CARDIOVASCULAR SYSTEMS INC
Form S-1/A
May 23, 2008

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As filed with the Securities and Exchange Commission on May 23, 2008
Registration No. 333-148798

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

AMENDMENT NO. 4 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 and Chief Executive 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 May 23, 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 9.

	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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Conquer plaque in the peripherals and move mountains in the treatment of pad. their toughest Challenge is our biggest opportunity. The ability to safely treat plaque including calcified plaque is the new frontier in treatment options for 8 to 12 million Peripheral Arterial Disease (PAD) patients in the U.S. The Diamondback 360°( ) Orbital Atherectomy System provides new options to surgery or amputation.

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new heights in Conquering CalCium ~ new options for saving limbs the market the technology The Diamondback 360° Orbital Atherectomy System treats complex diffuse disease including calcified plaque with a proprietary mechanism of action and features designed to optimize safety and efficiency. Prevalence of PAD Estimated Disease prevalence Differential sanding Restore flow with a large 2008 PAD comparison in the U.S. designed for safety luminal gain and a smooth, breakdown concentric lumen Allows for minimized incidence 20.8 M 2.5 M of arterial wall perforations and Pre-Treatment Above the dissections. The orbital mechanism Diagnosed knee: 78.4% Sub-total Occlusion of action lets the media flex away Peroneal 2.1mm* 12 M* from the crown. Below 5.5 9.5 M the knee: Diseased tissue provides Undiagnosed 21.6% resistance and allows grit to 5.8 M sand the plaque. Elastic healthy tissue gives Post-Treatment Stroke PAD Diabetes and may not be affected by Peroneal diamond grit. 4.0mm* The population is aging, increasing the incidence of PAD and diabetes. *average per company data Calcific disease is often associated with the diabetic patient. There are significant drawbacks with existing alternatives for interventional calcified plaque removal. Although awareness of the disease is growing, it still remains largely under-diagnosed. This represents a large untapped market and a significant opportunity to restore quality clinical confidence of life and save limbs. Proven performance backed by clinical trial data. Over 1,500 * Reflects upper bound of 8-12 million range patients treated since FDA clearance. A prospective, multi-center, FDA, IDE clinical study, OASIS, was conducted to evaluate the efficacy and safety of the Diamondback 360º System. In 124 patients with 201 lesions treated, the results met or outperformed the Objective Performance Criteria targets. More than 160,000 PAD related amputations are performed annually OASIS clinical study fda target oasis trial results Primary efficacy endpoint 55% reduction 59.4% reduction Acute debulking measured angiographically Primary safety endpoint 4.8% device related SAEs Cumulative number of patients with serious 8-16% SAEs 9.7% overall SAEs adverse events (SAEs) through 30 days Secondary efficacy/safety endpoint Target lesion revascularization (TLR) rate 20% TLR 2.4% TLR through 6 months The science of the smooth lumen 360°

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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 9 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. During the quarter ended March 31, 2008, we began our full commercial launch. 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

PAD affects approximately eight to 12 million people in the United States, as cited by the authors of the PARTNERS study published in the Journal of the American Medical Association in 2001. According to 2007 statistics from the American Heart Association, PAD becomes more common with age and affects approximately 12% to 20% of the 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

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knee are generally long, straight and relatively wide, while arteries below the knee are shorter and branch into arteries that are progressively smaller in diameter.

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

Physicians treat a significant portion of the 2.5 million people in the United States who are diagnosed with PAD using medical management, which includes lifestyle changes, such as diet and exercise, and drug treatment. For instance, within a reference group of over 1,000 patients from the PARTNERS study, 54% of the patients with a prior diagnosis of PAD were receiving antiplatelet medication treatment. While medications, diet and exercise may improve blood flow, they do not treat the underlying obstruction 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.

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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.

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 April 30, 2008, we held 16 issued U.S. patents and 27 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 have experienced an other-than-temporary decline in value, which has adversely affected 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.

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

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

We were incorporated in Minnesota in 1989. 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 to repay outstanding debt with a principal balance of $10.9 million at March 31, 2008, plus accrued interest, and 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 16,663,459 shares outstanding as of April 30, 2008, and excludes:

- 6,013,974 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of $6.56 per share;
- 929,175 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $5.55 per share; and
- 8,582 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 nine months ended March 31, 2007 and 2008 and consolidated balance sheet data as of March 31, 2008 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 nine months ended March 31, 2008 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,			Nine Months Ended March 31,	
	2005	2006	2007[1]	2007[1]	2008[1]
	(in thousands, except share and per share amounts)				
Consolidated Statements of Operations Data:					
Revenues	$	$	$	$	$ 12,285
Cost of goods sold					5,244
Gross profit					7,041
Expenses:					
Selling, general and administrative	1,177	1,735	6,691	4,077	23,276
Research and development	2,371	3,168	8,446	4,442	10,662
Total expenses	3,548	4,903	15,137	8,519	33,938
Loss from operations	(3,548)	(4,903)	(15,137)	(8,519)	(26,897)
Other income (expense):					
Interest expense		(48)	(1,340)	(881)	(912)
Interest income	37	56	881	746	1,012
Impairment on investments					(1,023)
Total other income (expense)	37	8	(459)	(135)	(923)
Net loss	(3,511)	(4,895)	(15,596)	(8,654)	(27,820)
Accretion of redeemable convertible preferred stock[2]			(16,835)	(12,403)	(19,422)

Net loss available to common shareholders	$ (3,511)	$ (4,895)	$ (32,431)	$ (21,057)	$ (47,242)
Loss per common share:					
Basic and diluted[3]	$ (0.61)	$ (0.79)	$ (5.22)	$ (3.39)	$ (7.14)
Weighted average common shares used in computation:					
Basic and diluted[3]	5,779,942	6,183,715	6,214,820	6,205,810	6,612,225
Pro forma loss per common share:					
Basic and diluted			$ (1.47)		$ (2.08)
Pro forma weighted average common shares used in computation:					
Basic and diluted			10,605,726		13,344,453

(footnotes appear on following page)

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(1) Operating expenses in the year ended June 30, 2007 and the nine months ended March 31, 2007 and 2008 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	Nine Months Ended March 31, 2007	Nine Months Ended March 31, 2008
		(in thousands)	
Cost of goods sold	$	$ 1	$ 141
Selling, general and administrative	327	202	5,893
Research and development	63	20	188

(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 March 31, 2008		
	Actual	Pro Forma[1]	Pro Forma as Adjusted[2]
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 16,087	$ 16,087	$
Working capital[3]	6,724	6,724	
Total current assets	24,930	24,930	
Total assets	48,817	48,817	
Redeemable convertible preferred stock warrants	3,982		
Total liabilities	22,290	18,308	
Redeemable convertible preferred stock	98,242		
Total shareholders (deficiency) equity	(71,715)	30,509	

(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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Quarterly Results of Operations

The following table presents our unaudited quarterly results of operations for each of our last eight quarters ended March 31, 2008. You should read the following table in conjunction with the consolidated financial statements and related notes contained elsewhere in this prospectus. We have prepared the unaudited information on the same basis as our audited consolidated financial statements. These interim financial statements reflect all adjustments consisting of normal recurring accruals, which, in the opinion of management, are necessary to present fairly the results of our operations for the interim periods. Results of operations for any quarter are not necessarily indicative of results for any future quarters or for a full year.

	June 30, 2006	September 30, 2006	December 31, 2006	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007	March 31, 2008
	(in thousands)							
Consolidated Statements of Operations Data:								
Revenues	$	$	$	$	$	$	$ 4,631	$ 7,654
Gross profit (loss)						(539)	2,438	5,142
Loss from operations	(1,510)	(1,572)	(2,964)	(3,984)	(6,618)	(7,419)	(10,187)	(9,291)
Net loss	(1,542)	(1,329)	(3,139)	(4,187)	(6,942)	(7,441)	(9,768)	(10,611)
Net loss available to common shareholders[(1)]	(1,542)	(5,207)	(7,266)	(8,584)	(11,374)	(12,294)	(10,121)	(24,827)

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

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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 have experienced an other-than-temporary decline in value, which has adversely affected our income. These circumstances, along with our history of incurring substantial operating losses and negative cash flows from operations, raise substantial doubt about our ability to continue as a going concern.

As of March 31, 2008, our investments included $23.0 million of AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program. These auction rate securities are debt instruments with a long-term maturity and with an interest rate that is reset in short intervals, primarily every 28 days, through auctions. The recent conditions in the global credit markets have prevented us from liquidating our holdings of auction rate securities because the amount of securities submitted for sale has exceeded the amount of purchase orders for such securities. In February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $23.0 million in auction rate securities held at March 31, 2008. Currently, these affected securities are not liquid and will not become liquid until a future auction for these investments is successful or they are redeemed by the issuer or they mature. In the event that we need to access the funds of our auction rate securities that have experienced insufficient demand at auctions, we will not be able to do so without the possible loss of principal, until a future auction for these investments is successful or they are redeemed by the issuer or they mature. If we are unable to sell these securities in the market or they are not redeemed, then we may be required to hold them to maturity and we may have insufficient funds to operate our business. At March 31, 2008, we recorded an other-than-temporary impairment loss of $1.0 million relating to these securities in our statement of operations. We will continue to monitor and evaluate the value of our investments each reporting period for further possible impairment or unrealized loss.

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 equity or debt capital prior to September 30, 2008. 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 to enable us to continue as a going concern. Although we obtained an $11.5 million margin loan from a financial institution secured by the auction rate securities on March 28, 2008, 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 $27.8 million in the nine months ended March 31, 2008. As of March 31, 2008, we had an accumulated deficit of approximately $107.0 million. We only commenced limited commercial sales of the Diamondback 360° Orbital Atherectomy System in September 2007, and our short commercialization experience makes it difficult for us to predict future performance. We also expect to incur significant additional expenses for sales and marketing and manufacturing as we continue to commercialize the Diamondback 360° and additional expenses as we seek to develop and commercialize future versions of the Diamondback 360° and other products. Additionally, we expect that our general and administrative expenses will increase as our business grows and we incur the legal and regulatory costs associated with being a public company. As a result, we expect to continue to incur significant operating losses for the foreseeable future.

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

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

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.

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

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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 to us and our customers, making us vulnerable to supply problems and price fluctuations.

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

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

Other than existing, unfulfilled purchase orders, our suppliers have no contractual obligations to supply us with, and we are not contractually obligated to purchase from them, any of our supplies. Any supply interruption from our suppliers or failure to obtain additional suppliers for any of the components used in our products would limit our ability to manufacture our products and could have a material adverse effect on our business, financial condition and results of operations. We have no reason to believe that any of our current suppliers could not be replaced if they were unable to deliver components to us in a timely manner or at an acceptable price and level of quality. However, if we lost one of these suppliers and were unable to obtain an alternate source on a timely basis or

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on terms acceptable to us, our production schedules could be delayed, our margins could be negatively impacted, and we could fail to meet our customers demand. Our customers rely upon our ability to meet committed delivery dates and any disruption in the supply of key components would adversely affect our ability to meet these dates and could result in legal action by our customers, cause us to lose customers or harm our ability to attract new customers, any of which could decrease our revenue and negatively impact our growth. In addition, to the extent that our suppliers use technology or manufacturing processes that are proprietary, we may be unable to obtain comparable materials or components from alternative sources.

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

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

The growth we may experience in the future will provide challenges to our organization, requiring us to rapidly expand our sales and marketing personnel and manufacturing operations. Our sales and marketing force has increased from six employees on January 1, 2007 to 73 employees on April 30, 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.

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

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

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

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

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

We are highly dependent on our senior management, especially David L. Martin, our President and Chief Executive Officer. Our success will depend on our ability to retain 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 six new executives to our management team, including our Chief Executive Officer, who joined us in February 2007, and our Chief Financial Officer, who joined us in April 2008. During the preparation for this offering, our board of directors determined that it would be in our best interests to replace James Flaherty in his role as Chief Financial Officer due to his consent to a court order enjoining him from any violation of certain provisions of federal securities law in connection with events that occurred while he was the Chief Financial Officer of Zomax Incorporated. The board of directors desired to retain Mr. Flaherty as a member of our executive team, and, accordingly, Mr. Flaherty became our Chief Administrative Officer, giving him responsibility over non-financial operations matters, and Mr. Martin became Interim Chief Financial Officer until the hiring of Laurence L. Betterley as our Chief Financial Officer. Our new executives lack long-term experience with us. We may experience instability in

the short term as our new executives become integrated into our company. Competition for qualified employees is intense and the loss of service of any of our executive officers or certain key employees could delay or curtail our research, development, commercialization and financial objectives.

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

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

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

We may be subject to damages or other remedies as a result of the ev3 litigation.

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

Risks Related to Government Regulation

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

The Diamondback 360° received FDA 510(k) clearance in the United States for use as a therapy in patients with PAD. This general clearance restricts our ability to market or advertise the Diamondback 360° beyond this use and could affect our growth. While off-label uses of medical devices are common and the FDA does not regulate physicians

choice of treatments, the FDA does restrict a manufacturer s communications regarding such off-label use. We will not actively promote or advertise the Diamondback 360° for off-label uses. In addition, we cannot make comparative claims regarding the use of the Diamondback 360° against any alternative treatments without conducting head-to-head comparative clinical trials, which would be expensive and time consuming. We do not have any current plans to conduct clinical trials in the near future to evaluate the Diamondback 360° against any

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alternative method of treatment. If our promotional activities fail to comply with the FDA s regulations or guidelines, we may be subject to FDA warnings or enforcement action.

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

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

- failure to obtain approval from the FDA or any foreign regulatory authority to commence an investigational study;
- conditions imposed on us by the FDA or any foreign regulatory authority regarding the scope or design of our clinical trials;
- delays in obtaining or maintaining required approvals from institutional review boards or other reviewing entities at clinical sites selected for participation in our clinical trials;
- insufficient supply of our future product candidates or other materials necessary to conduct our clinical trials;
- difficulties in enrolling patients in our clinical trials;
- negative or inconclusive results from clinical trials, results that are inconsistent with earlier results, or the likelihood that the part of the human anatomy involved is more prone to serious adverse events, necessitating additional clinical trials;
- serious or unexpected side effects experienced by patients who use our future product candidates; or
- failure by any of our third-party contractors or investigators to comply with regulatory requirements or meet other contractual obligations in a timely manner.

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

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

We may become subject to regulatory actions in the event we are found to promote the Diamondback 360° for unapproved uses.

If the FDA determines that our promotional materials, training or other activities constitute promotion of our product for an unapproved use, it could request that we cease use of or modify our training or promotional materials or subject us to regulatory enforcement actions, including the issuance of an untitled or warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider promotional, training or other materials to constitute promotion of our product for an unapproved or uncleared use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

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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 l