall. Moreover, the plaque particles sanded away by the device are so small that they reduce the risk of distal embolization and allow continuous blood flow during the entire procedure, which reduces the risk of complications such as excessive heat and tissue damage.

Proven Efficacy. The orbital motion of the device enables the continuous removal of plaque in both soft and calcified lesions, increasing blood flow through the resulting smooth lumen. The efficacy of the device was demonstrated in our pivotal OASIS trial.

Table of Contents

Ease of Use. Utilizing familiar techniques, a physician trained in endovascular surgery can complete the treatment with a single insertion while utilizing limited amounts of fluoroscopy during plaque removal.

Cost and Time Efficient Procedure. The Diamondback 360° can create various lumen sizes using a single sized crown, which limits hospital inventory costs and allows a physician to complete a procedure with a single insertion, potentially reducing procedural time. Use of the Diamondback 360° may also require less expensive capital equipment than other atherectomy procedures.

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:

driving device adoption with key opinion leaders through our direct sales organization;

collecting additional clinical evidence of the benefits of the Diamondback 360°;

expanding our product portfolio within the peripheral market;

increasing referrals to interventional cardiologists and radiologists through practice development programs or referral physician education;

leveraging core technology into the coronary market; and

pursuing strategic acquisitions and partnerships.

Patents and Intellectual Property

Since our inception, we have filed patent applications to protect what we believe to be the most important intellectual property that we have developed. 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 December 17, 2007, we held 16 issued U.S. patents and 26 issued non-U.S. patents covering aspects of our core technology.

Risks Associated with Our Business

Our business is subject to a number of risks discussed under the heading Risk Factors and elsewhere in this prospectus. You should carefully consider these factors, as well as all of the other information set forth in this prospectus.

Our Corporate Information

Founded originally as Shturman Cardiology Systems, Inc. in 1989, we changed our name to Cardiovascular Systems, Inc. in 2003. 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 prospectus.

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 prospectus are the property of their respective owners.

Table of Contents

SUMMARY OF THE OFFERING

Common stock offered by us	Shares
Common stock to be outstanding after this offering	Shares
Use of proceeds	We intend to use the net proceeds from this offering for working capital and general corporate purposes. See Use of Proceeds.
Risk Factors	You should read the Risk Factors section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Proposed Nasdaq Global Market symbol	CSII

The number of shares of our common stock that will be outstanding immediately after this offering is based on 15,952,945 shares outstanding as of December 17, 2007, and excludes:

- 4,930,361 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of $6.08 per share;
- 1,035,413 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $5.50 per share; and
- 1,865,745 additional shares of common stock reserved and available for future issuances under our 2007 Equity Incentive Plan.

Except as otherwise noted, all information in this prospectus assumes:

- the conversion of all our outstanding shares of preferred stock upon the closing of this offering into 9,088,136 shares of common stock and the conversion of all of our outstanding warrants to purchase preferred stock upon the closing of this offering into warrants to purchase 662,439 shares of common stock and no exercise of such warrants; and
- no exercise of the underwriters over-allotment option.

Table of Contents

SUMMARY CONSOLIDATED FINANCIAL DATA

The following table summarizes our consolidated financial data. We have derived the following summary of our consolidated statements of operations data for the years ended June 30, 2005, 2006 and 2007 from our audited consolidated financial statements and related notes included elsewhere in this prospectus. The consolidated statement of operations data for the three months ended September 30, 2006 and 2007 and consolidated balance sheet data as of September 30, 2007 have been derived from our unaudited financial statements and related notes included elsewhere in this prospectus. 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 Securities and Exchange Commission, or SEC, for interim 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 our consolidated financial position and results of operations for the interim periods. Our historical results are not necessarily indicative of the results that may be experienced in the future and the results for the three months ended September 30, 2007 are not necessarily indicative of results to be expected for the full year. You should read the summary financial data set forth below in conjunction with Selected Consolidated Financial Data, Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes, all included elsewhere in this prospectus.

	Years Ended June 30,			Three Months Ended September 30,	
	2005	2006	2007[1]	2006[1]	2007[1]
	(in thousands, except share and per share amounts)				
Consolidated Statements of Operations Data:					
Revenues	$	$	$	$	$
Cost of goods sold					539
Gross (loss) profit					(539)
Expenses:					
Selling, general and administrative	1,177	1,735	6,691	823	3,552
Research and development	2,371	3,168	8,446	749	3,328
Total expenses	3,548	4,903	15,137	1,572	6,880
Loss from operations	(3,548)	(4,903)	(15,137)	(1,572)	(7,419)
Other income (expense):					
Interest expense		(48)	(1,340)	(13)	(300)
Interest income	37	56	881	256	278
Total other income (expense)	37	8	(459)	243	(22)
Net loss	(3,511)	(4,895)	(15,596)	(1,329)	(7,441)
Accretion of redeemable convertible preferred stock[2]			(16,835)	(3,878)	(4,853)
Net loss available to common shareholders	$ (3,511)	$ (4,895)	$ (32,431)	$ (5,207)	$ (12,294)

Loss per common share:					
Basic and diluted[3]	$ (0.61)	$ (0.79)	$ (5.22)	$ (0.84)	$ (1.95)
Weighted average common shares used in computation:					
Basic and diluted[3]	5,779,942	6,183,715	6,214,820	6,199,204	6,291,512

(footnotes appear on following page)

Table of Contents

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

	Year Ended June 30, 2007	Three Months Ended September 30, 2006	Three Months Ended September 30, 2007
		(in thousands)	
Selling, general and administrative	$ 327	$ 9	$ 277
Research and development	63	2	73

(2) See Notes 1 and 9 of the notes to our consolidated financial statements for discussion of the accretion of redeemable convertible preferred stock.

(3) See Note 11 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 pro forma per common share calculations.

	As of September 30, 2007		
	Actual	Pro Forma[1]	Pro Forma as Adjusted[2]
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 3,265	$ 3,265	$
Short-term investments	18,499	18,499	
Working capital[3]	21,695	21,695	
Total current assets	25,973	25,973	
Total assets	27,316	27,316	
Redeemable convertible preferred stock warrants	3,394		
Total liabilities	7,760	4,366	
Redeemable convertible preferred stock	63,637		
Total shareholders (deficiency) equity	(44,081)	42,900	

(1) On a pro forma basis to reflect the adoption of our amended and restated articles of incorporation, the issuance of 2,162,150 shares of Series B convertible preferred stock on December 17, 2007, and the conversion of all our outstanding shares of preferred stock into shares of common stock upon the closing of this offering and the conversion of Series A convertible preferred stock warrants into common stock warrants.

(2) On a pro forma as adjusted basis to further reflect the receipt of the estimated net proceeds from the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the range on the cover page of this prospectus, after deducting underwriting discounts and

commissions and estimated offering expenses payable by us. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) cash, cash equivalents and short-term investments, working capital, total assets and total shareholders (deficiency) equity by $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commissions.

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

Table of Contents

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 prospectus 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

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

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 and $15.6 million in fiscal 2007, and $7.4 million in the three months ended September 30, 2007. As of September 30, 2007, we had an accumulated deficit of approximately $72.0 million. We only commenced limited 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 for the foreseeable future.

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, and 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.

Table of Contents

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.

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

Table of Contents

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.

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 the rate at which this product is adopted.

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 rates of adoption 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 smaller manufacturers including, among others, ev3 and Spectranetics, as well as other manufacturers that may enter the market due to the increasing demand for treatment of vascular disease. Several

Table of Contents

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 us;
- obtain regulatory clearances or approvals for competing medical device products more rapidly than us;
- market their products more effectively than us; 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 ours. 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 our competitors products.

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

Table of Contents

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, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers to provide certain components of 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. We depend on these suppliers to provide us with materials in a timely manner that meet our quality, quantity and cost requirements. Our 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. 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;
- 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 may not be able to obtain adequate supplies in a timely manner or on commercially acceptable terms;
- we may have difficulty locating and qualifying alternative suppliers for our 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 in a timely manner; and

our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our 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

Table of Contents

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 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 29 employees on December 17, 2007, 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.

We anticipate future losses and may 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 expect to incur losses for the foreseeable future, and we may require financing in addition to the proceeds of this offering 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. We believe that the net proceeds of this offering will be sufficient to satisfy our cash requirements for at least the next 12 months. However, 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:

- 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;

Table of Contents

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. Our failure to market this product outside of 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, Chief Executive Officer and Interim Chief Financial Officer. Our success will depend on our ability to retain our 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, 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 five new executives to our management team, including our Chief Executive Officer, who joined us in February 2007. These new executives lack long-term experience with us. In addition, effective January 14, 2008, our Chief Financial Officer was promoted into the position of Chief Administrative Officer and our Chief Executive Officer was appointed to serve as our Chief Financial Officer on an interim basis while we search for

a new Chief Financial Officer. We may experience instability in the short term as our new executives become integrated into our company. Competition for qualified employees is intense and a delay in our finding of a new Chief Financial Officer or the loss of service of any other executive officers or certain key employees could delay or curtail our research, development, commercialization and financial objectives.

Table of Contents

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 and by the Nasdaq Global Market, 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 the ev3 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 these 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. 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.

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. We do not have any current plans to conduct clinical trials in the near future to evaluate the Diamondback 360° against any

alternative method of treatment. 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.

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 in the event we are found to promote 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.

Table of Contents

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 letters or untitled 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;
- 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.

Table of Contents

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. 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

Table of Contents

finding of a violation of these laws would likely have a material adverse effect on our business, financial condition and results of operations.

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. 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. 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 December 17, 2007, we had a portfolio of 16 issued U.S. patents and 26 issued non-U.S. patents covering aspects of our core technology, which expire between 2017 and 2021. 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 can be filed 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 effect 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.

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 attorney 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.

We are currently involved in disputes with our founder, Dr. Leonid Shturman, and a company owned by Dr. Shturman regarding the ownership of certain counterbalance technology not used in the Diamondback 360°, for which Dr. Shturman and his company have attempted to seek patent protection in the United Kingdom and from the World Intellectual Property Organization. Our disputes with Dr. Shturman may result in a finding that we do not own the counterbalance technology that is the subject of these disputes, and we may be unable to use this technology in future products without incurring obligations to pay royalties, or at all. Moreover, the Shturman patent applications could prevent us from obtaining our own patents on similar technology. Additionally, Dr. Shturman has raised counterclaims with regard to two shaft winding machines that we imported from Russia. Dr. Shturman is seeking monetary damages for our use of the machines and the intellectual property they embody. 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.

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.

Table of Contents

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 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 attorney 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 this Offering and Ownership of Our Common Stock

Because there has not been a public market for our common stock and our stock price may be volatile, you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, you could not buy or sell our common stock publicly. We cannot predict the extent to which an active trading market for our common stock will develop or whether the market price of our common stock will be volatile following this offering. If an active trading market does not develop, you may have difficulty selling

Table of Contents

any of our common stock that you buy. The initial public offering price for our common stock was determined by negotiations between representatives of the underwriters and us and may not be indicative of prices that will prevail in the open market following this offering. Consequently, you may not be able to sell our common stock at prices equal to or greater than the price you paid in this offering. In addition, the stock markets have been extremely volatile. The risks related to our company discussed above, as well as decreases in market valuations of similar companies, could cause the market price of our common stock to decrease significantly from the price you pay in this offering.

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 market 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;
- 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, securities class action litigation often has been initiated when a company s stock price has fallen below the company s initial public offering price soon after the offering closes or following a period of volatility in the market price of the company s securities. If 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 market price of our stock to decline, and you may lose some or all of your investment.

Table of Contents

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, the 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.

Future sales of our common stock by our existing shareholders could cause our stock price to decline.

If our shareholders sell substantial amounts of our common stock in the public market, the market price of our common stock could decrease significantly. The perception in the public market that our shareholders might sell shares of our common stock could also depress the market price of our common stock. Substantially all of our shareholders prior to this offering are subject to lock-up agreements that restrict their ability to transfer their shares of our common stock. In addition, upon the closing of this offering we intend to file registration statements with the SEC covering any shares of our common stock acquired upon option exercises prior to the closing of this offering and all of the shares subject to options outstanding, but not exercised, as of the closing of this offering. The market price of shares of our common stock may decrease significantly when the restrictions on resale by our existing shareholders lapse and our shareholders, warrant holders and option holders are able to sell shares of our common stock into the market. A decline in the price of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities, and may cause you to lose part or all of your investment in our common stock.

We have broad discretion in the use of the proceeds of this offering and may apply the proceeds in ways with which you do not agree.

Our net proceeds from this offering will be used, as determined by management in its sole discretion, for working capital and general corporate purposes. We may also use a portion of the proceeds for the potential acquisition of businesses, technologies and products, although we have no current understandings, commitments or agreements to do so. Our management will have broad discretion over the use and investment of these net proceeds, and, accordingly, you will have to rely upon the judgment of our management with respect to our use of these net proceeds, with only limited information concerning management s specific intentions. You will not have the opportunity, as part of your investment decision, to assess whether we used the net proceeds from this offering appropriately. We may place the net proceeds in investments that do not produce income or that lose value, which may cause our stock price to decline.

Our directors and executive officers will continue to have substantial control over us after this offering and could limit your ability to influence the outcome of key transactions, including changes of control.

We anticipate that our executive officers and directors and entities affiliated with them will, in the aggregate, beneficially own % of our outstanding common stock following the completion of this offering, assuming the underwriters do not exercise their over-allotment option. 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. 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 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 may also have the effect of

Table of Contents

influencing the completion of a change in control that may not necessarily be in the best interests of all of our shareholders.

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 Anti-Takeover Provisions for a more detailed description of these provisions.

You will experience immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering.

If you purchase common stock in this offering, you will incur immediate dilution of $ in pro forma as adjusted net tangible book value per share of common stock, based on an assumed initial public offering price of $ per share, the midpoint of the range on the cover page of this prospectus, because the price that you pay will be substantially greater than the adjusted net tangible book value per share of common stock that you acquire. This dilution is due in large part to the fact that our earlier investors paid substantially less than the price of the shares being sold in this offering when they purchased their shares of our capital stock. In addition, if outstanding options to purchase our common stock are exercised, you will experience additional dilution. Please see Dilution for a more detailed description of how dilution will affect you.

We do not intend to declare dividends on our stock after this offering.

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.

Table of Contents

INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This prospectus 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 prospectus as being applicable to all related forward-looking statements wherever they appear in this prospectus. We cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. You should read this prospectus 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 prospectus 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 prospectus 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.

Table of Contents

USE OF PROCEEDS

Based on an assumed initial public offering price of $ per share, the midpoint of the range on the cover page of this prospectus, we estimate our net proceeds from the sale of shares of our common stock in this offering will be approximately $ million after deducting the underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters exercise their over-allotment option in full, we estimate that our net proceeds from this offering will be approximately $ million, after deducting the underwriting discounts and commissions, and estimated offering expenses payable by us.

A $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease the net proceeds to us from this offering by $ million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus remains the same and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering for working capital and general corporate purposes. We may also use a portion of the proceeds for the potential acquisition of businesses, technologies and products complementary to our existing operations, although we have no current understandings, commitments or agreements to do so.

As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering. Accordingly, our management will have broad discretion in the application of the net proceeds, and investors will be relying on the judgment of our management regarding the application of the net proceeds of this offering.

Pending the uses described above, we intend to invest the net proceeds in U.S. government securities and other short- and intermediate-term, investment-grade, interest-bearing instruments.

DIVIDEND POLICY

We have never declared or paid cash dividends on our common stock. Following the completion of this offering, we intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not expect to pay cash dividends on our common stock in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, outstanding indebtedness and plans for expansion and restrictions imposed by lenders, if any.

Table of Contents

CAPITALIZATION

The following table sets forth our capitalization as of September 30, 2007 on:

- an actual basis;
- a pro forma basis to reflect the adoption of our amended and restated articles of incorporation, the issuance of 2,162,150 shares of Series B convertible preferred stock on December 17, 2007, the conversion of all our outstanding shares of preferred stock into shares of common stock upon the closing of this offering, and the conversion of all Series A warrants into common stock warrants; and
- a pro forma as adjusted basis to further reflect the receipt of the estimated net proceeds from the sale of shares of common stock in this offering at an assumed initial public offering price of $ per share, the midpoint of the range on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this capitalization table together with our consolidated financial statements and the related notes included elsewhere in this prospectus, as well as Management s Discussion and Analysis of Financial Condition and Results of Operations and other financial information included in this prospectus.

	As of September 30, 2007		
	Actual	Pro Forma	Pro Forma as Adjusted[1]
	(in thousands, except share and per share data)		
Redeemable convertible preferred stock warrants	$ 3,394	$	$
Series A redeemable convertible preferred stock, no par value; 5,400,000 shares authorized, 4,728,547 issued and outstanding, actual; no shares issued and outstanding, pro forma; no shares issued and outstanding, pro forma as adjusted	43,503		
Series A-1 redeemable convertible preferred stock, no par value; 2,188,425 shares authorized, 2,188,425 issued and outstanding, actual; no shares issued and outstanding, pro forma; no shares issued and outstanding, pro forma as adjusted	20,134		
Shareholders (deficiency) equity:			
Common stock, no par value per share, 25,000,000 common shares and 2,811,575 undesignated shares authorized, 6,294,121 shares issued and outstanding, actual; 70,000,000 common shares and 5,000,000 undesignated shares authorized, 15,373,243 shares issued and outstanding, pro forma; 70,000,000 common shares and 5,000,000 undesignated shares authorized, shares issued and outstanding, pro forma as adjusted;	26,564	88,463	
Common stock warrants	1,366	3,133	
Accumulated other comprehensive loss	(1)	(1)	
Accumulated deficit	(72,010)	(48,695)	

Total shareholders (deficiency) equity	(44,081)	42,900	
Total capitalization	$ 22,950	$ 42,900	$

(1) A $1.00 increase or decrease in the assumed initial public offering price would result in an approximately $ million increase or decrease in each of pro forma as adjusted additional paid-in capital, pro forma as adjusted total shareholders equity and pro forma as adjusted total capitalization, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriting discounts and commission and estimated offering expenses payable by us.

Table of Contents

The outstanding shares set forth in the table above excludes, as of September 30, 2007:

- 4,599,361 shares of common stock issuable upon the exercise of outstanding stock options as of September 30, 2007 at a weighted average exercise price of $4.95 per share;
- 1,068,277 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $5.47 per share;
- 242,583 additional shares of common stock reserved and available for future issuances under our 2003 Stock Option Plan; and
- 3,000,000 additional shares of common stock reserved and available for future issuances under our 2007 Equity Incentive Plan.

Shares available for future issuance under our 2007 Equity Incentive Plan do not include shares that may become available for issuance pursuant to provisions in this plan that provide for the automatic annual increase in the number of shares reserved thereunder and the re-issuance of shares that are cancelled or forfeited in accordance with such plans. See Compensation Employee Benefit Plans 2007 Equity Incentive Plan.

Table of Contents

DILUTION

If you invest in our common stock, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after completion of this offering.

Our net tangible book value as of September 30, 2007 was $(44.7) million, or $(7.10) per share of common stock, not taking into account the conversion of our outstanding preferred stock. Net tangible book value per share is equal to our total tangible assets (total assets less intangible assets) less our total liabilities (including our preferred stock) divided by the number of shares of common stock outstanding. Prior to this offering, the pro forma net tangible book value of our common stock as of September 30, 2007 was approximately $42.3 million, or approximately $2.75 per share, based on the number of shares outstanding as of September 30, 2007, after giving effect to the issuance of the Series B convertible preferred stock and the conversion of all outstanding preferred stock into shares of common stock upon the closing of this offering.

After giving effect to our sale of shares of common stock at an assumed initial public offering price of $ per share, the midpoint of the range on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses, and applying the net proceeds from such sale, the pro forma as adjusted net tangible book value of our common stock, as of September 30, 2007, would have been approximately $ million, or $ per share. This amount represents an immediate increase in net tangible book value to our existing shareholders of $ per share and an immediate dilution to new investors of $ per share. The following table illustrates this per share dilution:

Assumed initial public offering price per share		$
Net tangible book value (deficit) per share as of September 30, 2007	$ (7.10)	
Increase per share attributable to conversion of preferred stock	9.85	
Pro forma net tangible book value per share as of September 30, 2007	2.75	
Increase per share attributable to new investors		
Pro forma as adjusted net tangible book value per share as of September 30, 2007		
Dilution per share to new investors in this offering		$

A $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, respectively, our pro forma as adjusted net tangible book value by $ million, the pro forma as adjusted net tangible book value per share by $ per share and the dilution in the net tangible book value to investors in this offering by $ per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us.

The following table summarizes, as of September 30, 2007, on a pro forma as adjusted basis, the number of shares of common stock purchased from us, the total consideration paid to us and the average price per share paid by our existing shareholders and by new investors, based upon an assumed initial public offering price of $ per share, and before deducting estimated underwriting discounts and commissions and offering expenses payable by us.

	Shares Purchased		Total Consideration		Weighted Average Price per Share
	Number	Percent	Amount	Percent	
Existing shareholders		%	$	%	$
New investors					
Total		100%		100%	

A $1.00 increase or decrease in the assumed initial public offering price of $ per share would increase or decrease, respectively, total consideration paid by new investors and total consideration paid by all shareholders by

Table of Contents

approximately $ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

Sales of common stock in the offering will reduce the number of shares of common stock held by existing shareholders to , or approximately % of the total shares of common stock outstanding, and will increase the number of shares held by new investors to , or approximately % of the total shares of common stock outstanding after the offering.

In the preceding tables, the shares of common stock outstanding as of September 30, 2007 exclude:

- 4,599,361 shares of common stock issuable upon the exercise of outstanding stock options as of September 30, 2007 at a weighted average exercise price of $4.95 per share;
- 1,068,277 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $5.47 per share;
- 242,583 additional shares of common stock reserved and available for future issuances under our 2003 Stock Option Plan; and
- 3,000,000 additional shares of common stock reserved and available for future issuances under our 2007 Equity Incentive Plan.

Shares available for future issuance under our 2007 Equity Incentive Plan do not include shares that may become available for issuance pursuant to provisions in this plan that provide for the automatic annual increase in the number of shares reserved thereunder and the re-issuance of shares that are cancelled or forfeited in accordance with such plan.

If the underwriters exercise their over-allotment option in full:

- the number of shares of our common stock held by existing shareholders would decrease to approximately % of the total number of shares of our common stock outstanding after this offering;
- the number of shares of our common stock held by new investors would increase to approximately % of the total number of shares of our common stock outstanding after this offering; and
- our pro forma as adjusted net tangible book value at September 30, 2007 would have been $ million, or $ per share of common stock, representing an immediate increase in pro forma net tangible book value of $ per share of common stock to our existing shareholders and an immediate dilution of $ per share to investors purchasing shares in this offering.

Because we expect the exercise prices of the outstanding options and warrants to be below the assumed initial public offering price of $ per share, investors purchasing common stock in this offering will suffer additional dilution when and if these options and warrants are exercised. If the options exercisable for 4,599,361 shares and warrants exercisable for 1,068,277 shares of common stock were exercised prior to this offering, but assuming no exercise of the underwriters over-allotment option, our existing shareholders would, after this offering, own approximately % of the total number of outstanding shares of our common stock while contributing % of the total consideration for all shares, and our new investors would own approximately % of the total number of outstanding shares of our common stock while contributing % of the total consideration for all shares.

29

Table of Contents

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, 2005, 2006 and 2007 and balance sheet data as of June 30, 2006 and 2007 from our audited consolidated financial statements and related notes that are included elsewhere in this prospectus. We derived the selected consolidated statements of operations data for the years ended June 30, 2003 and 2004 and the balance sheet data as of June 30, 2003, 2004, and 2005 from our audited consolidated financial statements that do not appear in this prospectus. We derived the consolidated statements of operations data for the three months ended September 30, 2006 and 2007 and the balance sheet data as of September 30, 2007 from our unaudited consolidated financial statements and related notes that are included elsewhere in this prospectus. 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. These interim financial statements reflect all adjustments consisting of normal recurring accruals, which, in the opinion of management, are necessary to present fairly our consolidated financial position and results of operations for the interim periods. 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, 2007 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 prospectus 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,	
	2003	2004	2005	2006	2007[1]	2006[1]	2007[1]
	(in thousands, except share and per share amounts)						
Consolidated Statements of Operations Data:							
Revenues	$	$	$	$	$	$	$
Cost of goods sold							539
Gross (loss) profit							(539)
Expenses[1]:							
Selling, general and administrative	829	984	1,177	1,735	6,691	823	3,552
Research and development	681	3,246	2,371	3,168	8,446	749	3,328
Total expenses	1,510	4,230	3,548	4,903	15,137	1,572	6,880

Loss from operations	(1,510)	(4,230)	(3,548)	(4,903)	(15,137)	(1,572)	(7,419)
Other income (expense):							
Interest expense	(275)			(48)	(1,340)	(13)	(300)
Interest income	10	18	37	56	881	256	278
Total other income (expense)	(265)	18	37	8	(459)	243	(22)
Net loss	(1,775)	(4,212)	(3,511)	(4,895)	(15,596)	(1,329)	(7,441)
Accretion of redeemable convertible preferred stock[2]					(16,835)	(3,878)	(4,853)
Net loss available to common shareholders	$ (1,775)	$ (4,212)	$ (3,511)	$ (4,895)	$ (32,431)	$ (5,207)	$ (12,294)
Loss per common share: Basic and diluted[3]	$ (0.44)	$ (0.78)	$ (0.61)	$ (0.79)	$ (5.22)	$ (0.84)	$ (1.95)
Weighted average common shares used in computation: Basic and diluted[3]	4,001,111	5,375,795	5,779,942	6,183,715	6,214,820	6,199,204	6,291,512

(footnotes appear on following page)

Table of Contents

(1) Operating expenses in the year ended June 30, 2007 and three months ended September 30, 2006 and 2007 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:

	Year Ended June 30, 2007	Three Months Ended September 30, 2006	Three Months Ended September 30, 2007
		(in thousands)	
Selling, general and administrative	$ 327	$ 9	$ 277
Research and development	63	2	73

(2) See Notes 1 and 9 of the notes to our consolidated financial statements for a discussion of the accretion of redeemable convertible preferred stock.

(3) See Note 11 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 pro forma per common share calculations.

	As of June 30,					As of September 30,
	2003	2004	2005	2006	2007	2007
				(in thousands)		
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 3,851	$ 3,144	$ 1,780	$ 1,554	$ 7,908	$ 3,265
Short-term investments					11,615	18,499
Working capital[(1)]	3,415	2,868	1,349	(1,240)	18,171	21,695
Total current assets	3,871	3,166	2,116	2,424	20,828	25,973
Total assets	4,550	4,031	2,874	3,296	22,025	27,316
Redeemable convertible preferred stock warrants					3,094	3,394
Total liabilities	456	298	767	3,723	5,830	7,760
Redeemable convertible preferred stock					48,498	63,637
Total shareholders (deficiency) equity	4,094	3,733	2,107	(427)	(32,303)	(44,081)

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

Table of Contents

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 prospectus. 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 prospectus.

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 formed in 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.

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. Through December 31, 2007, we shipped more than 1,700 single-use catheters to 57 hospitals and generated revenues of approximately $4.6 million.

We intend to market the Diamondback 360° in the United States through a direct sales force and will commence a full commercial launch in early 2008. We plan to expend significant capital to increase the size of our sales and marketing efforts to expand our customer base as we begin full commercialization of the Diamondback 360°. We intend to manufacture the Diamondback 360° internally at our facilities.

As of September 30, 2007, we had an accumulated deficit of $72.0 million. We expect our losses to continue and to increase as we continue our commercialization activities and develop additional product enhancements and make further regulatory submissions. To date, we have financed our operations primarily through the private placement of equity securities.

During the remainder of fiscal year 2008, we will 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. We believe the net proceeds of this offering, together with existing cash, cash equivalents, and short-term investments, will be sufficient to fund our ongoing capital needs for at least the next twelve months.

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 include ten single-use catheters and guidewires, along with a control unit. Reorders for single-use catheters and guidewires should occur as hospitals utilize the single-use catheters.

As of September 30, 2007, we had not recorded any revenues from the sale of the single-use catheters and guidewires. We have applied Emerging Issues Task Force Bulletin (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. As such, all revenues are deferred until completion of all contractual obligations in the sales contract. Initial shipments to customers included a loaner control unit until the new control unit was available. Accordingly, we had deferred revenue of $1.4 million as of September 30, 2007. Shipments of the new control units began in the quarter ended December 31, 2007, at which time deferred revenue was recognized.

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. We anticipate that gross margin percentages on single-use catheters will be higher than those achieved on the control unit and guidewires.

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.

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

Interest Expense. Interest expense resulted from 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. Upon completion of this offering 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 automatically upon the completion of this offering. As such, the preferred shareholders will forfeit their liquidation preferences and we will no longer record accretion.

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. As June 30, 2007, we had net operating loss carryforwards for federal and state income tax reporting purposes of approximately $40.8 million, which will expire at various dates through fiscal 2027.

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

Table of Contents

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. 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 derive our revenue through the sale of the Diamondback 360°, which includes single-use catheters, control units and guidewires used in the atherectomy procedure. The single-use catheters rely upon the use of the control units, thus our sales involve bundled transactions with multiple elements.

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 has occurred or delivery 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. However, when the arrangement with the customer imposes additional performance requirements, and we are unable to treat the additional performance requirements as a separate unit of accounting, then revenue is recognized when all such requirements have been satisfied. Payment terms are generally set at 30 days.

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 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:

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.

Table of Contents

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 on factors such as the price of the most recent preferred stock sales to investors taking into consideration the preferences held by the preferred stock class in favor of shares of common stock, the valuations of comparable companies, the status of our development and sales efforts, our cash and working capital amounts, revenue growth, the preferences held by the preferred stock classes in favor of shares of common stock, and additional objective and subjective factors relating to our business.

The following table sets forth the exercise prices of options granted during fiscal year 2007 and the quarter ended September 30, 2007, 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
July 1, 2006	132,000	$ 5.71	$ 2.43
July 17, 2006	230,000	5.71	2.43
August 15, 2006	239,500	5.71	2.43
October 3, 2006	375,000	5.71	2.58
December 19, 2006	446,100	5.71	2.79
February 14, 2007	48,000	5.71	3.58
February 15, 2007	540,000	5.71	3.58
April 18, 2007	299,250	5.71	4.63
June 12, 2007	315,000	5.11	5.95
August 7, 2007	402,500	5.11	5.95

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.

35

Table of Contents

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 and Series A-1 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 and Series A-1 convertible preferred stock during the fiscal year ended June 30, 2007 and the quarter ended September 30, 2007:

Date	Series A Convertible Preferred Stock	Series A-1 Convertible Preferred Stock
September 30, 2006	$ 5.71	$
December 31, 2006	6.64	
March 31, 2007	7.57	
June 30, 2007	8.50	8.50
September 30, 2007	9.20	9.20

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, 2007 and September 30, 2007. 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.

Table of Contents

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,		
	2005	2006	Percent Change	2006	2007	Percent Change	2006	2007	Percent Change
evenues	$	$		$	$		$	$	
ost of goods old								539	
ross (loss) rofit								(539)	
xpenses:									
elling, general nd dministrative	1,177	1,735	47.4%	1,735	6,691	285.6%	823	3,552	331.6%
esearch and evelopment	2,371	3,168	33.6	3,168	8,446	166.6	749	3,328	344.3
otal expenses	3,548	4,903	38.2	4,903	15,137	208.7	1,572	6,880	337.7
oss from perations	(3,548)	(4,903)	38.2	(4,903)	(15,137)	208.7	(1,572)	(7,419)	371.9
ther income expense):									
nterest expense		(48)	0	(48)	(1,340)	2,691.7	(13)	(300)	2,207.7
nterest income	37	56	51.4	56	881	1,473.2	256	278	8.6
otal other ncome expense)	37	8	78.3	8	(459)	5,837.5	243	(22)	1,090.5
et loss	(3,511)	(4,895)	39.4	(4,895)	(15,596)	218.6	(1,329)	(7,441)	459.9
ccretion of edeemable onvertible referred stock					(16,835)		(3,878)	(4,853)	
et loss vailable to ommon hareholders	$ (3,511)	$ (4,895)	39.4%	$ (4,895)	$ (32,431)	562.5%	$ (5,207)	$ (12,294)	136.1%

Comparison of the Three Months Ended September 30, 2006 and 2007

Revenues. 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, and as of September 30, 2007, we had not recorded any revenues from the sale of the control units, single-use catheters and guidewires. We have applied EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*, the primary impact of which was to treat original shipments of the Diamondback 360° as a single unit of accounting. As such, all revenues are deferred until completion of all contractual obligations in the sales contract. Initial shipments to customers included a loaner control unit until the new control unit was available. Accordingly, we had deferred revenue of $1.4 million as of September 30, 2007. Shipments of the new control units began in the quarter ended December 31, 2007, at which time deferred revenue was recognized.

Cost of Goods Sold. For the quarter ended September 30, 2007, cost of goods sold was $539,000. This amount represents the cost of goods sold for single-use catheters and guidewires shipped subsequent to obtaining FDA clearance for the Diamondback 360° in August 2007.

Table of Contents

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased by $2.7 million, from $823,000 for the three months ended September 30, 2006 to $3.6 million for the three months ended September 30, 2007. The primary reasons for the increase included the addition of three officers to our executive management team, contributing $300,000, the building of our sales and marketing team, contributing $1.9 million, and significant consulting and professional services, contributing $200,000. In addition, stock based compensation increased from $9,000 for the three months ended September 30, 2006 to $277,000 for the three months ended September 30, 2007. We expect our selling, general and administrative expenses to increase significantly due to the costs associated with expanding our sales and marketing organization to commercialize our products.

Research and Development Expenses. Our research and development expenses increased by $2.6 million, from $749,000 for the three months ended September 30, 2006 to $3.3 million for the three months ended September 30, 2007. Research and development spending increased as we increased the size of this department to improve our product, such as the development of a new control unit, shaft designs and crown designs. In addition, stock based compensation increased from $2,000 for the three months ended September 30, 2006 to $73,000 for the three months ended September 30, 2007. We expect our research and development expenses to increase as we attempt to expand our product portfolio within the peripheral market and leverage our core technology into the coronary market.

Interest Income. Interest income increased by $22,000, from $256,000 for the three months ended September 30, 2006 to $278,000 for the three months ended September 30, 2007. The increase was primarily due to higher average cash and cash equivalents and short-term investment balances. Average cash and cash equivalent and short-term investment balances were $20.7 million and $21.6 million for the three months ended September 30, 2006 and 2007, respectively.

Interest Expense. Interest expense increased by $287,000, from $13,000 for the three months ended September 30, 2006 to $300,000 for the three months ended September 30, 2007. The increase was due to the change in the fair value of convertible preferred stock warrants.

Accretion of Redeemable Convertible Preferred Stock. Accretion of redeemable convertible preferred stock was $3.9 million for the three months ended September 30, 2006, as compared to $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.

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

Table of Contents

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.

Comparison of the Fiscal Year Ended June 30, 2005 with the Fiscal Year Ended June 30, 2006

Revenues. We did not generate any revenues during the fiscal years ended June 30, 2005 or 2006.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased by $.5 million, from $1.2 million in fiscal 2005 to $1.7 million in fiscal 2006. This increase was primarily due to initial sales and marketing costs and increased rent for office and production facilities.

Research and Development Expenses. Our research and development expenses increased by $.8 million, from $2.4 million in fiscal 2005 to $3.2 million in fiscal 2006. The majority of the research and development increase was due to additional personnel and related costs, along with a significant increase in clinical costs related to our PAD I, PAD II and OASIS trials.

Interest Income. Interest income increased by $19,000, from $37,000 in fiscal 2005 to $56,000 in fiscal 2006. The increase was due to higher returns on average cash, cash equivalents and short-term investment balances. Average cash, cash equivalent and short-term investment balances were $2.2 million and $1.6 million in fiscal 2005 and 2006, respectively.

Interest Expense. Interest expense increased by $48,000, from $0 in fiscal 2005 to $48,000 in fiscal 2006. The increase was due to convertible promissory notes that we issued in 2006.

Liquidity and Capital Resources

We have incurred losses since our inception in February 1989, and as of September 30, 2007, we had an accumulated deficit of $72.0 million. We have funded our operations primarily from the issuance of common and preferred stock and convertible promissory notes. During fiscal 2006, we issued $3.1 million in convertible promissory notes. In fiscal 2007, these notes were converted to preferred stock as part of our Series A preferred stock financing. As of September 30, 2007, we had received proceeds of $42.4 million related to our Series A and Series A-1 preferred stock financings. On December 17, 2007, we completed the sale of $20.0 million of Series B convertible preferred stock.

The reported changes in cash and cash equivalents for the years ended June 30, 2005, 2006 and 2007 and for the three months ended September 30, 2006 and 2007 are summarized below.

Cash and Cash Equivalents. Cash and cash equivalents decreased by $9.9 million, from $13.2 million at September 30, 2006 to $3.3 million at September 30, 2007. Cash and cash equivalents increased by $6.3 million, from $1.6 million at June 30, 2006 to $7.9 million at June 30, 2007.

Short-Term Investments. Short-term investments increased by $11.5 million, from $7.0 million at September 30, 2006 to $18.5 million at September 30, 2007. Short-term investments increased by $11.6 million, from $0 at June 30, 2006 to $11.6 million at June 30, 2007.

Operating Activities. Net cash used in operating activities was $3.3 million, $5.0 million and $12.3 million in fiscal 2005, 2006 and 2007, respectively, and $1.5 million and $8.1 million for the three months ended September 30, 2006 and 2007, respectively.

Investing Activities. Net cash used in investing activities was $5,000, $228,000 and $11.9 million in fiscal 2005, 2006 and 2007, respectively, and $7.0 million in each of the three months ended September 30, 2006 and 2007. For the three months ended September 30, 2006, we purchased short-term investments in the amount of $7.0 million. For the three months ended September 30, 2007, we purchased and sold short-term investments in the amount of $12.7 million and $5.9 million, respectively. In fiscal 2007, we purchased and sold short-term

Table of Contents

investments in the amount of $23.2 million and $11.8 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 $7,000, $235,000 and $465,000 in fiscal 2005, 2006 and 2007, respectively, and $49,000 and $207,000 in the three months ended September 30, 2006 and 2007, respectively.

Financing Activities. Net cash provided by financing activities was $1.9 million, $5.0 million and $30.5 million in fiscal 2005, 2006 and 2007, respectively, and $20.1 million and $10.4 million in the three months ended September 30, 2006 and 2007, respectively. Cash provided by financing activities during these periods included:

- net proceeds from the sale of common stock of $2.3 million in each of fiscal 2005 and 2006;
- issuance of a note payable to a shareholder of $350,000 in fiscal 2005;
- proceeds from the issuance of convertible promissory notes of $3.1 million in fiscal 2006;
- proceeds from the issuance of Series A and Series A-1 convertible preferred stock of $30.3 million in fiscal 2007 and $20.1 million and $10.3 million in the three months ended September 30, 2006 and 2007, respectively; and
- issuance of convertible preferred stock warrants of $1.8 million in fiscal 2007.

Cash used in financing activities in these periods included:

- repurchase of common stock of $700,000 in fiscal 2005;
- repayment of a note payable to a shareholder of $350,000 in fiscal 2006; and
- payment of Series A offering costs of $1.8 million in the three months ended September 30, 2006.

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. We believe that our existing cash and cash equivalents and short-term investments, combined with our existing capital resources, will be sufficient to meet our capital and operating needs for at least the next 12 months, and that the proceeds from this offering will be sufficient to meet our capital and operating needs for at least 12 months from the consummation of the offering. To the extent that funds generated by this offering, together with existing cash and cash equivalents and short-term investments, are insufficient to fund our future activities, we may need to raise additional funds through public or private equity or debt financing. Although we are currently not a party to any agreement or letter of intent with respect to potential investments in, or acquisitions of, businesses, services or technologies, we may enter into these types of arrangements in the future, which could also require us to seek additional equity or debt financing. Additional funds may not be available on terms favorable to us, or at all. If we are unable to obtain additional financing or successfully market our products on a timely basis, we would have 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, 2007 are summarized below:

	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]	$ 1,722	$ 346	$ 733	$ 643	$ 0
Purchase commitments[2]	2,122	2,122			
Total	$ 3,844	$ 2,468	$ 733	$ 643	$ 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.

(2) This amount reflects open purchase orders.

Table of Contents

Related Party Transactions

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

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 July 2006, the FASB issued interpretation No. 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109* (FIN 48). FIN 48 clarifies the accounting treatment (recognition and measurement) for an income tax position taken in a tax return and recognized in a company s financial statement. The new standard also contains guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The provisions of FIN 48 are effective for fiscal years beginning after December 15, 2006.

We adopted the provisions of FIN 48 on July 1, 2007. Previously, we had accounted for tax contingencies in accordance with SFAS No. 5, *Accounting for Contingencies*. As required by FIN 48, which clarifies SFAS No. 109, *Accounting for Income Taxes*, we recognize the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. At the adoption date, we applied FIN 48 to all tax positions for which the statute of limitations remained open. We did not record any adjustment to the liability for unrecognized income tax benefits or accumulated deficit for the cumulative effect of the adoption of FIN 48.

In addition, the amount of unrecognized tax benefits as of July 1, 2007 was zero. There have been no material changes in unrecognized tax benefits since July 1, 2007, and we do not anticipate a significant change to the total amount of unrecognized tax benefits within the next 12 months. We did not have an accrual for the payment of interest and penalties related to unrecognized tax benefits as of July 1, 2007.

We are subject to income taxes in the U.S. federal jurisdiction and various state jurisdictions. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment to apply.

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. This standard is effective for financial statements issued for fiscal years beginning after November 15, 2007. We are currently evaluating the impact of this statement but believe that the adoption of SFAS No. 157 will not have a material impact on our financial position or consolidated results of operations.

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 is effective as of

the beginning of an entity s first fiscal year beginning after November 15, 2007, with early adoption permitted for an entity that has also elected to apply the provisions of SFAS No. 157. We are currently evaluating the impact of this statement but believe that the adoption of SFAS No. 159 will not have a material impact on our financial position or consolidated results of operations.

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

Table of Contents

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 believe that the adoption of SFAS No. 141(R) and 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 allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including commercial paper, money market fund and U.S. government securities. Our cash and cash equivalents as of September 30, 2007 included liquid money market accounts. Due to the short-term nature of our investments, we believe that there is no material exposure to interest rate risk.

Table of Contents

BUSINESS

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. According to the American Medical Association, PAD affects approximately eight to 12 million people in the United States. 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. Through December 31, 2007, we shipped more than 1,700 single-use catheters to 57 hospitals and have generated revenues of approximately $4.6 million.

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 or outperformed 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.

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.

The American Medical Association reports that PAD affects approximately eight to 12 million people in the United States. According to 2007 statistics from the American Heart Association, PAD becomes more common

Table of Contents

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, published in the Journal of the American Medical Association in 2001, 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 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 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. Current atherectomy techniques 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 in a back and forth motion. 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. Current 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.

Current atherectomy technologies 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 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.

Table of Contents

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 1.6% 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 4.8% rate of device-related serious adverse events, or SAEs, versus an FDA target rate of 8%.

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 or outperformed the FDA s efficacy targets.

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.

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

Table of Contents

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.

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 $20,000, 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 as of December 17, 2007 had 18 direct sales representatives. We anticipate broadening our commercialization efforts and adding additional sales representatives in 2008. 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.

Expand Product Portfolio within Peripheral Market. 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.

Table of Contents

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.

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

Table of Contents

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.

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. Compliant tissue flexes away from the crown and is not affected by the sanding of the diamond grit. Diseased tissue, particularly heavily calcified lesions, provides resistance and allows the orbiting crown to 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.

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.

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. A coronary application would require us to conduct a clinical trial and receive PMA from the

Table of Contents

FDA. We participated in a pre-IDE meeting with the FDA and expect to submit our IDE application following completion of our pre-clinical testing.

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

Table of Contents

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 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%	4.8% 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

Table of Contents

We submitted our OASIS data and received 510(k) clearance from the FDA for use of the Diamondback 360° 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 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 December 17, 2007, we had a 24-person direct sales force, including 18 district sales managers, four regional sales managers, a national training manager, and a director of customer support, all of whom report to our Vice President of Sales. Upon receiving 510(k) clearance from the FDA on August 30, 2007, we began limited commercialization of the Diamondback 360° in September 2007.

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 December 17, 2007, we had 21 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 2005, fiscal 2006 and fiscal 2007 were $2.4 million, $3.2 million and $8.4 million, respectively, and for the three months ended September 30, 2006 and 2007 were $749,000 and $3.3 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

Table of Contents

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.

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 smaller manufacturers including, among others, ev3 and Spectranetics, 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.

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;

Table of Contents

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 December 17, 2007, we held 20 issued U.S. patents and have 14 U.S. patent applications pending, as well as 26 issued foreign patents and 17 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 2021, 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 five U.S. trademark applications pending.

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,

Table of Contents

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 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;

Table of Contents

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.

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

Table of Contents

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

Table of Contents

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.

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

Table of Contents

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 December 17, 2007, we had 91 employees, including 22 employees in manufacturing, 24 employees in sales, five employees in marketing, three employees in clinicals, eight employees in general and administrative, 21 employees in research and development, and eight employees in management. 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.

Facilities

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 adequate for our current and anticipated future needs through the next 12 months.

Legal Proceedings

Shturman Legal Proceedings

We are party to two legal proceedings relating to a dispute with Dr. Leonid Shturman, our founder, and Shturman Medical Systems, Inc., or SMS, a company owned by Dr. Shturman. The proceedings relate to a Stock Purchase Agreement dated June 30, 1998 between us and SMS, and Dr. Shturman s employment agreement with us, dated January 7, 2000. Pursuant to the Stock Purchase Agreement, SMS purchased all the stock of our former Russian subsidiary, ZAO Shturman Cardiology Systems, Russia. In exchange, SMS agreed to transfer to us all present and future intellectual property and know-how associated with atherectomy products and associated accessory products that were developed by SMS and the Russian subsidiary. Pursuant to the employment agreement, Dr. Shturman was required to assign to us certain inventions made by him. On or about November 2006, we discovered that Dr. Shturman had sought patent protection in the United Kingdom and with the World Intellectual Property Organization as the sole inventor for technology relating to the use of counterbalance weights with rotational atherectomy devices, or the counterbalance technology, which we believe should have been assigned to us under the Stock Purchase Agreement and the employment agreement.

On August 16, 2007, we served and filed a Demand for Arbitration against SMS alleging that Dr. Shturman s filing for patent protection of the counterbalance technology and failure to assign these applications violated the assignment provision of the Stock Purchase Agreement. On September 28, 2007, SMS filed a Statement of Answer and Motion to Dismiss alleging that the Stock Purchase Agreement had expired, thus ending Dr. Shturman s obligation to assign atherectomy technology. This arbitration is venued in Minnesota with the American Arbitration Association. In this proceeding, we are seeking a declaration that the counterbalance technology must be assigned to us and a declaration that we are the rightful owner of the counterbalance technology.

Table of Contents

Also on August 16, 2007, we filed a complaint in the U.S. District Court in Minnesota against Dr. Shturman for a breach of his employment agreement. Specifically, under the employment agreement, Dr. Shturman was obligated to assign any inventions for the diagnosis or treatment of coronary or periphery vessels that were disclosed to patent attorneys or otherwise documented by Dr. Shturman during the employment term. We allege that Dr. Shturman researched and recorded the counterbalance technology during the term of his employment agreement and we are seeking judgment against Dr. Shturman for breach of the employment agreement and a declaratory judgment that we are the rightful owner of the counterbalance technology. On October 31, 2007, Dr. Shturman filed an answer and counterclaim against us and other co-defendants asserting conversion, theft and unjust enrichment for the alleged illegal removal and transport to the United States of two drive shaft winding devices purportedly developed by Shturman Cardiology Systems, Russia, as well as raising certain affirmative defenses. We believe that Dr. Shturman s counterclaims and affirmative defenses are without merit.

ev3 Legal Proceedings

On December 28, 2007, ev3 Inc., ev3 Endovascular, Inc. and FoxHollow Technologies, Inc., together referred to as the Plaintiffs, filed a complaint in the Ramsey County District Court for the State of Minnesota against us and Sean Collins and Aaron Lew, who are former employees of FoxHollow currently employed by us, as well as against additional former employees of FoxHollow currently employed by us. The complaint asserts that Messrs. Lew and Collins, among other things, violated provisions in their employment agreements with FoxHollow relating to confidentiality and nonsolicitation of employees. The complaint further alleges that we, Collins and Lew misappropriated trade secrets of the Plaintiffs, unfairly competed with the Plaintiffs and tortiously interfered with FoxHollow s employment relationships. The Plaintiffs also claim that all defendants conspired to improperly solicit employees of FoxHollow or ev3 and to misappropriate trade secrets or confidential information of FoxHollow or ev3. The Plaintiffs are seeking injunctions to prevent Messrs. Collins and Lew and the additional employees from violating the terms of their agreements with FoxHollow, preventing all defendants from using Plaintiffs confidential information or trade secrets, preventing us from employing Messrs. Collins and Lew and the additional employees for a period of one year, preventing all defendants from contacting certain of Plaintiffs customers for one year, and preventing us from hiring any of Plaintiffs current employees for a period of one year. Plaintiffs also seek monetary damages of at least $50,000 and payment of their attorneys fees. We believe that Plaintiffs claims against us in this lawsuit are without merit, and we are defending this litigation vigorously. However, if we are not successful in defending these claims, 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 are successful, it could have a material adverse effect on our business, operations and financial condition.

Also on December 28, 2007, the Plaintiffs made two motions to the court. The first motion was for an *ex parte* order requiring preservation of documents, which the court granted on December 28, 2007. The second motion was for a broad temporary restraining order, which the court denied in its order dated January 10, 2008. However, the court ordered that any of our current employees who were both formerly employed with any of the Plaintiffs and who signed a FoxHollow employment agreement must not disclose any of the Plaintiffs trade secrets and are barred from disclosing the identity of FoxHollow Key Opinion Leaders or Thought Leaders and from using this information to aid us. The court further ordered that any of these persons must not maintain, use or disclose any information about the FoxHollow Key Opinion Leaders or Thought Leaders that was received while they were employed with FoxHollow. The court also ordered that if any employee of ours who was formerly employed by FoxHollow or ev3 contacts any physician who is a FoxHollow Key Opinion Leader or Thought Leader, he must be able to trace, document and account, with specificity, how he was able to identify such prospects through information, records or documents obtained outside his employment with Plaintiffs. The court further directed that any of our employees who were

formerly employed by FoxHollow or ev3 and who left that employment less than a year ago must not be involved in soliciting or recruiting any current employee of the Plaintiffs to leave that employment or to accept employment with us.

Table of Contents

MANAGEMENT

Executive Officers and Directors

The name, age and position of each of our directors and executive officers as of January 14, 2008 are as follows:

Name	Age	Position
Glen D. Nelson, M.D.(3)	70	Chairman
David L. Martin	43	President, Chief Executive Officer, Interim Chief Financial Officer, and Director
James E. Flaherty	54	Chief Administrative Officer and Secretary
Michael J. Kallok, Ph.D.	59	Chief Scientific Officer, Director
John Borrell	40	Vice President of Sales
Brian Doughty	44	Vice President of Marketing
Robert J. Thatcher	53	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)	54	Director
Geoffrey O. Hartzler, M.D.(1)(3)	61	Director
Roger J. Howe, Ph.D.(2)	64	Director
Gary M. Petrucci(2)	66	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, Interim Chief Financial Officer and Director. Mr. Martin has been our President and Chief Executive Officer since February 2007, our Interim Chief Financial Officer since January 14, 2008, and a director since August 2006. 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.

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. Prior to joining us, Mr. Flaherty served as 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, 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 September 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

Table of Contents

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, 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 Renovis, Inc., a publicly-held company, and on the boards of directors of Trellis Bioscience, Inc., Xoft, Inc., Sanarus Inc., Genetix Pharmaceuticals, Inc. and PlaySpan 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.

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. Ms. Wyskiel plans to resign from the board immediately prior to this offering.

Board Composition

Our bylaws provide that the board of directors shall consist of one or more members, and the shareholders shall determine the number of directors at each regular meeting. Each director serves for a term that expires at the next regular meeting of the shareholders and until his successor is elected and qualified.

Our board of directors has determined that seven of our nine directors are independent directors, as defined under the applicable regulations of the SEC and under the applicable rules of the Nasdaq Stock Market LLC. The independent directors are Messrs. Nelson, Blackey, Friedman, Hartzler, Howe and Petrucci and Ms. Wyskiel.

Table of Contents

Currently, each of our directors serves on our board of directors pursuant to a stockholders agreement and provisions of our articles of incorporation relating to our preferred stock. The provisions of the stockholders agreement and our articles of incorporation relating to the nomination and election of directors will terminate upon the closing of this offering, but members previously elected to our board of directors pursuant to these agreements will continue to serve as directors until their resignation or until their successors are duly elected by our shareholders.

Board Committees

Our board of directors has designated an audit committee, a compensation committee and a nominating and corporate governance committee. In addition, from time to time, the board of directors may designate special committees when necessary to address specific issues.

Audit Committee

The audit committee of our board of directors is a standing committee of, and operates under a written charter adopted by, our board of directors. Our audit committee currently consists of Messrs. Blackey and Hartzler and Ms. Wyskiel. Each member of our audit committee satisfies the Nasdaq independence standards and the independence standards of Rule 10A-3(b)(1) of the Securities Exchange Act. Ms. Wyskiel plans to resign from the audit committee and our board of directors immediately prior to this offering, and the board plans to seek a replacement for Ms. Wyskiel. Our board of directors has determined that each member of our audit committee possesses the financial qualifications required of audit committee members set forth in the rules and regulations of Nasdaq and under the Securities Exchange Act. Our board of directors also determined that Mr. Blackey is an audit committee financial expert as defined under the applicable rules of the SEC. In making this determination our board of directors considered Mr. Blackey s previous employment experience, including his experience as an audit partner at Ernst & Young LLP and Arthur Andersen LLP, and his experience as the Chief Operating Officer of Holiday Companies.

The functions of our audit committee include, among other things:

- reviewing and pre-approving the engagement of our independent registered public accounting firm to perform audit services and any permissible non-audit services;
- evaluating the qualifications, independence and performance of our independent registered public accounting firm;
- reviewing and monitoring the integrity of our financial statements;
- reviewing and approving all related-party transactions;
- reviewing with our independent registered public accounting firm and management the performance of our internal audit function, financial reporting process, systems of internal controls over financial reporting and disclosure of controls and procedures; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters.

Our independent registered public accounting firm and other key committee advisors have regular contact with our audit committee. Following each committee meeting, the audit committee reports to the full board of directors.

Compensation Committee

The compensation committee of our board of directors is a standing committee of, and operates under a written charter adopted by, our board of directors. Our compensation committee currently consists of Messrs. Howe, Petrucci and Friedman. Mr. Friedman serves as the chair of this committee. The function of the compensation committee is described in Compensation Discussion and Analysis Role of Compensation Committee.

Table of Contents

Nominating and Corporate Governance Committee

The nominating and corporate governance committee of our board of directors is a standing committee of, and operates under a written charter adopted by, our board of directors. Our nominating and corporate governance committee currently consists of Messrs. Nelson and Hartzler, who serve as the co-chairs of this committee. The functions of this committee include, among other things:

identifying individuals qualified to become members of the board of directors;

recommending director nominees for each annual meeting of shareholders and director nominees to fill any vacancies that may occur between meetings of the shareholders; and

reviewing and updating our corporate governance standards and performing those functions specified therein and in the committee charter.

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.

Code of Ethics and Business Conduct

The board of directors has approved a Code of Ethics and Business Conduct that applies to all of our employees, directors and officers, including its principal executive officer, principal financial officer, principal accounting officer and controller. The Code of Ethics and Business Conduct addresses such topics as protection and proper use of our assets, compliance with applicable laws and regulations, accuracy and preservation of records, accounting and financial reporting, conflicts of interest and insider trading. We plan to make our Code of Ethics and Business Conduct available on our website at www.csi360.com prior to the completion of this offering.

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.

The following table provides summary information concerning the compensation of each non-employee director during the fiscal year ended June 30, 2007.

Name	**Option Awards[(1)(2)]**

Brent G. Blackey[3]	$
John H. Friedman[4]	5,611
Geoffrey O. Hartzler, M.D.[5]	16,540
Roger J. Howe, Ph.D.[5]	16,540
Glen D. Nelson, M.D.[5]	21,148
Gary M. Petrucci[5]	24,810
Christy Wyskiel[4]	5,611

(footnotes on next page)

Table of Contents

(1) The value of options in this table includes (a) the dollar amount we recognized for financial statement reporting purposes in accordance with SFAS No. 123(R) for stock options granted in fiscal year 2007 and (b) the dollar amount that we would have recognized for financial statement reporting purposes in fiscal 2007 under the disclosure provisions of SFAS No. 123 for awards of stock options granted prior to fiscal 2007. For a discussion of valuation assumptions and additional SFAS No. 123(R) disclosures, see Note 5 to our consolidated financial statements regarding stock compensation at page F-16 of this prospectus. The value of options in this table includes the compensation cost for fiscal year 2007 of option awards granted in and prior to fiscal year 2007.

(2) Our stock option agreements provide that in the event of a change of control, the vesting of all options will accelerate and the options will be immediately exercisable as of the effective date of the change of control. Change of control is defined as the sale by the company of substantially all of its assets and the consequent discontinuance of its business, or in the event of a merger, exchange or liquidation of the company.

(3) Mr. Blackey was elected to our board of directors on October 9, 2007.

(4) In connection with their initial election to the board of directors, Mr. Friedman and Ms. Wyskiel were each granted a five-year option to purchase 60,000 shares of our common stock at $5.71 per share on August 15, 2006, such option to vest one-third on each of the first three anniversaries of the date of grant. The options held by Mr. Friedman are held for the benefit of Easton Capital Partners, LP. 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.

(5) As compensation for their continued board service, on December 19, 2006 each of Messrs. Hartzler, Howe, Nelson and Petrucci were granted options to purchase 20,000 shares of our common stock at $5.71 per share. Mr. Petrucci was granted an option to purchase an additional 10,000 shares in connection with his service as chairman of the board.

Table of Contents

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, Chief Financial Officer 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 2007 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 2007.

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 regarding the elements of executive compensation and determines the level of each element, the mix among the elements and total compensation based upon the objectives and philosophies set forth above, and by considering 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.

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. 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.

Table of Contents

Executive Compensation Components for 2007

The principal elements of our executive compensation program for 2007 were:

- base salary;
- annual and quarterly cash incentive compensation;
- equity-based compensation, 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. The 2007 compensation for three of our named executive officers was determined in the context of negotiating the terms under which they would join us as new employees. John Borrell joined us as Vice President of Sales and Marketing in July 2006, Paul Tyska joined us as Vice President of Business Development in August 2006, and David Martin joined us as Chief Executive Officer in February 2007.

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 and stock options.

Our employment agreement with David Martin provides that his annual base salary for calendar 2007 shall 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.

We paid each of John Borrell and Paul Tyska at an annual base salary rate of $200,000 during fiscal 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.

Table of Contents

Each of Michael J. Kallok, James E. Flaherty and Robert Thatcher have served as officers from the dates listed below. Their fiscal 2006 and 2007 base salary rates and the percentage changes from 2006 to 2007 are set forth below.

		Annual Base Salary Rates		
Name	**Start Date**	**Fiscal 2006**	**Fiscal 2007**	**% Change**
James E. Flaherty	3/11/03	$ 148,315	$ 185,000	25%
Michael J. Kallok, Ph.D.	12/1/02	210,000	250,000	19
Robert J. Thatcher	10/17/05	175,000	185,573	6

The increased base salaries for Messrs. Flaherty, Kallok and Thatcher in fiscal 2007 were intended to reflect cost of living adjustments as well as individual performance in the prior year.

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.

Annual /Quarterly 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 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. Payments were made based on the evaluation by our board and compensation committee of a broad range of information relating to these factors rather than the achievement of specific goals. Shortly after Mr. Martin joined us in February 2007 and upon his recommendation, the compensation committee established a bonus program 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 bonus program, the compensation committee sets an annual target bonus amount for each officer expressed as a percentage of that officer s base salary. The percentage assigned to each officer is 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 has delegated to the Chief Executive Officer the authority to set individual quarterly objectives which must be achieved to earn the bonus. We believe that quarterly objectives provide an incentive to maintain the rapid pace of

growth of our business at its current stage. The objectives reflect specific tasks for which the individual executive is responsible that are consistent with our overall fiscal year operating plan established by our board of directors. Because the quarterly objectives were in place for only the second half of fiscal 2007, achievement of the objectives was considered along with the executive s performance in the first half of the year in determining whether the bonus for fiscal 2007 was earned. During fiscal 2008, executives that have achieved their quarterly objectives have the ability to earn 25% of their annual target bonus at the end of each quarter.

Generally, the objectives require 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

Table of Contents

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.

The compensation committee evaluates whether the Chief Executive Officer has earned his annual target bonus amount only at the end of the calendar year based on our overall progress relative to our business plan. The committee did not establish specific objectives for Mr. Martin and will evaluate Mr. Martin s entitlement to his bonus at the end of the calendar year.

The following sets forth for each of our named executive officers the target bonus as a percentage of base salary and total bonus payments for fiscal 2007:

Name	Target Bonus as % of Base Salary	Total 2007 Bonus Payments
David L. Martin	25%	$ 0
James E. Flaherty	40	76,562
Michael J. Kallok, Ph.D.	40	100,000
John Borrell	100	200,000
Paul Tyska	50	83,333
Robert J. Thatcher	40	86,695

Stock Option 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 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. 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.

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.

For named executive officers other than our Chief Executive Officer, 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 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

Table of Contents

individual performance, which is a significant factor in the committee s decisions. We granted options in fiscal 2007 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 2003 Stock Option Plan.

From time to time we may make one-time grants to recognize promotion or consistent long-term contribution, or for specific incentive purposes. We also granted stock options to our named executive officers in connection with their initial employment.

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 grants made to our named executive officers for fiscal 2007 is available in the Summary Compensation Table for Fiscal Year 2007 on page 74, and in the Outstanding Equity Awards at Fiscal Year-end for Fiscal Year 2007 Table on page 76.

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.

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
- following the completion of this offering, 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 2007, 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 2007, the compensation committee met with our Chief Executive Officer to consider and determine executive

Table of Contents

compensation, based on recommendations by our Chief Executive Officer and our third-party compensation consultant.

Summary Compensation Table for Fiscal Year 2007

The following table provides information regarding the compensation earned during the fiscal year ended June 30, 2007 by the two individuals who served as our Chief Executive Officer during fiscal 2007 (including David Martin, our current Chief Executive Officer, and Michael Kallok, our former Chief Executive Officer), our Chief Financial Officer and each of our other three most highly compensated executive officers. We refer to these persons as our named executive officers elsewhere in this prospectus.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards[1] ($)	Non-Equity Incentive Plan Compensation ($)	All Other Compensation ($)	Total ($)
David L. Martin *President, Chief Executive Officer and Interim Chief Financial Officer*[2]	2007	$ 129,573	$ 0	$ 99,108	$ 0	$ 67,000	$ 295,681
James E. Flaherty *Chief Administrative Officer and former Chief Financial Officer*[3]	2007	166,658	39,562	26,179	37,000	0	269,399
Michael J. Kallok, Ph.D. *Chief Scientific Officer and former Chief Executive Officer*	2007	246,923	50,000	49,184	50,000	0	396,107
John Borrell *Vice President of Sales*[4]	2007	196,154	0	19,729	200,000	7,800	423,683
Paul Tyska *Vice President Business Development*[5]	2007	167,692	0	12,774	83,333	6,825	270,624
Robert J. Thatcher *Executive Vice President*	2007	180,287	49,581	48,269	37,114	0	315,251

(1) The value of options in this table includes (a) the dollar amount we recognized for financial statement reporting purposes in accordance with SFAS No. 123(R) for stock options granted in fiscal year 2007 and (b) the dollar amount that we would have recognized for financial statement reporting purposes in fiscal 2007 under the disclosure provisions of SFAS No. 123 for awards of stock options granted prior to fiscal 2007. For a discussion

of valuation assumptions and additional SFAS No. 123(R) disclosures, see Note 5 to our consolidated financial statements regarding stock compensation at page F-16 of this prospectus. The value of options in this table includes the compensation cost for fiscal year 2007 of option awards granted in and prior to fiscal year 2007.

(2) Mr. Martin commenced employment on February 15, 2007 with an annual base salary of $370,000. The amounts under All Other Compensation for Mr. Martin consist of a housing allowance of $6,000 per month, a car allowance of $900 per month and a moving allowance of $40,000.

(3) Effective January 14, 2008, Mr. Flaherty was promoted to serve as our Chief Administrative Officer. Mr. Martin was appointed our Interim Chief Financial Officer pending the appointment of a new Chief Financial Officer.

(4) Mr. Borrell commenced employment on July 1, 2006 with an annual base salary of $200,000 per year. The amounts under All Other Compensation for Mr. Borrell consist of a car allowance of $650 per month.

(5) Mr. Tyska commenced employment on August 23, 2006 with an annual base salary of $200,000 per year. 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 2007

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 2003 Stock Incentive Plan. See Employee Benefit Plans Current Equity Plans 2007 Equity Compensation Plan

Table of Contents

and Employee Benefit Plans Prior Equity Plans 2003 Stock Option 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, 2007. We omitted columns related to non-equity and equity incentive plan awards as none of our named executive officers earned any such awards during fiscal 2007.

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards Target/Maximum	All Other Option Awards: Number of Securities Underlying Options	Exercise or Base Price of Option Awards[1]	Grant Date Fair Market Value of Stock and Option Awards[2]
David L. Martin	7/17/06	$ 92,500	180,000	$ 5.71	$ 437,400
	8/15/06		60,000	5.71	145,800
	2/15/07		540,000	5.71	1,933,200
	6/12/07		140,000	5.11	833,000
James E. Flaherty	12/19/06	80,000	14,500	5.71	40,455
	4/18/07		39,000	5.71	180,570
Michael J. Kallok, Ph.D.	7/17/06	100,000	50,000	5.71	121,500
	12/19/06		100,000	5.71	279,000
John Borrell	7/1/06	200,000	132,000	5.71	320,760
	12/19/06		8,000	5.71	22,320
	4/18/07		34,000	5.71	157,420
Paul Tyska	10/3/06	100,000	140,000	5.71	361,200
Robert J. Thatcher	12/19/06	80,000	12,000	5.71	33,480
	4/18/07		46,000	5.71	212,980

(1) See Note 5 to our consolidated financial statements regarding stock compensation at page F-16 of this prospectus for a discussion of the methodology for determining the exercise price.

(2) Reflects the grant date fair market value of option awards granted in 2007, computed in accordance with SFAS No. 123(R). For a discussion of valuation assumptions, see Note 5 to our consolidated financial statements regarding stock compensation at page F-16 of this prospectus.

Table of Contents

Outstanding Equity Awards at Fiscal Year-end for Fiscal Year 2007

The following table sets forth certain information regarding outstanding equity awards held by our named executive officers as of June 30, 2007.

		Option 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**
David L. Martin[2]	7/17/06	55,000	125,000	$ 5.71	7/16/11
	8/15/06	0	60,000	5.71	8/14/11
	2/15/07	60,000	480,000	5.71	2/14/12
	6/12/07	0	140,000	5.11	6/11/17
James E. Flaherty[3]	2/17/04	20,000	0	6.00	2/16/09
	11/16/04	5,000	2,500	6.00	11/15/09
	7/01/05	8,333	16,667	8.00	6/30/10
	11/08/05	4,000	8,000	8.00	11/7/10
	12/19/06	0	14,500	5.71	12/18/16
	4/18/07	0	39,000	5.71	4/17/17
	3/11/03	40,000	0	5.00	3/10/08
Michael J. Kallok, Ph.D.[3]	6/21/04	25,000	0	6.00	2/16/09
	11/16/04	13,334	6,666	6.00	11/15/09
	11/08/05	16,667	33,333	8.00	11/07/10
	7/17/06	0	50,000	5.71	7/16/11
	12/19/06	0	100,000	5.71	12/18/16
	12/18/02	260,000	0	1.00	12/17/07
John Borrell[3]	7/01/06	0	132,000	5.71	6/30/11
	12/19/06	0	8,000	5.71	12/18/16
	4/18/07	0	34,000	5.71	4/17/17
Paul Tyska[3]	10/03/06	0	140,000	5.71	10/02/11
Robert J. Thatcher[3]	10/17/05	33,333	66,667	8.00	10/16/10
	12/19/06	0	12,000	5.71	12/18/16
	4/18/07	0	46,000	5.71	4/17/17

(1) See Note 5 to our consolidated financial statements regarding stock compensation at page F-16 of this prospectus 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.
(3) All option awards vest at the rate of one-third per year starting on the first anniversary of the grant date.

Option Exercises and Stock Vested for Fiscal Year 2007

During the fiscal year ended June 30, 2007, there were no option exercises by our named executive officers and there was no stock vesting.

Table of Contents

Potential Payments Upon Termination or Change in Control

The majority of our stock option agreements provide that in the event of a change of control, the vesting of all options will accelerate and the options will be immediately exercisable as of the effective date of the change of control. Change of control is defined as the sale by the company of substantially all of its assets and the consequent discontinuance of its business, or in the event of a merger, exchange or liquidation of the company. We estimate the potential value of acceleration of options held by each of our named executive officers to be as follows:

Name	Value of Accelerated Options
David L. Martin	$ 305,000
James E. Flaherty	51,000
Michael J. Kallok, Ph.D.	1,323,000
John Borrell	42,000
Paul Tyska	34,000
Robert J. Thatcher	14,000

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. Kallok, we will pay Mr. 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 Mr. Kallok is terminated by us without cause, or if Mr. Kallok terminates his employment for good reason, as defined in the agreement. Good reason is generally defined as the assignment of job responsibilities to Mr. Kallok that are not comparable in status or responsibility to those job responsibilities set forth in the agreement, a reduction in Mr. Kallok s base salary without his consent, or our failure to provide Mr. Kallok the benefits promised under his employment agreement. As a condition to receiving his severance benefits, Mr. Kallok is required to execute a release of claims agreement in favor of us.

The following table shows as of June 30, 2007 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	$ 370,000	$ 15,000	$ N/A	$ 385,000
Michael J. Kallok, Ph.D.	225,000	15,000	100,000	340,000

Non-Competition Agreements

The employment agreements for David Martin, Michael Kallok, James Flaherty, Paul Koehn, Robert Thatcher and Brian Doughty 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.

Table of Contents

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 that may be issued initially pursuant to stock awards under the 2007 Plan is 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 December 17, 2007, we had 929,917 options outstanding under our 2007 Plan at a weighted average exercise price of $7.78 per share and 204,338 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

Table of Contents

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 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.

Table of Contents

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. Three million eight hundred thousand (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 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 December 17, 2007 there were 3,666,833 options outstanding under the 2003 Plan with a weighted average exercise price of $5.75 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. Seven hundred fifty thousand (750,000) shares of common stock were originally reserved for issuance pursuant

to options granted under the 1991 Plan. With the creation of the 2003 Plan, no additional options were granted under the 1991 Plan. As of December 17, 2007, 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.

Table of Contents

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 December 17, 2007 there were 285,000 such options outstanding with a weighted average exercise price of $3.76 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 2007, we made no contributions to the plan.

Table of Contents

CERTAIN RELATIONSHIPS AND RELATED PARTY 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 prospectus entitled Compensation Discussion and Analysis.

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
Entities affiliated with Maverick Capital, Ltd.[2][3]	108,108	999,999

(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.

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
Entities affiliated with Maverick Capital, Ltd.[2][3]	235,394		2,000,850
Mitsui & Co. Venture Partners II, L.P.[4]	117,647		1,000,000
Robert J. Thatcher	12,000		102,000

(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.

Table of Contents

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 ($)
Entities affiliated with Easton Capital Investment Group[1][2]	1,225,920	174,080	$ 7,000,000
Entities affiliated with 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

(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.

Common Stock Issuances

2005 Private Placement

Between April 15, 2005 and August 25, 2005, we issued an aggregate of 452,500 shares of our common stock at a price per share of $8.00, for an aggregate purchase price of approximately $3.6 million. GDN Holdings, LLC, an entity wholly-owned by Glen Nelson, one of our directors, purchased 12,500 shares of our common stock in the offering for an aggregate purchase price of $100,000. The terms of this purchase were the same as those made available to unaffiliated purchasers.

2004 Private Placement

Between January 12, 2004 and March 2, 2005, we issued an aggregate of 600,504 shares of our common stock at a price per share of $6.00, for an aggregate purchase price of approximately $3.6 million. GDN Holdings, LLC, an entity wholly-owned by Glen Nelson, one of our directors, purchased 16,667 shares of our common stock in the offering for an aggregate purchase price of $100,002. The terms of this purchase were the same as those made available to unaffiliated purchasers.

Investors Rights Agreement

We are a party to an investors rights agreement, which provides that holders of our convertible preferred stock have the right to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. For a more detailed description of these registration rights, see Description of Capital Stock Registration Rights.

Table of Contents

Stockholders Agreement

We are party to a stockholders agreement, which provides that holders of our convertible preferred stock have the right to elect up to two directors to our board of directors, to maintain a pro rata interest in our company through participation in offerings that occur before we become a public company, and to force other parties to the agreement to vote in favor of significant corporate transactions such as a consolidation, merger, sale of substantially all of the assets of our company or sale of more than 50% of our voting capital stock. In addition, the stockholders agreement places certain transfer restrictions upon the holders of our convertible preferred stock. The stockholders agreement will terminate upon the closing of this offering.

Other Transactions

We have granted stock options to our executive officers and certain of our directors. For a description of these options, see Management Grants of Plan-Based Awards Table.

In fiscal year 2005, as compensation for their director services to us, we granted each of Gary Petrucci and Roger Howe warrants to purchase 20,000 shares of our common stock at an exercise price of $6.00 per share. These warrants expire in November 2009.

Policies and Procedures for Related Party Transactions

As provided by our audit committee charter, our audit committee must review and approve in advance any related party transaction. All of our directors, officers and employees are required to report to our audit committee any such related party transaction prior to its completion.

Table of Contents

PRINCIPAL SHAREHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of December 17, 2007 and as adjusted to reflect the sale of the common stock in this offering for:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common 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 15,952,945 shares of common stock outstanding as of December 17, 2007, assuming the conversion of all outstanding shares of our preferred stock as of December 17, 2007, and the issuance of shares of common stock in this offering. The percentage ownership information assumes no exercise of the underwriters over-allotment option.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common 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 issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before February 15, 2008, which is 60 days after December 17, 2007. 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.

Table of Contents

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.

Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned Before Offering[1]	After Offering
Named Executive Officers and Directors			
David L. Martin[2]	296,000	1.9%	
James E. Flaherty[3]	102,499	*	
Michael J. Kallok, Ph.D.[4]	133,834	*	
John Borrell[5]	81,431	*	
Brian Doughty[6]	28,233	*	
Paul Tyska[7]	56,666	*	
Paul Koehn[8]	3,784	*	
Robert J. Thatcher[9]	82,666	*	
John H. Friedman[10]	50,000	*	
Geoffrey O. Hartzler, M.D.[11]	325,663	2.0%	
Roger J. Howe, Ph.D.[12]	139,500	*	
Brent G. Blackey[13]	10,900	*	
Glen D. Nelson, M.D.[14]	532,135	3.3%	
Gary M. Petrucci[15]	548,329	3.4%	
Christy Wyskiel[16]	50,000	*	
All Directors and Executive Officers as a Group (14 individuals)	2,441,640	15.3%	
5% Shareholders			
Entities affiliated with Easton Capital Investment Group[17]	1,450,000	9.1%	
Entities affiliated with Maverick Capital, Ltd.[18]	2,393,501	15.0%	
Mitsui & Co. Venture Partners II, L.P.[19]	888,666	5.6%	

* Less than 1% of the outstanding shares.

(1) Based on 15,952,945 shares of common stock outstanding as of December 17, 2007, assuming the conversion of all outstanding shares of our preferred stock into common stock. Unless otherwise indicated, each person or entity listed has sole investment and voting power with respect to the shares listed.

(2) Consists of 76,000 shares of our common stock and options to acquire a total of 220,000 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Mr. Martin.

(3) Consists of 45,000 shares of our common stock and options to acquire a total of 56,999 shares and warrants to acquire a total of 500 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Mr. Flaherty.

(4) Consists of 5,000 shares of our common stock and options to acquire a total of 128,334 shares and warrants to acquire a total of 500 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Dr. Kallok.

(5)

Consists of 34,764 shares of our common stock and options to acquire a total of 46,667 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Mr. Borrell.

(6) Consists of 4,900 shares of our common stock and options to acquire a total of 23,333 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Mr. Doughty.

(7) Consists of 10,000 shares of our common stock held by Mr. Tyska and options to acquire a total of 46,666 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Mr. Tyska.

(8) Consists of 3,784 shares of our common stock held by Mr. Koehn.

(9) Consists of 12,000 shares of our common stock held by Mr. Thatcher and options to acquire a total of 70,666 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Mr. Thatcher.

(footnotes on next page)

Table of Contents

(10) Consists of options to acquire a total of 50,000 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Mr. Friedman. These options are held for the benefit of entities affiliated with Easton Capital Investment Group.

(11) Consists of 177,063 shares of our common stock and options to acquire a total of 145,000 shares and warrants to acquire a total of 3,600 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 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 December 17, 2007 held by Sonora Web LLLP , of which Dr. Howe is the general partner, and options to acquire a total of 85,000 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Dr. Howe.

(13) Consists of 10,900 shares of our common stock held by Mr. Blackey.

(14) Consists of (i) 376,483 shares of our common stock and warrants to acquire a total of 20,652 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 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 December 17, 2007 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) 351,949 shares of our common stock, options to acquire a total of 110,000 shares and warrants to acquire a total of 36,380 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Mr. Petrucci.

(16) Consists of options to acquire a total of 50,000 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 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 612,960 shares of our common stock held and 87,040 shares which may be purchased by Easton Hunt Capital Partners, L.P. upon exercise of currently exercisable warrants, 612,960 shares of our common stock held and 87,040 shares which may be purchased by Easton Capital Partners, LP upon exercise of currently exercisable warrants, and options to acquire a total of 50,000 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 held by Mr. Friedman, one of our directors. Mr. Friedman disclaims any beneficial ownership of the shares held by entities affiliated with Easton Capital Investment Group. The address for the entities affiliated with Easton Capital Investment Group is 767 Third Avenue, 7th Floor, New York, NY 10017.

(18) Consists of 921,281 shares of our common stock held and 109,370 shares which may be purchased by Maverick Fund, L.D.C. upon exercise of currently exercisable warrants, 371,942 shares of our common stock held and 44,155 shares which may be purchased by Maverick Fund USA, Ltd. upon exercise of currently exercisable warrants, 801,592 shares of our common stock held and 95,161 shares which may be purchased by Maverick Fund II, Ltd. upon exercise of currently exercisable warrants, and options to acquire a total of 50,000 shares of our common stock currently exercisable or exercisable within 60 days after December 17, 2007 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, has 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, TX 75201.

(19) Consists of 792,795 shares of our common stock held and 95,871 shares which may be purchased by Mitsui & Co. Venture Partners II, L.P. upon exercise of currently exercisable warrants. The address of Mitsui & Co. Venture Partners II, L.P. is 200 Park Avenue, New York, NY 10166.

Table of Contents

DESCRIPTION OF CAPITAL STOCK

Upon the closing of this offering, our authorized capital stock will consist of 70,000,000 shares of common stock, no par value per share, 5,400,000 shares of Series A convertible preferred stock, 2,188,425 shares of Series A-1 convertible preferred stock and 2,162,162 shares of Series B convertible preferred stock.

The following summarizes important provisions of our capital stock and describes all material provisions of our articles of incorporation and bylaws, as amended. This summary is qualified by our articles of incorporation and bylaws, copies of which have been filed as exhibits to the registration statement of which this prospectus is a part, and by the provisions of applicable law.

Common Stock

Outstanding Shares. As of December 17, 2007, there were 15,952,945 shares of common stock outstanding held of record by 720 shareholders, assuming conversion of all shares of preferred stock into 9,088,136 shares of common stock upon the completion of this offering. After giving effect to the sale of common stock offered in this offering, there will be shares of common stock outstanding.

Dividend Rights. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from out of legally available funds at the times and the amounts as our board of directors may from time to time determine.

Voting Rights. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the shareholders, including the election of directors. Our articles of incorporation and bylaws do not provide for cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

No Preemptive or Similar Rights. The common stock is not entitled to preemptive rights and is not subject to conversion or redemption.

Right to Receive Liquidation Distributions. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to shareholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Preferred Stock

Upon the closing of this offering, all previously outstanding shares of preferred stock will convert into shares of common stock.

Under our amended and restated articles of incorporation, our board of directors has the authority, without further action by the shareholders, to issue up to 5,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any series, but not below the number of shares of the series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Table of Contents

Options

As of December 17, 2007, we had outstanding options to purchase an aggregate of 48,611 shares of our common stock at a weighted average exercise price of $12.00 per share under our 1991 Stock Option Plan, outstanding options to purchase an aggregate of 3,666,833 shares of our common stock at a weighted average exercise price of $5.75 per share under our 2003 Stock Option Plan, outstanding options to purchase an aggregate of 929,917 shares of our common stock at a weighted average exercise price of $7.78 per share under our 2007 Equity Incentive Plan, and outstanding options to purchase an aggregate of 285,000 shares of our common stock at a weighted average exercise price of $3.76 per share issued outside of our equity incentive plans. All outstanding options provide for anti-dilution adjustments in the event of a merger, consolidation, reorganization, recapitalization, stock dividend, stock split or other similar change in our corporate structure. We have reserved 1,865,745 shares for issuance under our 2007 Equity Incentive Plan.

Warrants

As of December 17, 2007, we had outstanding warrants to purchase a total of:

372,974 shares of our common stock at a weighted average exercise price of $5.12 per share. These warrants are currently exercisable through July 2013.

662,439 shares of our Series A convertible preferred stock at an exercise price of $5.71 per share. These warrants are currently exercisable through March 2008. Upon the conversion of the preferred stock and the closing of this offering, the Series A warrants will automatically become exercisable for up to 662,439 shares of our common stock.

We issued the common stock warrants in connection with various private offerings of our securities and to certain of our directors and business advisors as compensation for their services. We issued the Series A warrants in connection with a private placement of our Series A convertible preferred stock in 2006. Each warrant has a net exercise provision under which the holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares of, respectively, common stock or Series A convertible preferred stock based on the fair market value of the stock at the time of exercise of the warrant after deduction of the aggregate exercise price. The Series A warrants and a majority of the common stock warrants provide for anti-dilution adjustments in the event of a merger, consolidation, reorganization, recapitalization, stock dividend, stock split or other similar change in our corporate structure.

Registration Rights

The holders of 9,088,136 shares of common stock, assuming the conversion of our preferred stock, have entered into an Investors Rights Agreement with us that provides certain registration rights to such holders and certain future transferees of their securities.

Demand Rights. At any time after the earlier of July 19, 2010 or six months after our initial public offering, the holders of a majority of the preferred stock (including for this purpose all shares of common stock issued upon conversion of any preferred stock) including the preferred stock held by entities affiliated with Easton Capital Investment Group and Maverick Capital, Ltd., may demand that we file a registration statement on up to three occasions, covering all or a portion of the common stock underlying the preferred stock.

Piggyback Rights. Holders of the preferred stock are also entitled to piggyback registration rights that entitle them to participate in any registration undertaken by us (except registrations for business combinations or employee benefit

plans) subject to the right of an underwriter to cut back participation pro rata if the number of shares is deemed excessive. The piggyback registration rights are not applicable in the event of our initial public offering, and thus do not apply to this offering.

Shelf Registration Rights. In addition, if we become a publicly traded company and have been filing reports with the Securities and Exchange Commission for at least 12 months, the holders of the preferred stock may demand that we file a registration statement on Form S-3, provided that at least $1 million of stock is included in the registration.

Table of Contents

Potential Anti-Takeover Effects of Certain Provisions of Minnesota State Law and Our Articles of Incorporation and Bylaws

Minnesota State Law

Certain provisions of Minnesota law described below could have an anti-takeover effect. These provisions are intended to provide management flexibility, to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by our board of directors and to discourage an unsolicited takeover if our board of directors determines that such a takeover is not in our best interests or the best interests of our shareholders. However, these provisions could have the effect of discouraging certain attempts to acquire us that could deprive our shareholders of opportunities to sell their shares of our stock at higher values.

Section 302A.671 of the Minnesota Statutes applies, with certain exceptions, to any acquisitions of our stock (from a person other than us, and other than in connection with certain mergers and exchanges to which we are a party) resulting in the beneficial ownership of 20% or more of the voting stock then outstanding. Section 302A.671 requires approval of any such acquisition 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 has failed to give a timely information statement to us or the date the 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, or any of our subsidiaries, with an interested shareholder, which means 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.

Articles of Incorporation and Bylaws

Our articles of incorporation and bylaws include provisions that may have the effect of discouraging, delaying or preventing a change in control or an unsolicited acquisition proposal that a shareholder might consider favorable, including a proposal that might result in the payment of a premium over the market price for the shares held by shareholders. First, our board of directors can issue up to 5,000,000 shares of preferred stock, with any rights or preferences, including the right to approve or not approve an acquisition or other change in control. Second, our amended and restated articles of incorporation do not provide for shareholder actions to be effected by written consent. Third, our bylaws provide that shareholders seeking to present proposals before a meeting of shareholders or to nominate candidates for election as directors at a meeting of shareholders must provide timely notice in writing. Our bylaws also specify requirements as to the form and content of a shareholder s notice. These provisions may delay or preclude shareholders from bringing matters before a meeting of shareholders or from making nominations for directors at a meeting of shareholders, which could delay or deter takeover attempts or changes in management. Fourth, our amended and restated articles of incorporation do not provide for cumulative voting for our directors. The absence of cumulative voting may make it more difficult for shareholders owning less than a majority of our stock to elect any directors to our board.

Limitation of Liability and Indemnification of Directors and Officers

Section 302A.521 of the Minnesota Business Corporation Act requires that we indemnify our current and former officers, directors, employees and agents against expenses (including attorneys fees), judgments, penalties, fines and amounts paid in settlement which, in each case, were incurred in connection with actions, suits or proceedings in which such person is a party by reason of the fact that he or she was an officer, director, employee or agent of the

corporation, if such person, (i) has not been indemnified by another organization or employee benefit plan for the same judgments, penalties, fines, including without limitation, excise taxes assessed against the person with respect to an employee benefit plan, settlements and reasonable expenses, including attorneys fees and disbursements, incurred by the person in connection with the proceeding with respect to the same acts or omissions, (ii) acted in good faith, (iii) received no improper personal benefit and statutory procedure has been followed in the case of any conflict of interest by a director, (iv) in the case of any criminal proceedings, had no reasonable cause to believe the conduct was unlawful, and (v) in the case of acts or omissions occurring in the person s performance in

Table of Contents

the official capacity of director or, for a person not a director, in the official capacity of officer, committee member, employee or agent, reasonably believed that the conduct was in the best interests of the corporation, or, in the case of performance by a director, officer, employee or agent of the corporation as a director, officer, partner, trustee, employee or agent of another organization or employee benefit plan, reasonably believed that the conduct was not opposed to the best interests of the corporation. Section 302A.521 requires us to advance, in certain circumstances and upon written request, reasonable expenses prior to final disposition. Section 302A.521 also permits us to purchase and maintain insurance on behalf of our officers, directors, employees and agents against any liability which may be asserted against, or incurred by, such persons in their capacities as officers, directors, employees and agents of the corporation, whether or not we would have been required to indemnify the person against the liability under the provisions of such section.

Our amended and restated articles of incorporation limit personal liability for breach of the fiduciary duty of our directors to the fullest extent provided by the Minnesota Business Corporation Act. Our articles of incorporation eliminate the personal liability of directors for damages occasioned by breach of fiduciary duty, except for liability based on (i) the director s duty of loyalty to us, (ii) acts or omissions not made in good faith, (iii) acts or omissions involving intentional misconduct, (iv) payments of improper dividends, (v) violations of state securities laws and (vi) acts occurring prior to the date such provision establishing limited personal liability was added to our articles. Any amendment to or repeal of such provision shall not adversely affect any right or protection of a director of ours for or with respect to any acts or omissions of such director occurring prior to such amendment or repeal. Our amended and restated bylaws provide that each director and officer, past or present, and each person who serves or may have served at our request as a director, officer, employee or agent of another corporation or employee benefit plan and their respective heirs, administrators and executors, will be indemnified by us to such extent as permitted by Minnesota Statutes, Section 302A.521, as now enacted or hereafter amended.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Nasdaq Global Market Listing

We intend to apply for listing of our common stock on the Nasdaq Global Market under the symbol CSII.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is .

Table of Contents

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there was no public market for our common stock. We cannot predict the effect, if any, that market sales of shares of our common stock or the availability of shares of our common stock for sale will have on the market price of our common stock. Sales of substantial amounts of our common stock in the public market could adversely affect the market prices of our common stock and could impair our future ability to raise capital through the sale of our equity securities.

Upon completion of this offering, based on our outstanding shares as of , 2008, and assuming no exercise of outstanding options or warrants, we will have outstanding an aggregate of shares of our common stock (shares if the underwriters over-allotment option is exercised in full). Of these shares, all of the shares sold in this offering (plus any shares sold as a result of the underwriters exercise of the over-allotment option) will be freely tradable without restriction or further registration under the Securities Act, unless those shares are purchased by our affiliates, as that term is defined in Rule 144 under the Securities Act.

The remaining shares of common stock to be outstanding after this offering will be restricted as a result of securities laws or lock-up agreements. Of these restricted securities, shares will be subject to transfer restrictions for 180 days from the date of this prospectus pursuant to the lock-up agreements. Upon expiration of the 180-day transfer restriction period, as extended, shares will be eligible for unlimited resale under Rule 144 and shares will be eligible for resale under Rule 144, subject to volume limitations. Restricted securities may be sold in the public market only if they have been registered or if they qualify for an exemption from registration under Rule 144 or 701 under the Securities Act.

Rule 144

In general, under Rule 144 as currently in effect, a person who has beneficially owned shares of our common stock that are deemed restricted securities for at least one year would be entitled to sell, within any three-month period a number of shares that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to that sale.

These sales may commence beginning 90 days after the date of this prospectus, subject to continued availability of current public information about us. Such sales under Rule 144 are also subject to certain manner of sale provisions and notice requirements.

A person who is not one of our affiliates and who is not deemed to have been one of our affiliates at any time during the three months preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years, including the holding period of any prior owner other than an affiliate, is entitled to sell those shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

The SEC recently adopted amendments to Rule 144, which will become effective on February 15, 2008. Under these amendments, the holding period for a person who is not one of our affiliates and who is not deemed to have been one of our affiliates at any time during the three months preceding a sale has been shortened from one year to six months, subject to the continued availability of current public information about us (which requirement is eliminated after a

one-year holding period).

The amendments also permit resales by affiliates after a six month holding period, subject to compliance with the volume limitations described above, notice of sale, and the continued availability of current public information about us.

Rule 701

Rule 701 generally allows a shareholder who purchased shares of our common stock pursuant to a written compensatory plan or written agreement relating to compensation and who is not deemed to have been an affiliate of

Table of Contents

our company to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits our affiliates to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. However, substantially all of the shares issued pursuant to Rule 701 are subject to the lock-up agreements described below under the heading Underwriting and will only become eligible for sale upon the expiration or waiver of those agreements.

Lock-up Agreements

We, all of our officers, directors and substantially all of our shareholders and option holders have agreed, subject to limited exceptions, not to offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly any shares of our common stock or enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock held prior to the offering during the period beginning on the date of this prospectus and ending 180 days thereafter, whether any such transaction is to be settled by delivery of our common stock or such other securities, cash or otherwise, without the prior written consent of Morgan Stanley & Co. Incorporated and Citigroup Global Markets Inc.

Morgan Stanley & Co. Incorporated and Citigroup Global Markets Inc. may in their sole discretion choose to release any or all of these shares from these restrictions prior to the expiration of the 180-day period. The lock-up restrictions will not apply to certain transfers not involving a disposition for value, provided that the recipient agrees to be bound by these lock-up restrictions and provided that such transfers are not required to be reported in any public report or filing with the SEC, or otherwise, during the lock-up period.

The 180-day restricted period described above will be extended if:

- during the last 17 days of the 180-day restricted period, we issue an earnings release or disclose material news or a material event relating to our company occurs; or

- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period;

in which case the restrictions described above will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release, the disclosure of the material news or the occurrence of the material event.

Registration Rights

The holders of 9,088,136 shares of common stock, assuming the conversion of our preferred stock, have entered into an Investor s Rights Agreement with us that provides certain registration rights to such holders and certain future transferees of their securities. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares held by affiliates. See Description of Capital Stock Registration Rights.

Equity Incentive Plans

We intend to file registration statements under the Securities Act as promptly as possible after the effective date of this offering to register shares to be issued pursuant to our employee benefit plans. As a result, any options or rights

exercised under our 2003 Stock Option Plan and 2007 Equity Incentive Plan or any other benefit plan after the effectiveness of the registration statements will also be freely tradable in the public market, subject to the lock-up agreements discussed above. However, such shares held by affiliates will still be subject to the volume limitation, manner of sale, notice and public information requirements of Rule 144 and the 180-day lock-up arrangement described above, if applicable.

Table of Contents

MATERIAL U.S. FEDERAL INCOME AND ESTATE TAX CONSEQUENCES TO NON-U.S. HOLDERS

This section summarizes certain material U.S. federal income and estate tax considerations relating to the ownership and disposition of our common stock. This summary does not provide a complete analysis of all potential tax considerations. The information provided below is based on provisions of the Internal Revenue Code of 1986, as amended, or the Code, and final, temporary and proposed Regulations, administrative pronouncements and judicial decisions as of the date of this prospectus. These authorities may change, possibly with retroactive effect, or the Internal Revenue Service, or IRS, might interpret the existing authorities differently. Consequently, the tax considerations of owning or disposing of our common stock could differ from those described below. For purposes of this summary, a non-U.S. holder is any holder that is not, for U.S. federal income tax purposes, any of the following:

an individual citizen or resident of the United States;

a corporation organized under the laws of the United States or any state;

a trust that is (i) subject to the primary supervision of a U.S. court and the control of one or more U.S. persons or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person; or

an estate the income of which is subject to U.S. federal income taxation regardless of source.

If a partnership or other flow-through entity is the owner of our common stock, the tax treatment of a partner in the partnership or an owner of the entity will depend upon the status of the partner or other owner and the activities of the partnership or other entity. Accordingly, partnerships and flow-through entities that hold our common stock and partners or owners of such partnerships or entities, as applicable, should consult their own tax advisors.

This summary does not represent a detailed description of the U.S. federal income and estate tax consequences applicable to you if you are subject to special treatment under the U.S. federal income tax laws (including if you are a U.S. expatriate, controlled foreign corporation, passive foreign investment company, bank, insurance company or other financial institution, dealer or trader in securities, a person who holds our common stock as a position in a hedging transaction, straddle or conversion transaction, or other person subject to special tax treatment). We cannot assure you that a change in law will not alter significantly the tax considerations that we describe in this summary. Finally, this summary does not describe the effects of any applicable foreign, state, or local laws.

INVESTORS CONSIDERING THE PURCHASE OF OUR COMMON STOCK SHOULD CONSULT THEIR OWN TAX ADVISORS REGARDING THE APPLICATION OF THE U.S. FEDERAL INCOME AND ESTATE TAX LAWS TO THEIR PARTICULAR SITUATIONS AND THE TAX CONSEQUENCES OF FOREIGN, STATE OR LOCAL LAWS AND TAX TREATIES.

Dividends

As discussed under Dividend Policy above, we do not currently expect to pay dividends. In the event that we do pay dividends, dividends paid to a non-U.S. holder in respect of our common stock generally will be subject to U.S. withholding tax at a 30% rate. The withholding tax might apply at a reduced rate under the terms of an applicable income tax treaty between the United States and the non-U.S. holder s country of residence. A non-U.S. holder must demonstrate its entitlement to treaty benefits by certifying its nonresident status. A non-U.S. holder can meet this certification requirement by providing a Form W-8BEN or other applicable form to us or our paying agent. If the

non-U.S. holder holds the stock through a financial institution or other agent acting on the holder s behalf, the holder will be required to provide appropriate documentation to the agent. The holder s agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. For payments made to a foreign partnership or other flow-through entity, the certification requirements generally apply to the partners or other owners rather than to the partnership or other entity, and the partnership or other entity must provide the partners or other owners documentation to us or our paying agent. Special rules, described below, apply if a dividend is effectively connected with a U.S. trade or business conducted

Table of Contents

by the non-U.S. holder. A non-U.S. holder eligible for a reduced rate of U.S. withholding tax pursuant to an income tax treaty generally may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS.

Sale of Common Stock

Non-U.S. holders generally will not be subject to U.S. federal income tax on any gains realized on the sale, exchange, or other disposition of our common stock. This general rule, however, is subject to several exceptions. For example, the gain would be subject to U.S. federal income tax if:

- the gain is effectively connected with the conduct by the non-U.S. holder of a U.S. trade or business or, if a treaty applies, is attributable to a permanent establishment of the non-U.S. holder in the United States, in which case the special rules described below apply;

- the non-U.S. holder is an individual who holds our common stock as a capital asset and who is present in the United States for 183 days or more in the taxable year of the sale, exchange, or other disposition, and certain other requirements are met; or

- the rules of the Foreign Investment in Real Property Tax Act, or FIRPTA (described below), treat the gain as effectively connected with a U.S. trade or business.

An individual non-U.S. holder described in the second bullet point immediately above will be subject to a flat 30% tax on the gain derived from the sale, which may be offset by United States source capital losses, even though the individual is not considered a resident of the United States.

The FIRPTA rules may apply to a sale, exchange or other disposition of our common stock if we are, or were at any time during the five years before the sale, exchange or disposition, a U.S. real property holding corporation, or USRPHC. In general, we would be a USRPHC if interests in U.S. real estate comprised most of our assets. We believe that we are not a USRPHC, and do not anticipate becoming one in the future. Even if we become a USRPHC, if our common stock is regularly traded on an established securities market, our common stock will be treated as United States real property interests only if the non-U.S. holder actually or constructively holds or has held more than 5% of our common stock.

Dividends or Gain Effectively Connected With a U.S. Trade or Business

If any dividend on our common stock, or gain from the sale, exchange or other disposition of our common stock, is effectively connected with a U.S. trade or business conducted by the non-U.S. holder, then the dividend or gain will be subject to U.S. federal income tax at the regular graduated U.S. federal income tax rates (including, for individuals, the rates applicable to capital gains). If the non-U.S. holder is eligible for the benefits of a tax treaty between the United States and the holder s country of residence, any effectively connected dividend or gain would generally be subject to U.S. federal income tax only if it is also attributable to a permanent establishment or fixed base maintained by the holder in the United States. Payments of dividends that are effectively connected with a U.S. trade or business will not be subject to the 30% withholding tax, provided that the holder certifies its qualification, on Form W-8ECI. If the non-U.S. holder is a corporation, that portion of its earnings and profits that is effectively connected with its U.S. trade or business would generally be subject to a branch profits tax. The branch profits tax rate is generally 30%, although an applicable income tax treaty might provide for a lower rate.

U.S. Federal Estate Tax

The estates of nonresident alien individuals generally are subject to U.S. federal estate tax on property with a U.S. situs. Because we are a U.S. corporation, our common stock will be U.S. situs property and therefore will be included in the taxable estate of a nonresident alien decedent. The U.S. federal estate tax liability of the estate of a nonresident alien may be affected by a tax treaty between the United States and the decedent s country of residence.

Table of Contents

Backup Withholding and Information Reporting

The Code and the Treasury regulations require those who make specified payments to report the payments to the IRS. Among the specified payments are dividends and proceeds paid by brokers to their customers. The required information returns enable the IRS to determine whether the recipient properly included the payments in income. This reporting regime is reinforced by backup withholding rules. These rules require the payers to withhold tax from payments subject to information reporting if the recipient fails to provide its taxpayer identification number to the payer, furnishes an incorrect identification number, or repeatedly fails to report interest or dividends on its returns. The withholding tax rate is currently 28%. The backup withholding rules do not apply to payments to corporations, whether domestic or foreign.

Payments to non-U.S. holders of dividends on our common stock will generally not be subject to backup withholding, and payments of proceeds made to non-U.S. holders by a broker upon a sale of our common stock will not be subject to information reporting or backup withholding, in each case so long as the non-U.S. holder certifies its nonresident status and the payer does not have actual knowledge or reason to know that such holder is a U.S. person as defined under the Code or such holder otherwise establishes an exemption. A non-U.S. holder may comply with the certification procedures by providing a Form W-8BEN or other applicable form to us or our paying agent, as described under Material U.S. Federal Income and Estate Tax Consequences to Non-U.S. Holders Dividends. We must report annually to the IRS any dividends paid to each non-U.S. holder and the tax withheld, if any, with respect to such dividends. Copies of these reports may be made available to tax authorities in the country where the non-U.S. holder resides.

Any amounts withheld from a payment to a holder of our common stock under the backup withholding rules generally may be credited against any U.S. federal income tax liability of the holder and may entitle the holder to a refund, provided that the required information is furnished to the IRS.

THE PRECEDING DISCUSSION OF U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE PARTICULAR U.S. FEDERAL, STATE, LOCAL AND FOREIGN TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

Table of Contents

UNDERWRITING

Morgan Stanley & Co. Incorporated and Citigroup Global Markets Inc. are acting as joint book-running managers of this offering and, together with William Blair & Company, L.L.C. are acting as the managing underwriters of this offering. Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. Incorporated and Citigroup Global Markets Inc. are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, the number of shares of common stock indicated in the table below:

Underwriter	Number of Shares
Morgan Stanley & Co. Incorporated	
Citigroup Global Markets Inc.	
William Blair & Company, L.L.C.	
Total	

The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions, and part to certain dealers at a price that represents a concession not in excess of $ a share under the public offering price. No underwriter may allow, and no dealer may re-allow, any concession to other underwriters or to certain dealers. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

At our request, the underwriters have reserved up to 5% of the shares of common stock offered by this prospectus for sale, at the initial public offering price, to our directors, officers, employees, business associates and related persons. The number of shares of common stock available for sale to the general public will be reduced to the extent these individuals purchase such reserved shares. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares offered by this prospectus.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of additional shares of common stock at the public offering price, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares of common stock as the number listed next to the underwriter s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table. If the underwriters over-allotment option is exercised in full, the total price to the public would be $, the total underwriters discounts and commissions would be $ and the total proceeds to us would be $.

The following table shows the per share and total underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters option.

	No Exercise	Full Exercise
Per share paid by us	$	$
Total		

Table of Contents

In addition, we estimate that the expenses of this offering other than underwriting discounts and commissions payable by us will be approximately $.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

We, all of our directors and officers and holders of substantially all of our outstanding shareholders and holders of securities exercisable for or convertible into shares of our common stock have agreed that, without the prior written consent of Morgan Stanley & Co. Incorporated and Citigroup Global Markets Inc., on behalf of the underwriters, we and they will not, during the period beginning on the date of this prospectus and ending 180 days thereafter:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or

- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise.

The restrictions described in this paragraph do not apply to:

- the sale by us of shares to the underwriters in connection with the offering;

- the issuance by us of shares of common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing;

- the establishment of a trading plan pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, provided that the plan does not provide for the transfer of common stock during the restricted period; or

- the transfer of shares of common stock or any security convertible into shares of common stock as a bona fide gift, as a distribution to general or limited partners, shareholders, members or wholly-owned subsidiaries of our shareholders, or by will or intestate succession.

With respect to the last bullet, it shall be a condition to the transfer or distribution that the transferee execute a copy of the lock-up agreement, that no filing by any donee or transferee under Section 16(a) of the Securities Exchange Act of 1934, as amended, shall be required or shall be made voluntarily in connection with such transfer or distribution.

The 180-day restricted period described in the preceding paragraph will be extended if:

- during the last 17 days of the 180-day restricted period we issue a release regarding earnings or regarding material news or events relating to us; or

- prior to the expiration of the 180-day restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 180-day restricted period,

in which case the restrictions described in the preceding paragraph will continue to apply until the expiration of the 18-day period beginning on the issuance of the release or the occurrence of the material news or material event.

Morgan Stanley & Co. Incorporated and Citigroup Global Markets Inc. may in their sole discretion choose to release any or all of these shares from these restrictions prior to the expiration of the 180-day period. The lock-up restrictions will not apply to certain transfers not involving a disposition for value, provided that the recipient agrees to be bound by these lock-up restrictions and provided that such transfers are not required to be reported in any public report or filing with the SEC, or otherwise, during the lock-up period.

Table of Contents

In order to facilitate this offering of common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or by purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. In addition, to stabilize the price of the common stock, the underwriters may bid for and purchase shares of common stock in the open market. Finally, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the common stock in the offering, if the syndicate repurchases previously distributed common stock to cover syndicate short positions or to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

The underwriters may in the future provide investment banking services to us for which they would receive customary compensation.

We have applied to have our common stock approved for quotation on the Nasdaq Global Market under the symbol CSII.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), from and including the date on which the Prospectus Directive is implemented in that Member State, each underwriter has represented and agreed that it has not made and will not make an offer to the public of any shares of common stock in that Relevant Member State, except that it may, with effect from and including such date, make an offer to the public of shares of common stock in that Relevant Member State at any time under the following exemptions under the Prospectus Directive:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than 43,000,000 and (3) an annual net turnover of more than 50,000,000, as shown in its last annual or consolidated accounts; or
- in any other circumstances which do not require the publication by us of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of the above, the expression an offer to the public in relation to any shares of common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the

terms of the offer and the shares of common stock to be offered so as to enable an investor to decide to purchase or subscribe the shares of common stock, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression Prospectus Directive means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

Table of Contents

United Kingdom

Each underwriter has represented and agreed that it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000) in connection with the issue or sale of the common stock in circumstances in which Section 21(1) of such Act does not apply to us and it has complied and will comply with all applicable provisions of such Act with respect to anything done by it in relation to any shares of common stock in, from or otherwise involving the United Kingdom.

Pricing of the Offering

Prior to this offering, there has been no public market for the shares of common stock. The initial public offering price will be determined by negotiations between us and the representatives of the underwriters. Among the factors to be considered in determining the initial public offering price will be our future prospects and those of our industry in general; sales, earnings and other financial operating information in recent periods; and the price-earnings ratios, price-sales ratios and market prices of securities and certain financial and operating information of companies engaged in activities similar to ours. The estimated initial public offering price range set forth on the cover page of this preliminary prospectus is subject to change as a result of market conditions and other factors. An active trading market for the shares may not develop, and it is possible that after the offering the shares will not trade in the market above their initial offering price.

A prospectus in electronic format may be made available on the web sites maintained by one or more of the underwriters, and one or more of the underwriters may distribute prospectuses electronically. The underwriters may agree to allocate a number of shares to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters that make Internet distributions on the same basis as other allocations.

Table of Contents

LEGAL MATTERS

The validity of the shares of common stock offered hereby and certain other legal matters will be passed upon for us by Fredrikson & Byron, P.A., Minneapolis, Minnesota. Attorneys at Fredrikson & Byron hold an aggregate of 8,441 shares of our common stock. The underwriters have been represented in connection with this offering by Davis Polk & Wardwell, Menlo Park, California.

EXPERTS

The consolidated financial statements as of June 30, 2006 and 2007 and for each of the three years in the period ended June 30, 2007 included in this prospectus have been so included in reliance on the report of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information included in the registration statement or the exhibits and schedules filed therewith. For further information pertaining to us and the common stock to be sold in this offering, you should refer to the registration statement and its exhibits and schedules. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document filed as an exhibit to the registration statement or such other document, each such statement being qualified in all respects by such reference. On the closing of this offering, we will be subject to the informational requirements of the Securities Exchange Act of 1934 and will be required to file annual, quarterly and current reports, proxy statements and other information with the SEC. We anticipate making these documents publicly available, free of charge, on our website at www.csi360.com as soon as reasonably practicable after filing such documents with the SEC. The information contained in, or that can be accessed through, our website is not part of this prospectus.

You can read the registration statement and our future filings with the SEC over the Internet at the SEC s website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facility at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

Cardiovascular Systems, Inc.

Index

Table of Contents

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of
Cardiovascular Systems, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, changes in shareholders (deficiency) equity and comprehensive (loss) income and cash flows present fairly, in all material respects, the financial position of Cardiovascular Systems, Inc. (the Company) at June 30, 2006 and 2007, and the results of its operations and its cash flows for each of the three years in the period ended June 30, 2007, in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for stock-based compensation effective July 1, 2006.

/s/ PricewaterhouseCoopers LLP
Minneapolis, Minnesota
January 22, 2008

Table of Contents

Cardiovascular Systems, Inc.

Consolidated Balance Sheets
(Dollars in thousands, except per share and share amounts)

	June 30, 2006	June 30, 2007	September 30, 2007 (unaudited)	Pro Forma September 30, 2007 (unaudited see note 1)
ASSETS				
Current assets				
Cash and cash equivalents	$ 1,554	$ 7,908	$ 3,265	$ 3,265
Short-term investments		11,615	18,499	18,499
Accounts receivable, net			1,395	1,395
Inventories	728	1,050	2,572	2,572
Prepaid expenses	142	255	242	242
Total current assets	2,424	20,828	25,973	25,973
Property and equipment, net	273	585	745	745
Patents, net	599	612	598	598
Total assets	$ 3,296	$ 22,025	$ 27,316	$ 27,316
LIABILITIES AND SHAREHOLDERS (DEFICIENCY) EQUITY				
Current liabilities				
Accounts payable	$ 200	$ 1,909	$ 1,479	$ 1,479
Accrued expenses	357	748	1,371	1,371
Deferred revenue			1,428	1,428
Convertible promissory notes	3,107			
Total current liabilities	3,664	2,657	4,278	4,278
Long-term liabilities				
Redeemable convertible preferred stock warrants		3,094	3,394	
Deferred rent	59	79	88	88
Total long-term liabilities	59	3,173	3,482	88
Total liabilities	3,723	5,830	7,760	