CARDIOVASCULAR SYSTEMS INC
Form S-1/A
March 20, 2008

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As filed with the Securities and Exchange Commission on March 20, 2008
Registration No. 333-148798

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

AMENDMENT NO. 1 TO
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:

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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

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

Large accelerated filer o	Accelerated filer o	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company o

CALCULATION OF REGISTRATION FEE

Title of Each Class of	**Proposed Maximum Aggregate**	**Amount of Registration**

Securities to be Registered	Offering Price[1][2]	Fee[3]
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.
(3) Previously paid.

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.

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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 March 20, 2008

Shares

Cardiovascular Systems, Inc.

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 8.

	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

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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.

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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.

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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 8 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. This limited commercial introduction intentionally limited the size of our sales force and the number of customers each member of the sales force served in order to focus on obtaining quality and timely product feedback on initial product usages. We 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.

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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, or inadvisable, for patients with heart disease, which often exists in PAD patients. As a result of these challenges, many medically managed patients develop more severe symptoms that require procedural intervention.

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.

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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 market for the treatment of peripheral arteries;

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 February 15, 2008, 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, including the following:

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

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

We have a limited history selling and manufacturing the Diamondback 360°, which is currently our only product.

The Diamondback 360° may never achieve market acceptance.

Our customers may not be able to achieve adequate reimbursement for using the Diamondback 360°.

We have limited data and experience regarding the safety and efficacy of the Diamondback 360°.

We will face significant competition.

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

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We may experience difficulties managing growth.

We may not obtain necessary FDA clearances or approvals to market our future products.

We may become subject to regulatory actions or our products could be subject to restrictions or withdrawal from the market in the event we are found to promote them for unapproved uses or if we or our suppliers fail to comply with ongoing regulatory requirements.

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.

We may incur liabilities and costs and be forced to redesign or discontinue selling certain products if third parties claim that we are infringing their intellectual property rights.

You should carefully consider these factors, as well as all of the other information set forth in this prospectus, before making an investment decision.

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.

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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 16,262,695 shares outstanding as of February 15, 2008, and excludes:

- 6,068,808 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of $6.55 per share;
- 1,032,113 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $5.50 per share; and
- 330,848 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.

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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 six months ended December 31, 2006 and 2007 and consolidated balance sheet data as of December 31, 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 six months ended December 31, 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,			Six Months Ended December 31,	
	2005	2006	2007[1]	2006[1]	2007[1]
	(in thousands, except share and per share amounts)				
Consolidated Statements of Operations Data:					
Revenues	$	$	$	$	$ 4,631
Cost of goods sold					2,732
Gross profit					1,899
Expenses:					
Selling, general and administrative	1,177	1,735	6,691	2,400	13,181
Research and development	2,371	3,168	8,446	2,136	6,324
Total expenses	3,548	4,903	15,137	4,536	19,505
Loss from operations	(3,548)	(4,903)	(15,137)	(4,536)	(17,606)
Other income (expense):					
Interest expense		(48)	(1,340)	(402)	(216)
Interest income	37	56	881	471	613
Total other income (expense)	37	8	(459)	69	397
Net loss	(3,511)	(4,895)	(15,596)	(4,467)	(17,209)
Accretion of redeemable convertible preferred stock[2]			(16,835)	(8,006)	(5,206)
	$ (3,511)	$ (4,895)	$ (32,431)	$ (12,473)	$ (22,415)

Net loss available to common shareholders					
Loss per common share:					
Basic and diluted[3]	$ (0.61)	$ (0.79)	$ (5.22)	$ (2.01)	$ (3.50)
Weighted average common shares used in computation:					
Basic and diluted[3]	5,779,942	6,183,715	6,214,820	6,203,933	6,400,027
Pro forma loss per common share:					
Basic and diluted			$ (1.47)		$ (1.35)
Pro forma weighted average common shares used in computation:					
Basic and diluted			10,605,726		12,711,140

(footnotes appear on following page)

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(1) Operating expenses in the year ended June 30, 2007 and the six months ended December 31, 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	Six Months Ended December 31, 2006	Six Months Ended December 31, 2007
		(in thousands)	
Cost of goods sold	$	$	$ 69
Selling, general and administrative	327	127	4,777
Research and development	63	5	100

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

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

	As of December 31, 2007		
	Actual	Pro Forma[1]	Pro Forma as Adjusted[2]
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 7,088	$ 7,088	$
Short-term investments	7,213	7,213	
Working capital[3]	16,317	16,317	
Total current assets	20,644	20,644	
Total assets	43,285	43,285	
Redeemable convertible preferred stock warrants	3,286		
Total liabilities	7,700	4,414	
Redeemable convertible preferred stock	84,039		
Total shareholders (deficiency) equity	(48,454)	38,871	

(1) On a pro forma basis to reflect 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 upon the closing of this offering.

(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.

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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

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

As of December 31, 2007, our investments included $23.2 million of AAA rated auction rate securities issued primarily by state agencies and backed by student loans guaranteed by the Federal Family Education Loan Program. These auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals, primarily every 28 days, through auctions. The recent conditions in the global credit markets have prevented us from liquidating our holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. During February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $21.0 million of our $23.2 million in auction rate securities held as of December 31, 2007. Currently, these affected securities are not liquid and will not become liquid until a future auction for these investments is successful or they are redeemed by the issuer or they mature. In the event that we need to access the funds of our auction rate securities that have experienced insufficient demand at auctions, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them to maturity and we may have insufficient funds to operate our business. If the credit ratings of the issuers of these securities deteriorate and any decline in fair value of these securities is determined to be other-than-temporary, we would be required to adjust the carrying value of the investment through an impairment charge, which could be material and adversely affect our results of operations.

In addition, we have incurred substantial operating losses and negative cash flows from operations, all of which will require us to obtain additional funding to continue our operations, management has concluded that there is substantial doubt about our ability to continue as a going concern. Based on the factors described above, our independent registered public accountants have included an explanatory paragraph in their report for our fiscal year ended June 30, 2007 with respect to our ability to continue as a going concern. Based on current operating levels combined with limited liquid capital resources, financing our operations for the next 12 months will require us to raise additional equity or debt capital. If we fail to raise sufficient equity or debt capital, management would implement cost reduction measures, including workforce reductions, as well as reductions in overhead costs and capital expenditures. There can be no assurance that these sources will provide sufficient cash flows to enable us to continue as a going concern. We currently have no commitments for additional debt or equity financing and may experience difficulty in obtaining additional financing on favorable terms, if at all.

The existence of the explanatory paragraph may adversely affect our relationships with current and prospective customers, suppliers and investors, and therefore could have a material adverse effect on our business, financial condition, results of operations and cash flows. Furthermore, if we are not able to continue as a going concern, you could lose your investment in our common stock.

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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 $17.2 million in the six months ended December 31, 2007. As of December 31, 2007, we had an accumulated deficit of approximately $82.1 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.

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;

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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 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.

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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 manufacturers of atherectomy catheters including, among others, ev3, Spectranetics and Boston Scientific, as well as other manufacturers that may enter the market due to the increasing demand for treatment of vascular disease. Several other companies provide products used by surgeons in peripheral bypass procedures. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of mild to moderate PAD and companies that provide products used by surgeons in peripheral bypass procedures.

Our competitors may:

- develop and patent processes or products earlier than 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.

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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 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.

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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 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

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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 50 employees on February 15, 2008, and we expect to continue to grow our sales and marketing force. We also expect to significantly expand our manufacturing operations to meet anticipated growth in demand for our products. Rapid expansion in personnel means that less experienced people may be producing and selling our product, which could result in unanticipated costs and disruptions to our operations. If we cannot scale and manage our business appropriately, our anticipated growth may be impaired and our financial results will suffer.

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;
- 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

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commercialization goals and have a material adverse effect on our business, financial condition and results of operations.

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

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

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

We are highly dependent on our senior management, especially David L. Martin, our President, 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.

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

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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.

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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.

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.

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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.

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.

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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 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. One of these physicians was one of 20 principal investigators in our OASIS clinical trial at the

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

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

Risks Relating to Intellectual Property

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

Our success and ability to compete depends, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patents, copyrights and trademarks, as well as trade secrets and nondisclosure agreements, to protect our intellectual property. As of February 15, 2008, 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.

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To protect our proprietary rights, we may, in the future, need to assert claims of infringement against third parties to protect our intellectual property. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our financial condition, reputation and results of operations regardless of the final outcome of such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, invalid or unenforceable, and could order us to pay third-party 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, which he believes to be in excess of $1.0 million, 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.

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

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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 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.

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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.

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

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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 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

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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.

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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.

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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.

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CAPITALIZATION

The following table sets forth our capitalization as of December 31, 2007 on:

- an actual basis;
- a pro forma basis to reflect 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 upon the closing of this offering; 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 December 31, 2007		
	Actual	Pro Forma	Pro Forma as Adjusted[1]
	(in thousands, except share and per share data)		
Redeemable convertible preferred stock warrants	$ 3,286	$	$
Series A redeemable convertible preferred stock, no par value; 5,400,000 shares authorized, 4,737,561 issued and outstanding, actual; no shares issued and outstanding, pro forma; no shares issued and outstanding, pro forma as adjusted	43,739		
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	20,238		
Series B redeemable convertible preferred stock, no par value; 2,162,162 shares authorized, 2,162,150 issued and outstanding, actual; no shares issued and outstanding, pro forma; no shares issued and outstanding, pro forma as adjusted	20,062		
Shareholders (deficiency) equity:			
Common stock, no par value per share, 25,000,000 common shares and 2,811,575 undesignated shares authorized, 6,868,109 shares issued and outstanding, actual; 70,000,000 common shares and 5,000,000 undesignated shares authorized, 15,956,245 shares issued and outstanding, pro forma; 70,000,000 common shares and 5,000,000 undesignated shares authorized, shares issued and	32,434	116,473	

outstanding, pro forma as adjusted;			
Common stock warrants	1,242	4,528	
Accumulated other comprehensive loss	1	1	
Accumulated deficit	(82,131)	(82,131)	
Total shareholders (deficiency) equity	(48,454)	$ 38,871	
Total capitalization	$ 38,871	$ 38,871	$

(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.

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The outstanding shares set forth in the table above excludes, as of December 31, 2007:

- 5,986,595 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of $6.39 per share;
- 1,032,113 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $5.50 per share; and
- 809,511 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.

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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 December 31, 2007 was $(49.2) million, or $(7.16) 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 December 31, 2007 was approximately $38.1 million, or approximately $2.39 per share, based on the number of shares outstanding as of December 31, 2007, after giving effect to 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 December 31, 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 December 31, 2007	$ (7.16)	
Increase per share attributable to conversion of preferred stock	9.55	
Pro forma net tangible book value per share as of December 31, 2007	2.39	
Increase per share attributable to new investors		
Pro forma as adjusted net tangible book value per share as of December 31, 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 December 31, 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

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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 December 31, 2007 exclude:

- 5,986,595 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of $6.39 per share;
- 1,032,113 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $5.50 per share; and
- 809,511 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 December 31, 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 5,986,595 shares and warrants exercisable for 1,032,113 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.

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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 six months ended December 31, 2006 and 2007 and the balance sheet data as of December 31, 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 six months ended December 31, 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,					Six Months Ended December 31,	
	2003	2004	2005	2006	2007[1]	2006[1]	2007[1]
	(in thousands, except share and per share amounts)						
Consolidated Statements of Operations Data:							
Revenues	$	$	$	$	$	$	$ 4,631
Cost of goods sold							2,732
Gross profit							1,899
Expenses[1]**:**							
Selling, general and administrative	829	984	1,177	1,735	6,691	2,400	13,181
Research and development	681	3,246	2,371	3,168	8,446	2,136	6,324
Total expenses	1,510	4,230	3,548	4,903	15,137	4,536	19,505

Loss from operations	(1,510)	(4,230)	(3,548)	(4,903)	(15,137)	(4,536)	(17,606)
Other income (expense):							
Interest expense	(275)			(48)	(1,340)	(402)	(216)
Interest income	10	18	37	56	881	471	613
Total other income (expense)	(265)	18	37	8	(459)	69	397
Net loss	(1,775)	(4,212)	(3,511)	(4,895)	(15,596)	(4,467)	(17,209)
Accretion of redeemable convertible preferred stock[(2)]					(16,835)	(8,006)	(5,206)
Net loss available to common shareholders	$ (1,775)	$ (4,212)	$ (3,511)	$ (4,895)	$ (32,431)	$ (12,473)	$ (22,415)
Loss per common share: Basic and diluted[(3)]	$ (0.44)	$ (0.78)	$ (0.61)	$ (0.79)	$ (5.22)	$ (2.01)	$ (3.50)
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	6,203,933	6,400,027
Pro forma loss per common share: Basic and diluted					$ (1.47)		$ (1.35)
Pro forma weighted average common shares used in computation: Basic and diluted					10,605,726		12,711,140

(footnotes appear on following page)

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(1) Operating expenses in the year ended June 30, 2007 and six months ended December 31, 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	Six Months Ended December 31, 2006	Six Months Ended December 31, 2007
		(in thousands)	
Cost of goods sold	$	$	$ 69
Selling, general and administrative	327	127	4,777
Research and development	63	5	100

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

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

	As of June 30,					As of December 31,
	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	$ 7,088
Short-term investments					11,615	7,213
Working capital[(1)]	3,415	2,868	1,349	(1,240)	18,171	16,317
Total current assets	3,871	3,166	2,116	2,424	20,828	20,644
Total assets	4,550	4,031	2,874	3,296	22,025	43,285
Redeemable convertible preferred stock warrants					3,094	3,286
Total liabilities	456	298	767	3,723	5,830	7,700
Redeemable convertible preferred stock					48,498	84,039
Total shareholders (deficiency) equity	4,094	3,733	2,107	(427)	(32,303)	(48,454)

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

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

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and the related notes included elsewhere in this 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. This limited commercial introduction intentionally limited the size of our sales force and the number of customers each member of the sales force served in order to focus on obtaining quality and timely product feedback on initial product usages.

We intend to market the Diamondback 360° in the United States through a direct sales force and commenced 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 December 31, 2007, we had an accumulated deficit of $82.1 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.

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Since our inception, we have experienced substantial operating losses and negative cash flows from operations. We had cash, cash equivalents and liquid short-term investments of $14.3 million at December 31, 2007. During the six months ended December 31,

2007 and the year ended June 30, 2007, net cash used in operations amounted to $15.3 million and $12.2 million, respectively. In February 2008, we were notified that recent conditions in the global credit markets have caused insufficient demand for auction rate securities, resulting in failed auctions for $21.0 million of our $23.2 million in auction rate securities held as of December 31, 2007. These securities are currently not liquid, as we have an inability to sell the securities due to continued failed auctions. These factors raise substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern ultimately depends on our ability to raise additional debt or equity capital. If this offering is not consummated or we are unable to raise additional debt or equity financing on terms acceptable to us, there will continue to be substantial doubt about our ability to continue as a going concern.

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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 12 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 occur as hospitals utilize the single-use catheters.

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, revenues are deferred until the title and risk of loss of all Diamondback 360° components passes to the customer. Many initial shipments to customers included a loaner control unit, which we provided, until the new control unit received clearance from the FDA and was subsequently available for sale. The loaner control units are company-owned property and we maintain legal title to these units. The loaner control units were held in inventory at the time they were loaned to the various accounts under our limited commercial launch. The net inventory value of the loaner control units was $20,246 at June 30, 2007. At December 31, 2007, the loaner control units were fully reserved, as we had received FDA clearance on the new control unit and began shipping our new control unit during the quarter then ended. However, we could not meet the production demands of the new control units and, as a result, we continued to ship loaner control units during the quarter ended December 31, 2007. Accordingly, we had deferred revenue of $1.1 million as of December 31, 2007, reflecting all disposable component shipments to customers pending a purchase of a new control unit. Shipments of the new control units have continued subsequent to December 31, 2007, at which time deferred revenue is being 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. With the anticipated benefits of future cost reduction initiatives and increased volume and related economies of scale, we anticipate that gross margin percentages on single-use catheters that we assemble will be higher than those achieved on the control unit and guidewires that we purchase from third parties.

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

Research and Development. Research and development expenses include costs associated with the design, development, testing, enhancement and regulatory approval of our products. Research and development expenses include employee compensation including stock-based compensation, supplies and materials, consulting expenses, travel and facilities overhead. We also incur significant expenses to operate our clinical trials, including trial design, third-party fees, clinical site reimbursement, data management and travel expenses. All research and development expenses are expensed as incurred.

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.

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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.

Net Operating Loss Carryforwards. We have established valuation allowances to fully offset our deferred tax assets due to the uncertainty about our ability to generate the future taxable income necessary to realize these deferred assets, particularly in light of our historical losses. The future use of net operating loss carryforwards is dependent on our attaining profitable operations and will be limited in any one year under Internal Revenue Code Section 382 due to significant ownership changes (as defined in Section 382) resulting from our equity financings. At June 30, 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 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. We have applied Emerging Issues Task Force (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. This determination was made based on the following: (1) each individual component of the Diamondback 360° system is necessary to utilize the entire system, (2) currently there is no fair market value for each component, and (3) the individual components are not used for any other purpose. Further, as there is no prior history of selling the components separately and the components have no value on a stand-alone basis or objective reliable evidence of fair value, we have treated the individual components as a single

unit of accounting.

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

have no additional contractual obligations or performance requirements regarding revenue recognition once these criteria have been met. The customer has no right of return on any component once the above criteria have been met. Payment terms are generally set at 30 days.

Investments. We classify all investments as available-for-sale. Investments are recorded at fair value and unrealized gains and losses are recorded as a separate component of shareholders deficiency until realized. Realized gains and losses are accounted for on the specific identification method. We place our investments primarily in auction rate securities, U.S. government securities, and commercial paper. These investments, a portion of which have original maturities beyond one year, are classified as short-term based on their liquid nature. The securities that have stated maturities beyond one year have certain economic characteristics of short-term investments due to a rate-setting mechanism and the ability to sell them through a Dutch auction process that occurs at pre-determined intervals, primarily every 28 days. For the year ended June 30, 2007 and six months ended December 31, 2007, the amount of gross realized gains and losses were insignificant.

During February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $21.0 million of our $23.2 million in our auction rate securities held as of December 31, 2007. During 2007 and prior to February 2008, we had not experienced any failed auctions on our auction rate securities, and, in fact, sold $2.2 million of these securities subsequent to December 31, 2007. In addition, prior to the auctions failing in February 2008, all of our auction rate securities owned at December 31, 2007 had at least one successful auction in 2008. Currently, these affected securities are not liquid and will not become liquid until a future auction for these investments is successful or they are redeemed by the issuer or they mature. As a result, at December 31, 2007, we have classified $21.0 million of auction rate securities as a long-term asset. This amount represents the fair value of all auction rate securities held at December 31, 2007 that were not subsequently sold at auctions.

In accordance with EITF 03-01 and FSP FAS 115-1 and 124-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments,* we review several factors to determine whether a loss is other-than-temporary. These factors include but are not limited to: (1) the length of time a security is in an unrealized loss position, (2) the extent to which fair value is less than cost, (3) the financial condition and near term prospects of the issuer, and (4) our intent and ability to hold the security for a period of time sufficient to allow for any unanticipated recovery in fair value. As of December 31, 2007, we do not believe there is any other-than-temporary impairment to any of our investment holdings. We will continue to monitor and evaluate the value of our investments each reporting period for a possible impairment if a decline in fair value occurs. In the event that we need to access the funds of our auction rate securities that have experienced insufficient demand at auctions, we will not be able to do so without the possible loss of principal, which would result in an impairment charge recorded in our statement of operations.

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.

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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.

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 various factors, including the following:

Financing Activity: Between July 19, 2006 and October 3, 2006, we sold $27.0 million in Series A convertible preferred stock at $5.71 per share; between May 16, 2007 and September 19, 2007, we sold $18.6 million in Series A-1 convertible preferred stock at $8.50 per share; and between November 13, 2007 and December 17, 2007, we sold $20.0 million in Series B convertible preferred stock at $9.25 per share. New and existing investors participated in the convertible preferred stock offerings, while certain existing investors declined the opportunity to participate.

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

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amounts assuming the conversion of the preferred stock. The aggregate liquidation preferences of our preferred stock at the dates listed below are as follows:

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

Stock Valuations: We have conducted retrospective stock valuations using the option pricing method and contemporaneous stock valuations using the probability weighted expected return method. These valuations utilized discounts from the price of the most recently issued preferred stock ranging from 45% as of July 2006 to 10% as of December 2007, reflecting in each case the significant preferences on the preferred stock over the common stock. Management and the board of directors believe that the discounts used to reflect the preferences on the preferred stock over the common stock were appropriate and accurately reflect the state of product development, product and market acceptance, and the anticipated time until a liquidity event, including this offering.

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

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

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

Limited Commercial Launch: Upon receiving FDA 510(k) clearance, we began shipping product to customers under our limited commercial launch plan.

Merger and Acquisition Process: During the period from July 2007 through September 2007, we engaged investment bankers to explore potential merger and acquisition opportunities.

Offering Process: Beginning in the quarter ended June 30, 2007, we began discussions with investment bankers concerning our initial public offering process, and the organizational meeting for this offering occurred in October 2007.

Revenues: We recognized $4.6 million in revenues for the three months ended December 31, 2007.

Our management and board of directors also considered the valuations of comparable companies, our cash and working capital amounts, and additional objective and subjective factors relating to our business. Our management and board of directors set the exercise prices for option grants based upon their best estimate of the fair market value of our common stock at the time they made such grants, taking into account all information available at those times. In some cases, management and the board of directors made retrospective assessments of the valuation of our common stock at later dates and determined that the fair market value of our common stock at the times the grants were made was higher than the exercise prices established for those grants. In these cases, we recognized stock compensation expense for the excess of the fair market value of the common stock over the exercise price.

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The following table sets forth the exercise prices of options granted during fiscal year 2007 and the six months ended December 31, 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
October 9, 2007	331,083	5.11	7.36
November 13, 2007	154,917	7.36	7.90
December 12, 2007	775,000	7.86	8.44
December 31, 2007	1,056,234	7.86	8.44

We also granted 204,338 restricted stock awards on December 12, 2007 with vesting terms ranging from 12 to 36 months. The fair market value of our common stock on this date, as determined by our management and board of directors, was $8.44.

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.

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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, Series A-1 convertible preferred stock and Series B convertible preferred stock at the dates noted during the fiscal year ended June 30, 2007 and the six months ended December 31, 2007:

Date	Series A Convertible Preferred Stock	Series A-1 Convertible Preferred Stock	Series B 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	
December 31, 2007	9.25	9.25	9.25

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 December 31, 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.

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Results of Operations

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

	Years Ended June 30,			Years Ended June 30,			Six Months Ended December 31,		
	2005	2006	Percent Change	2006	2007	Percent Change	2006	2007	Percent Change
evenues	$	$		$	$		$	$ 4,631	
ost of goods ld								2,732	
ross profit								1,899	
xpenses:									
elling, general d ministrative	1,177	1,735	47.4%	1,735	6,691	285.6%	2,400	13,181	449.2%
esearch and velopment	2,371	3,168	33.6	3,168	8,446	166.6	2,136	6,324	196.1
otal expenses	3,548	4,903	38.2	4,903	15,137	208.7	4,536	19,505	330.0
oss from erations	(3,548)	(4,903)	38.2	(4,903)	(15,137)	208.7	(4,536)	(17,606)	288.1
ther income xpense):									
terest expense		(48)	0	(48)	(1,340)	2,691.7	(402)	(216)	46.3
terest income	37	56	51.4	56	881	1,473.2	471	613	30.1
otal other come xpense)	37	8	78.3	8	(459)	5,837.5	69	397	475.4
et loss	(3,511)	(4,895)	39.4	(4,895)	(15,596)	218.6	(4,467)	(17,209)	285.2
ccretion of deemable nvertible eferred stock					(16,835)		(8,006)	(5,206)	
et loss ailable to mmon areholders	$ (3,511)	$ (4,895)	39.4%	$ (4,895)	$ (32,431)	562.5%	$ (12,473)	$ (22,415)	79.7%

Comparison of the Six Months Ended December 31, 2006 and 2007

Revenues. We generated revenues of $4.6 million during the six months ended December 31, 2007 attributable to sales of the Diamondback 360° to customers following FDA clearance in August 2007. We commenced a limited commercial introduction of the Diamondback 360° in the United States in September 2007. During this limited introduction, we expanded our sales and marketing efforts and have shipped more than 1,700 single-use catheters through December 31, 2007. We expect our revenue to increase as we continue to expand our sales and marketing teams to increase penetration of the U.S. PAD market.

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, revenues are deferred until the title and risk of loss of each Diamondback 360° component, consisting of catheters, guidewires, and a control unit, are transferred to the customer based on the shipping terms. Many initial shipments to customers also included a loaner control unit, which we provided, until the new control unit received clearance from the FDA and was subsequently available for sale. The loaner control units are company-owned property and we maintain

legal title to these units. Accordingly, we had deferred revenue of $1.1 million as of December 31, 2007, reflecting all component shipments to customers pending a purchase of a new control unit. Shipments of the new control units will continue subsequent to December 31, 2007, at which time deferred revenue will be recognized.

Cost of Goods Sold. For the six months ended December 31, 2007, cost of goods sold was $2.7 million. This amount represents the cost of materials, labor and overhead for single-use catheters, guidewires and control units shipped subsequent to obtaining FDA clearance for the Diamondback 360° in August 2007. Cost of goods sold for the six months ended December 31, 2007 includes $339,000 relating to component shipments for which there is no associated revenue and $69,000 for stock based compensation. At December 31, 2007, the legal title and risk of loss of each disposable component had transferred to the customer and we have no future economic benefit in these disposables. As a result, the cost of goods sold related to these disposable units has been recorded in the six months ended December 31, 2007. We expect that cost of goods sold as a percentage of revenues will continue to decrease as we implement cost reduction initiatives and benefit from increased volume and related economies of scale.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased by $10.8 million, from $2.4 million for the six months ended December 31, 2006 to $13.2 million for the six months ended December 31, 2007. The primary reasons for the increase included the building of our sales and marketing team, contributing $4.9 million, and significant consulting and professional services, contributing $500,000. In addition, stock based compensation increased from $127,000 for the six months ended December 31, 2006 to $4.8 million for the six months ended December 31, 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 $4.2 million, from $2.1 million for the six months ended December 31, 2006 to $6.3 million for the six months ended December 31, 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 $5,000 for the six months ended December 31, 2006 to $100,000 for the six months ended December 31, 2007. We expect our research and development expenses to increase as we attempt to expand our product portfolio within the market for the treatment of peripheral arteries and leverage our core technology into the coronary market.

Interest Income. Interest income increased by $142,000, from $471,000 for the six months ended December 31, 2006 to $613,000 for the six months ended December 31, 2007. The increase was primarily due to higher average cash and cash equivalents and investment balances. Average cash and cash equivalent and investment balances were $20.5 million and $22.9 million for the six months ended December 31, 2006 and 2007, respectively.

Interest Expense. Interest expense decreased by $186,000, from $402,000 for the six months ended December 31, 2006 to $216,000 for the six months ended December 31, 2007. The decrease 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 $8.0 million for the six months ended December 31, 2006, as compared to $5.2 million for the six months ended December 31, 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.

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

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

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

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

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

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. We had cash, cash equivalents and liquid short-term investments of $14.3 million at December 31, 2007. During the six months ended December 31, 2007 and the year ended June 30, 2007, net cash used in operations amounted to $15.3 million and $12.2 million, respectively. As of December 31, 2007, we had an accumulated deficit of $82.1 million. We have historically funded our operating losses primarily from the issuance of common and preferred stock and convertible promissory notes. We

have incurred negative cash flows and net losses since inception. In addition, in February 2008, we were notified that recent conditions in the global credit markets have caused insufficient demand for auction rate securities, resulting in failed auctions for $21.0 million of our $23.2 million in auction rate securities held as of December 31, 2007. These securities are currently not liquid, as we have an inability to sell the securities due to continued failed auctions. Based on current operating levels combined with limited capital resources, financing our operations for the next 12 months will require us to raise additional equity or debt capital. If we fail to raise sufficient equity or debt capital, management would implement cost reduction measures, including workforce reductions, as well as reductions in overhead costs and capital expenditures. There can be no assurance that these

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sources will provide sufficient cash flows to enable us to continue as a going concern. We currently have no commitments for additional debt or equity financing and may experience difficulty in obtaining additional financing on favorable terms, if at all. All of these factors raise substantial doubt about our ability to continue as a going concern. Our independent registered public accountants have included an explanatory paragraph in their report for our fiscal year ended June 30, 2007 with respect to our ability to continue as a going concern.

The reported changes in cash and cash equivalents and investments for the years ended June 30, 2005, 2006 and 2007 and for the six months ended December 31, 2006 and 2007 are summarized below.

Cash and Cash Equivalents. Cash and cash equivalents increased by $3.8 million, from $3.3 million at December 31, 2006 to $7.1 million at December 31, 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.

Investments. Short-term Investments decreased by $8.9 million, from $16.1 million at December 31, 2006 to $7.2 million at December 31, 2007. Short-term investments increased by $11.6 million, from $0 at June 30, 2006 to $11.6 million at June 30, 2007.

As of December 31, 2007, our investments included AAA rated auction rate securities issued primarily by state agencies and backed by student loans guaranteed by the Federal Family Education Loan Program. During February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $21.0 million of our $23.2 million in our auction rate securities held as of December 31, 2007. During 2007 and prior to February 2008, we had not experienced any failed auctions on our auction rate securities, and, in fact, sold $2.2 million of these securities subsequent to December 31, 2007. In addition, prior to the auctions failing in February 2008, all of our auction rate securities owned at December 31, 2007 had at least one successful auction in 2008. Currently, these affected securities are not liquid and will not become liquid until a future auction for these investments is successful or they are redeemed by the issuer or they mature. As a result, at December 31, 2007, we have classified $21.0 million of auction rate securities as a long-term asset. This amount represents the fair value of all auction rate securities held at December 31, 2007 that were not subsequently sold at auctions. For a discussion of liquidity issues relating to our auction rate securities, see Quantitative and Qualitative Disclosures About Market Risk.

Operating Activities. Net cash used in operating activities was $3.3 million, $5.0 million and $12.3 million in fiscal 2005, 2006 and 2007, respectively, and $4.3 million and $15.3 million for the six months ended December 31, 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 $16.1 million and $17.1 million for the six months ended December 31, 2006 and 2007, respectively. For the six months ended December 31, 2006, we purchased investments in the amount of $15.9 million. For the six months ended December 31, 2007, we purchased and sold investments in the amount of $27.3 million and $10.8 million, respectively. In fiscal 2007, we purchased and sold 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 $135,000 and $438,000 in the six months ended December 31, 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 $22.2 million and $31.6 million in the six months ended December 31, 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 $22.0 million and $30.3 million in the six months ended December 31, 2006 and 2007, respectively;

issuance of convertible preferred stock warrants of $1.8 million in fiscal 2007; and

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exercise of stock options and warrants of $1.4 million during the six months ended December 31, 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 $1.7 million in the six months ended December 31, 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, and 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. If this offering is not consummated or we are unable to raise additional debt or equity financing on terms acceptable to us, there will continue to be substantial doubt about our ability to continue as a going concern. 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.

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

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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 standards continue the movement toward the greater use of fair values in financial reporting. SFAS No. 141(R) will significantly change how business acquisitions are accounted for and will impact financial statements both on the acquisition date and in subsequent periods, including the accounting for contingent consideration. SFAS No. 160 will change the accounting and reporting for minority interests, which will be recharacterized as noncontrolling interests and classified as a component of equity. SFAS No. 141(R) and SFAS No. 160 are effective for fiscal years beginning on or after December 15, 2008, with SFAS No. 141(R) to be applied prospectively while SFAS No. 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements of SFAS No. 160 shall be applied prospectively. Early adoption is prohibited for both standards. We are currently evaluating the impact of these statements but expect that the adoption of SFAS No. 141(R) will have a material impact

on how we will identify, negotiate and value any future acquisitions and a material impact on how an acquisition will affect our consolidated financial statements, and that SFAS No. 160 will not have a material impact on our financial position or consolidated results of operations.

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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 auction rate securities, commercial paper, money market funds, and U.S. government securities. Our cash and cash equivalents as of December 31, 2007 include 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.

All of our investment securities are classified as available-for-sale and therefore reported on the balance sheet at fair value. Our investment securities consist of auction rate securities, commercial paper and U.S. government securities. As of December 31, 2007, our investments included AAA rated auction rate securities issued primarily by state agencies and backed by student loans guaranteed by the Federal Family Education Loan Program. Our auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals, primarily every 28 days, through auctions. The recent conditions in the global credit markets have prevented some investors from liquidating their holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. If there is insufficient demand for the securities at the time of an auction, the auction may not be completed and the rates may be reset to predetermined penalty or maximum rates. When auctions for these securities fail, the investments may not be readily convertible to cash until a future auction of these investments is successful or they are redeemed by the issuer or they mature. If the credit ratings of the security issuers deteriorate and any decline in fair value is determined to be other-than-temporary, we would be required to adjust the carrying value of the investment through an impairment charge.

During February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $21.0 million of our $23.2 million in auction rate securities held as of December 31, 2007. During 2007 and prior to February 2008, we had not experienced any failed auctions on our auction rate securities, and, in fact, sold $2.2 million of these securities subsequent to December 31, 2007. In addition, prior to the auctions failing in February 2008, all of our auction rate securities owned at December 31, 2007 had at least one successful auction in 2008. Currently, these affected securities are not liquid and will not become liquid until a future auction for these investments is successful or they are redeemed by the issuer or they mature. As a result, at December 31, 2007, we have classified $21.0 million of auction rate securities as a long-term asset. This amount represents the fair value of all auction rate securities held at December 31, 2007 that were not subsequently sold at auctions.

In the event that we need to access the funds of our auction rate securities that have experienced insufficient demand at auctions, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. Management has not obtained sufficient evidence to conclude that these investments are impaired or that they will not be settled in the short term, although the market for these investments is presently uncertain. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them to maturity. We will continue to monitor and evaluate these investments on an ongoing basis for impairment.

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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. This limited commercial introduction intentionally limited the size of our sales force and the number of customers each member of the sales force served in order to focus on obtaining quality and timely product feedback on initial product usages.

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.

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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 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, or inadvisable, for patients with heart disease, which often exists in PAD patients. As a result of these challenges, many medically managed patients develop more severe symptoms that require procedural intervention.

Conventional Interventional Treatments for PAD and Their Limitations

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

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

Catheter-Based Interventions. Minimally invasive catheter-based interventions include angioplasty, stenting and atherectomy procedures. Angioplasty involves inserting a catheter with a balloon tip into the site of arterial blockage and then inflating the balloon to compress plaque and expand the artery wall. Stenting involves implanting and expanding a cylindrical metal tube into the diseased artery to hold the arterial wall open. Both angioplasty and stenting can improve blood flow in plaque-lined arteries by opening lumens and are relatively fast and inexpensive compared to surgical procedures. However, these techniques are not as effective in long or

calcified lesions or in lesions located below the knee, nor do they remove any plaque from the artery. Moreover, most stents are not FDA-approved for use in arteries in the lower extremities. Additional concerns include the potential to damage the artery when the balloon is expanded in angioplasty and the potential for stent fracture during normal leg movement. Both angioplasty and stenting have also been associated with high rates of restenosis, or re-narrowing of the arteries, in the months following the procedure.

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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 a rotational atherectomy catheter designed to differentiate between plaque and compliant arterial tissue, a concept that we refer to as differential sanding. The particles of plaque resulting from differential sanding are generally smaller than red blood cells and are carried away by the blood stream. As the physician increases the rotational speed of the drive shaft, the crown not only rotates faster but also, due to centrifugal force, begins to orbit with an increasing circumference. The Diamondback 360° can create a lumen that is approximately 100% larger than the actual diameter of the device, for a device-to-lumen ratio of 1.0 to 2.0. By giving physicians the ability to create different lumen diameters with a change in rotational speed, the Diamondback 360° can reduce the need to use

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multiple catheters of different sizes to treat a single lesion, thus reducing hospital inventory costs and procedure times.

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.

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. Other rotational atherectomy catheters remove plaque by abrading the lesion with a spinning, abrasive burr, which acts in a manner similar to a drill and only creates a lumen the same size or slightly smaller than the size of the burr.

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

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Ease of Use

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

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 February 15, 2008 had 33 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. We have requested clinical data from each subsequent use of the system following these clinical trials. These data are tabulated and disseminated internally to our sales, marketing and research and development departments in an effort to better understand the system s performance, identify any potential trends in the data, and drive product improvements. The

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data are also presented to groups of physicians for their education, comments and feedback. We are considering other clinical studies to further demonstrate the advantages of the Diamondback 360° but have not yet undertaken any additional studies.

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

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

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

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.

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

Technology Overview

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

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

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

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

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

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

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

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cells that are washed away downstream with the patient s natural blood flow. Of 36 consecutive experiments that we performed in carbon blocks, animal and cadaver models:

93.1% of particles were smaller than a red blood cell, with a 99% confidence interval; and

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

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

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

Applications

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

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

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

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

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

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

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

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

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

PAD I Feasibility Trial

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

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

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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

We submitted our OASIS data and received 510(k) clearance from the FDA for use of the Diamondback 360°, including the initial version of the control unit, with a hollow crown as a therapy for patients with PAD in August 2007. The FDA s labeling requirements reflected the inclusion criteria for the OASIS trial listed above. We received 510(k) clearances in October 2007 for the updated control unit used with the Diamondback 360° and in November

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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 February 15, 2008, we had a 44-person direct sales force, including 33 district sales managers, five regional sales managers, two sales directors, a national training manager, a director of field operations, a director of customer support, and a customer service specialist, 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 February 15, 2008, we had 18 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 six months ended December 31, 2006 and 2007 were $2.1 million and $6.3 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 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.

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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 manufacturers of atherectomy catheters including, among others, ev3, Spectranetics and Boston Scientific, as well as other manufacturers that may enter the market due to the increasing demand for treatment of vascular disease. Several other companies provide products used by surgeons in peripheral bypass procedures. Other competitors include pharmaceutical companies that manufacture drugs for the treatment of mild to moderate PAD and companies that provide products used by surgeons in peripheral bypass procedures. We are not aware of any competing catheter systems either currently on the market or in development that also use an orbital motion to create lumens larger than the catheter itself.

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

safety and efficacy;

predictable clinical performance;

ease of use;

price;

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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 February 15, 2008, 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, and adherence to the FDA s current good manufacturing practice requirements, as reflected in its Quality System

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

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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 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;

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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;

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.

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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 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

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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 February 15, 2008, we had 127 employees, including 36 employees in manufacturing, 44 employees in sales, six employees in marketing, four employees in clinicals, 11 employees in general and administrative, 18 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.

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

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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 filed our answer on November 16, 2007. We are defending this litigation vigorously and 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.

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. In the memorandum accompanying the January 10, 2008 order, the court noted that Mr. Collins admitted he took confidential sales information just prior to the conclusion of his employment with Plaintiffs in violation of his employment agreement, and noted that Mr. Collins has indicated a willingness to return that information to Plaintiffs.

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Our Diamondback 360° is in direct competition with one of Plaintiffs products. Our current Chief Executive Officer, Vice President of Sales, Vice President of Marketing and Vice President of Business Development were formerly employed by one of the Plaintiffs. These officers remain subject to confidentiality provisions in their employment agreements with Plaintiffs, but all nonsolicitation provisions have expired. Twenty-six of the 44 members of our sales department, or 59.1%, were formerly employed by one of the Plaintiffs.

We believe the January 10, 2008 court order and the continuing confidentiality obligations of our officers and employees under employment agreements with Plaintiffs will have no material impact on our sales efforts and the efforts of our management. We have undertaken an effort to document and account, with specificity, how our employees identified each of our existing physician customers and have implemented procedures to document how we identify each new physician customer. We believe all of our existing physician customers were identified through appropriate sources such as publicly-available information, employees preexisting physician relationships and referrals from existing physician customers. In addition, we do not believe the court order will impose any meaningful restriction on identifying and contacting new physician prospects since these physicians are typically well-known in their industry and easily identified through appropriate sources. Accordingly, we do not anticipate that the court order will materially impact our sales efforts.

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MANAGEMENT

Executive Officers and Directors

The name, age and position of each of our directors and executive officers as of February 15, 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)	65	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. Our new Chief Financial Officer, when appointed, will report directly to Mr. Martin, and Mr. Martin will resign as Interim Chief Financial Officer.

James E. Flaherty, Chief Administrative Officer and Secretary. Mr. Flaherty has been our Chief Administrative Officer since January 14, 2008. Mr. Flaherty was our Chief Financial Officer from March 2003 to January 14, 2008. As Chief Administrative Officer, Mr. Flaherty reports directly to our Chief Executive Officer and has responsibility

for information technology, facilities, legal matters, financial analysis of business development opportunities and business operations. Mr. Flaherty is assisting with our public offering process, including financial matters, and will assist with the transition of our new Chief Financial Officer, when appointed. As our Chief Financial Officer, Mr. Flaherty had primary responsibility for the preparation of historical financial statements, but he no longer has any such responsibility, although he may assist our Controller and Interim Chief Financial Officer with the preparation of financial statements from time to time until we appoint a new Chief

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Financial Officer. Prior to joining us, Mr. Flaherty served as an independent financial consultant from 2001 to 2003 and Chief Financial Officer of Zomax Incorporated from 1997 to 2001. Mr. Flaherty served as Chief Financial Officer of Racotek, Inc. from 1990 to 1996, of Time Management Corporation from 1986 to 1990, and of Nugget Oil Corp. from 1980 to 1985. Mr. Flaherty was an accountant at Coopers & Lybrand from 1975 to 1980. On June 9, 2005, the Securities and Exchange Commission filed a civil injunctive action charging Zomax Incorporated with violations of federal securities law by filing a materially misstated Form 10-Q for the period ended June 30, 2000. The SEC further charged that in a conference call with analysts, certain of Zomax s executive officers, 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

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position held until his retirement in 2002. Before joining Medtronic, Dr. Nelson practiced surgery from 1969 to 1986. Dr. Nelson was Chairman of the Board and Chief Executive Officer of American MedCenters, Inc. from 1984 to 1986. Dr. Nelson also was Chairman, President and Chief Executive Officer of the Park Nicollet Medical Center, a large multi-specialty group practice in Minneapolis, from 1975 to 1986. Dr. Nelson is on the board of directors of DexCom, Inc. and The Travelers Companies, Inc., both publicly-held companies, and also serves as a director for ten private companies.

Brent G. Blackey. Mr. Blackey has been a member of our board of directors since 2007. Since 2004, Mr. Blackey has served as the President and Chief Operating Officer for Holiday Companies. Between 2002 and 2004 Mr. Blackey was a Senior Partner at the accounting firm of Ernst & Young LLP. Prior to 2002, Mr. Blackey served most recently as a Senior Partner at the accounting firm of Arthur Anderson LLP. Mr. Blackey serves on the board of directors of Datalink Corporation, and also serves on the Board of Overseers for the University of Minnesota, Carlson School of Management.

John H. Friedman. Mr. Friedman has been a member of our board of directors since 2006. Mr. Friedman is the Managing Partner of the Easton Capital Investment Group, a private equity firm. Prior to founding Easton Capital, 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. Dr. Howe currently serves on the boards of directors of Stemedica Cell Technologies, Inc., BioPharma Scientific, Inc., America s Back & Neck Clinic, Inc. and Reliant Pictures Corporation, all of which are privately-held companies.

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

Technologies, Inc. and the University of Minnesota Landscape Arboretum.

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

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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.

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. We intend to use the Nasdaq phase-in provisions applicable to audit committee composition and the board will appoint an audit committee member that satisfies both Nasdaq independence standards and the independence standards of Rule 10A-3(b)(1) of the Securities Exchange Act to replace Ms. Wyskiel prior to the expiration of the phase-in period. 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;

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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.

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

(footnotes on next page)

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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][3]
Brent G. Blackey[4]	$
John H. Friedman[5]	5,611
Geoffrey O. Hartzler, M.D.[6]	16,540
Roger J. Howe, Ph.D.[6]	16,540
Glen D. Nelson, M.D.[6]	21,148
Gary M. Petrucci[6]	24,810
Christy Wyskiel[5]	5,611

(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) The aggregate number of shares subject to outstanding option awards held by each of the directors listed in the table above as of June 30, 2007 was as follows: Mr. Blackey no shares, Mr. Friedman 60,000 shares, Dr. Hartzler 115,000 shares, Dr. Howe 155,000 shares, Dr. Nelson 105,000 shares, Mr. Petrucci 310,000 shares and Ms. Wyskiel 60,000 shares.

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

(5) 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 grant date fair value of the option award granted to each of Mr. Friedman and Ms. Wyskiel, computed in accordance with SFAS No. 123(R), was $19,260. 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.

(6) 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. The grant date fair value of the option award granted to each of Drs. Hartzler, Howe and Nelson, computed in accordance with SFAS No. 123(R), was $16,540. The grant date fair value of the option award granted to Mr. Petrucci, computed in accordance with SFAS No. 123(R), was $24,810.

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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.

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Executive Compensation Components for 2007

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

- base salary;
- annual 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. For example, the compensation committee sets each executive s annual incentive compensation at a level designed to motivate the executive to achieve goals consistent with our long term business objectives, typically by establishing annual incentive opportunities ranging from 40% to 100% of the executive s base salary. The compensation committee believes this allocation of cash compensation between base salary and annual incentive compensation strikes the appropriate balance between guaranteeing executives an income adequate to satisfy living expenses and providing an incentive for the achievement of our goals. Equity-based compensation is also compensation at risk, since the equity increases in value only if we are successful in achieving our business goals, and serves to provide an incentive over a longer term. The compensation committee s judgment of the appropriate mix of compensation elements is also influenced by information they have reviewed as to the allocations made by other medical products companies at a similar stage of development and the experience of our compensation committee members. The 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

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could have obtained with other, more established employers. In order to induce Mr. Borrell and Mr. Tyska to accept positions with us despite lower base salaries, we agreed that each would also have the opportunity to earn performance-based incentive compensation, as described below, as well as equity awards. We believed that it was appropriate to make a significant portion of Mr. Borrell s cash compensation (a higher percentage than most other executives) subject to the achievement of performance objectives because of the particularly important role the Vice President of Sales and Marketing would play in the commercial introduction of our first product.

Each of Michael J. Kallok, 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 salary for Mr. Flaherty was awarded in recognition of his efforts in obtaining financing for our business, including the sales of Series A convertible preferred stock completed on July 19, 2006 and July 28, 2006, and his assumption of additional responsibilities such as oversight of our information technology systems. The increased base salary for Dr. Kallok was awarded in recognition of Dr. Kallok s efforts in advancing our clinical trials, including the PAD II trial in Europe and the preparation for the OASIS trial in the United States, as well as Dr. Kallok s leadership during his tenure as Chief Executive Officer. Mr. Thatcher s increase in base salary was intended primarily as a cost-of-living adjustment. In each case, the compensation committee also considered the range of compensation it believed to be paid by companies in our industry at a similar stage of development for the same position, the responsibility of the position as compared to other positions within our management team, and the tenure of the employee with us. The compensation committee did not attempt to assign values to particular elements of performance or the other factors considered and considered all of these factors generally in making its judgment regarding base salaries.

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 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. Because we had no revenues, the elements of company performance considered typically included progress in product development and clinical testing and achievement of financing goals. Payments were made based on the evaluation by our board and compensation committee of a broad range of information relating to individual and company performance rather than the achievement of specific goals. All of our executive officers

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were eligible to receive these discretionary annual bonuses, including James E. Flaherty, Michael J. Kallok, Robert J. Thatcher, John Borrell and Paul Tyska. Shortly after Mr. Martin joined us in February 2007 and upon his recommendation, the compensation committee established an incentive program for calendar 2007 designed to reward named executive officers with quarterly payments for achieving specific individual goals related to financial growth, product development and commercialization and operational improvement.

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

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

Michael J. Kallok, Ph.D.

Objectives

Perform and submit to FDA by May 15 a statistical analysis in support of our 510(k) application.
File application for critical limb ischemia Investigational Device Exemption by May 31.
Complete analysis of particle size and other matters by June 30.

James E. Flaherty

Objectives

Complete installation of new Enterprise Resource Planning system by June 30.
Complete venture debt financing by June 30.
Make adequate progress with respect to multiple financing options by June 30.

John Borrell

Objectives

Meet with product development team bi-weekly to communicate feedback from the field.
Install scheduled reporting and communications process within the sales department and across other departments.
Complete timely follow up of patients from OASIS trial.

Robert J. Thatcher

Objectives

Advance all product development projects to meet June 30 milestones.
Hire a Director of Quality by May 30.

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Paul Tyska

Objectives
Present OASIS data to potential strategic partners by June 30.
Obtain six site installations for critical limb ischemia study by June 30.
Obtain participation in early adoption of the Diamondback 360^0 by six key opinion leaders by June 30.

Following the end of fiscal 2007, Mr. Martin and the compensation committee concluded that each of the executive officers listed above had substantially satisfied all of the objectives and we paid the full target bonus amount to each officer. The compensation committee did not assign values to individual objectives or otherwise quantify the bonus amount payable with respect to any particular objective or group of objectives.

Generally, the objectives 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 Executive Officer and compensation committee retain the discretion to increase or decrease a named executive officer s quarterly or annual bonus payout to recognize either inferior or superior individual performance in cases where this performance is not fully represented by the achievement or non-achievement of the pre-established objectives. For example, our compensation committee reserves the right to award an officer 100% of his or her annual target bonus even if that officer had not achieved any quarterly objectives. Neither the Chief Executive Officer nor the compensation committee exercised discretion to award any bonus with respect to fiscal 2007 in circumstances where applicable performance objectives had not been substantially met.

The compensation committee evaluated whether the Chief Executive Officer had earned his 2007 annual target bonus amount only at the end of the calendar year based on our overall progress relative to our business plan. The compensation committee did not establish specific individual objectives for Mr. Martin under the incentive program for 2007 because the committee concluded that defining appropriate objectives would be difficult given that Mr. Martin was new in his position. The committee decided that our overall results would be a more effective indicator of Mr. Martin s success as Chief Executive Officer than any specific quarterly objectives that might be established for Mr. Martin. Accordingly, shortly after Mr. Martin joined us, the compensation committee agreed, consistent with Mr. Martin s employment agreement, that Mr. Martin would have the opportunity to earn incentive pay of up to 25% of his base salary at the end of calendar 2007, provided his performance was satisfactory to the compensation committee. In December 2007, the compensation committee concluded that Mr. Martin had performed well during calendar 2007 and awarded him a bonus of $92,500, 100% of his target bonus for 2007. In January 2008, the compensation committee established a new incentive plan that conditions the payment of incentive compensation to all participants, including Mr. Martin, upon our achievement of certain financial goals, including revenues and gross margin. None of our named executive officers is subject to individual goals under this plan.

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

	Total Fiscal 2007 Bonus and Non-Equity Incentive Plan

Name	Target Incentive Compensation as % of Base Salary	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

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

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 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. The compensation committee did not consider specific performance objectives but generally concluded that each of our executive officers had performed well and deserved option grants intended to move their equity ownership closer to the compensation committee s targeted levels.

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

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

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Summary Compensation Table for Fiscal Year 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 and Employee Benefit Plans Prior Equity Plans 2003 Stock Option Plan for a complete description of terms of the options grants.

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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 equity incentive plan awards as none of our named executive officers earned any such awards during fiscal 2007.

