CARDIOVASCULAR SYSTEMS INC
Form S-1/A
September 08, 2008

As filed with the Securities and Exchange Commission on September 8, 2008
Registration No. 333-148798

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

AMENDMENT NO. 6 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)

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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 Securities to be Registered	**Proposed Maximum Aggregate Offering Price[1][2]**	**Amount of Registration 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.

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 September 8, 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

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.

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.

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.

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

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.

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 July 31, 2008, we held 16 issued U.S. patents and 32 issued or granted 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 broad 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.

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.

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 balance of $22.9 million at August 31, 2008, 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 12,018,012 shares outstanding as of July 31, 2008, and excludes:

- 4,198,576 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of $9.22 per share;
- 646,719 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $7.78 per share; and
- 176,591 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:

- a 0.71-for-1 reverse stock split of our common stock and preferred stock that will occur prior to the consummation of this offering;
- the conversion of all our outstanding shares of preferred stock upon the closing of this offering into 6,491,358 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 473,152 shares of common stock and no exercise of such warrants; and
- no exercise of the underwriters over-allotment option.

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, 2006, 2007 and 2008 and the consolidated balance sheet data as of June 30, 2008 from our audited consolidated financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be experienced in the future. 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,		
	2006	2007[1]	2008[1]
	(in thousands, except share and per share amounts)		
Consolidated Statements of Operations Data:			
Revenues	$	$	$ 22,177
Cost of goods sold			8,927
Gross profit			13,250
Expenses:			
Selling, general and administrative	1,735	6,691	35,326
Research and development	3,168	8,446	16,068
Total expenses	4,903	15,137	51,394
Loss from operations	(4,903)	(15,137)	(38,144)
Other income (expense):			
Interest expense	(48)	(1,340)	(923)
Interest income	56	881	1,167
Impairment on investments			(1,267)
Total other income (expense)	8	(459)	(1,023)
Net loss	(4,895)	(15,596)	(39,167)
Accretion of redeemable convertible preferred stock[2]		(16,835)	(19,422)
Net loss available to common shareholders	$ (4,895)	$ (32,431)	$ (58,589)
Loss per common share:			
Basic and diluted[3]	$ (1.11)	$ (7.31)	$ (12.00)
Weighted average common shares used in computation:			
Basic and diluted[3]	4,416,939	4,439,157	4,882,233
Pro forma loss per common share:			
Basic and diluted			$ (3.73)

Pro forma weighted average common shares used in computation:	
Basic and diluted	10,508,095

(1) Operating expenses in the years ended June 30, 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:

	Years Ended June 30,	
	2007	**2008**
Cost of goods sold	$	$ 232
Selling, general and administrative	327	6,852
Research and development	63	297

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

(footnotes appear on following page)

(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 June 30, 2008		
	Actual	Pro Forma[1]	Pro Forma as Adjusted[2]
		(in thousands)	
Consolidated Balance Sheet Data:			
Cash and cash equivalents	$ 7,595	$ 7,595	
Working capital[3]	(3,118)	(3,118)	
Total current assets	18,204	18,204	
Total assets	41,958	41,958	
Redeemable convertible preferred stock warrants	3,986		
Total liabilities	25,408	21,422	
Redeemable convertible preferred stock	98,242		
Total shareholders (deficiency) equity	(81,692)	20,536	

(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. The repayment of $11.9 million of outstanding indebtedness as described under Use of Proceeds has not been reflected in the Pro Forma as Adjusted column. A $1.00 increase (decrease) in the assumed initial public offering price of $ per share would increase (decrease) cash and cash equivalents, working capital, total current assets, 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.

Quarterly Results of Operations

The following table presents our unaudited quarterly results of operations for each of our last eight quarters ended June 30, 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.

	September 30, 2006	December 31, 2006	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007	March 31, 2008	June 30, 2008
	(in thousands)							
Consolidated Statements of Operations Data:								
Revenues	$	$	$	$	$	$ 4,631	$ 7,654	$ 9,892
Gross profit (loss)					(539)	2,438	5,142	6,209
Loss from operations	(1,571)	(2,964)	(3,984)	(6,618)	(7,419)	(10,187)	(9,291)	(11,247)
Net loss	(1,328)	(3,139)	(4,187)	(6,942)	(7,441)	(9,768)	(10,611)	(11,347)
Net loss available to common shareholders[(1)]	(5,207)	(7,266)	(8,584)	(11,374)	(12,294)	(10,121)	(24,827)	(11,347)

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

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

In addition, we have incurred substantial operating losses and negative cash flows from operations, all of which will require us to obtain additional funding to continue our operations, management has concluded that there is substantial doubt about our ability to continue as a going concern. Based on the factors described above, our independent registered public accountants have included an explanatory paragraph in their report for our fiscal year ended June 30, 2008 with respect to our ability to continue as a going concern. On March 28, 2008, we obtained a margin loan from UBS Financial Services, Inc., the entity through which we originally purchased our auction rate securities, for up to $12.0 million, which was secured by the $23.0 million par value of our auction rate securities. On August 21, 2008, we replaced this loan with a margin loan from UBS Bank USA, which increased maximum borrowings available to $23.0 million. Based on anticipated operating requirements, combined with limited capital resources, financing our operations will require that we raise additional equity or debt capital prior to December 31, 2008 if we do not

complete this offering. 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.

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, $15.6 million in fiscal 2007, and $39.2 million in fiscal 2008. As of June 30, 2008, we had an accumulated deficit of approximately $118.3 million. We only commenced commercial sales of the Diamondback 360° Orbital Atherectomy System in September 2007, and our short commercialization experience makes it difficult for us to predict future performance. We also expect to incur significant additional expenses for sales and marketing and manufacturing as we continue to commercialize the Diamondback 360° and additional expenses as we seek to develop and commercialize future versions of the Diamondback 360° and other products. Additionally, we expect that our general and administrative expenses will increase as our business grows and we incur the legal and regulatory costs associated with being a public company. As a result, we expect to continue to incur significant operating losses 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;

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.

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

Our competitors may:

- develop and patent processes or products earlier than we will;

obtain regulatory clearances or approvals for competing medical device products more rapidly than we will;

market their products more effectively than we will; or

develop more effective or less expensive products or technologies that render our technology or products obsolete or non-competitive.

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

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

The market for medical devices is highly competitive, dynamic and marked by rapid and substantial technological development and product innovations. Our ability to compete depends on our ability to innovate successfully, and there are few barriers that would prevent new entrants or existing competitors from developing products that compete directly with 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.

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 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 101 employees on July 31, 2008, and we expect to continue to grow our sales and marketing force. We also expect to significantly expand our manufacturing operations to meet anticipated growth in demand for our products. Rapid expansion in personnel means that less experienced people may be producing and selling our product, which could result in unanticipated costs and disruptions to our operations. If we cannot scale and manage our business appropriately, our anticipated growth may be impaired and our financial results will suffer.

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 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.

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 certain of our employees violated their employment agreements with FoxHollow requiring them to refrain from soliciting FoxHollow employees. This litigation is in an early stage and there can be no assurance as to its outcome. We are defending this litigation vigorously. If we are not successful in defending it, we could be required to pay substantial damages and be subject to equitable relief that could include a requirement that we terminate the employment of certain employees, including certain key sales personnel who were formerly employed by FoxHollow. In any event, the defense of this litigation, regardless of the outcome, could result in substantial legal costs and diversion of our management s time and efforts from the operation of our business. If the plaintiffs in this litigation are successful, it could have a material adverse effect on our business, operations and financial condition.

Risks Related to Government Regulation

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

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

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

study. We may encounter problems with our clinical trials, and any of those problems could cause us or the FDA to suspend those trials, or delay the analysis of the data derived from them.

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

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

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

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

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

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

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

The FDA and similar governmental authorities in other countries have the authority to require the recall of commercialized products in the event of material regulatory deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design or labeling defects. We have not had any instances requiring consideration of a recall, although as we continue to grow and develop our products, including the Diamondback 360°, we may see instances of field

performance requiring a recall. Any recalls of our product would divert managerial and financial resources, harm our reputation with customers and have an adverse effect on our financial condition and results of operations.

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

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

warning letters or untitled letters from the FDA;

fines, injunctions and civil penalties;

product recall or seizure;

unanticipated expenditures;

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

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

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

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

criminal prosecution.

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

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

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

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

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

carotid arteries, as opposed to peripheral arteries, is more likely to result in complications that have serious consequences, including heart attacks or strokes which could result, in certain circumstances, in death.

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

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

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

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

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

Our relationships with physicians, hospitals and the marketers of our products are subject to scrutiny under various federal anti-kickback, self-referral, false claims and similar laws, often referred to collectively as healthcare fraud and abuse laws. Healthcare fraud and abuse laws are complex, and even minor, inadvertent violations can give rise to claims that the relevant law has been violated. If our operations are found to be in violation of these laws, we, as well as our employees, may be subject to penalties, including monetary fines, civil and criminal penalties, exclusion from federal and state healthcare programs, including Medicare, Medicaid, Veterans Administration health programs, workers compensation programs and TRICARE (the healthcare system administered by or on behalf of the U.S. Department of Defense for uniformed services beneficiaries, including active duty and their dependents, retirees and their dependents), and forfeiture of amounts collected in violation of such prohibitions. Individual employees may need to defend such suits on behalf of us or themselves, which could lead to significant disruption in our present and future operations. Certain states in which we intend to market our products have similar fraud and abuse laws, imposing substantial penalties for violations. Any government investigation or a 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 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 July 31, 2008, we had a portfolio of 16 issued U.S. patents and 32 issued or granted non-U.S. patents covering aspects of our core technology, which expire between 2017 and 2022. However, our issued patents and related intellectual property may not be adequate to protect us or permit us to gain or maintain a competitive advantage. The issuance of a patent is not conclusive as to its scope, validity or enforceability. The scope, validity or enforceability of our issued patents can be challenged in litigation or proceedings before the U.S. Patent and Trademark Office, or the USPTO. In addition, our pending patent applications include claims to numerous important aspects of our products under development that are not currently protected by any of our issued patents. We cannot assure you that any of our pending patent applications will result in the issuance of patents to us. The USPTO may deny or require significant narrowing of claims in our pending patent applications. Even if any patents are issued as a result of pending patent applications, they may not provide us with significant commercial protection or be issued in a form that is advantageous to us. Proceedings before the USPTO could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. Further, if any patents we obtain or license are deemed invalid and unenforceable, or have their scope narrowed, it could impact our ability to commercialize or license our technology.

Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. For instance, the U.S. Supreme Court has recently modified some tests used by the USPTO in granting patents during the past 20 years, which may decrease the likelihood that we will be

able to obtain patents and increase the likelihood of challenge of any patents we obtain or license. In addition, the USPTO has adopted new rules of practice (the application of which has been enjoined as a result of litigation) that limit the number of claims that may be filed in a patent application and the number of continuation or continuation-in-part applications that can be filed may result in patent applicants being unable to secure all of the rights that they would otherwise have been entitled to in the absence of the new rules and, therefore, may negatively

effect our ability to obtain comprehensive patent coverage. The laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, if at all.

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

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

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

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

The medical technology industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. The likelihood that patent infringement or misappropriation claims may be brought against us increases as we achieve more visibility in the marketplace and introduce products to market. All issued patents are entitled to a presumption of validity under the laws of the United States. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Our competitors may assert that our products are covered by U.S. or foreign patents held by them. We are aware of numerous patents issued to third parties that relate to the manufacture and use of medical devices for interventional cardiology. The owners of each of these patents could assert that the manufacture, use or sale of our products infringes one or more claims of their patents. Because patent applications may take years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that we infringe. If another party has filed

a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings can be substantial, and it is possible that such efforts would be unsuccessful if unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. There could also be existing patents of which we are unaware that one or more aspects of our technology may inadvertently infringe. In some cases, litigation may be

threatened or brought by a patent-holding company or other adverse patent owner who has no relevant product revenues and against whom our patents may provide little or no deterrence.

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

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 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. Holders of over % of our outstanding common stock immediately prior to this offering (including all of our officers and directors, and assuming conversion of all of our preferred stock into common stock) have agreed not to transfer their shares without the consent of the representatives of the underwriters for 180 days from the date of this prospectus. 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 for the repayment of outstanding debt and, 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 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.

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.

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 to repay a margin loan we obtained from UBS Bank USA for up to $23.0 million, and for working capital and general corporate purposes. The margin loan has a floating interest rate equal to 30-day LIBOR, plus 1.0%, has no maturity date and is due on demand. The outstanding balance of this debt at August 31, 2008 was $22.9 million. 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.

CAPITALIZATION

The following table sets forth our capitalization as of June 30, 2008 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 and the application of a portion of the proceeds therefrom as set forth under Use of Proceeds.

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 June 30, 2008		
	Actual	Pro Forma	Pro Forma as Adjusted[1]
	(in thousands, except share and per share data)		
Redeemable convertible preferred stock warrants	$ 3,986	$	$
Series A redeemable convertible preferred stock, no par value; 3,857,116 shares authorized, 3,383,949 issued and outstanding, actual; no shares issued and outstanding, pro forma; no shares issued and outstanding, pro forma as adjusted	51,213		
Series A-1 redeemable convertible preferred stock, no par value; 1,563,057 shares authorized, 1,563,057 issued and outstanding, actual; no shares issued and outstanding, pro forma; no shares issued and outstanding, pro forma as adjusted	23,657		
Series B redeemable convertible preferred stock, no par value; 1,544,360 shares authorized, 1,544,352 issued and outstanding, actual; no shares issued and outstanding, pro forma; no shares issued and outstanding, pro forma as adjusted	23,372		
Shareholders (deficiency) equity:			
Common stock, no par value per share, 50,000,000 common shares and 3,571,428 undesignated shares authorized, 5,410,322 shares issued and outstanding, actual; 50,000,000 common shares and 3,571,428 undesignated shares authorized, 11,901,680 shares issued and outstanding, pro forma; 50,000,000 common shares and	35,933	134,175	

3,571,428 undesignated shares authorized, shares issued and outstanding, pro forma as adjusted;		
Common stock warrants	680	4,666
Accumulated deficit	(118,305)	(118,305)
Total shareholders (deficiency) equity	(81,692)	$ 20,536
Total capitalization	$ 20,536	$ 20,536

(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 common stock, 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.

The outstanding shares set forth in the table above excludes, as of June 30, 2008:

- 4,198,576 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of $9.22 per share;

- 647,611 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $7.78 per share; and

- 21,032 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.

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 June 30, 2008 was $(82.7) million, or $(15.28) 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 June 30, 2008 was approximately $19.6 million, or approximately $1.64 per share, based on the number of shares outstanding as of June 30, 2008, 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 June 30, 2008, 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 June 30, 2008	$ (15.28)	
Increase per share attributable to conversion of preferred stock	16.92	
Pro forma net tangible book value per share as of June 30, 2008	1.64	
Increase per share attributable to new investors		
Pro forma as adjusted net tangible book value per share as of June 30, 2008		
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 June 30, 2008, 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 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 percentage of shares of common stock held by existing shareholders to 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 June 30, 2008 exclude:

- 4,198,576 shares of common stock issuable upon the exercise of outstanding stock options at a weighted average exercise price of $9.22 per share;
- 647,611 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of $7.78 per share; and
- 21,032 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 June 30, 2008 would have been $ million, or $ per share of common stock, representing an immediate increase in pro forma net tangible book value of $ per share of common stock to our existing shareholders and an immediate dilution of $ per share to investors purchasing shares in this offering.

Because we expect the exercise prices of the outstanding options and warrants to be below the assumed initial public offering price of $ per share, investors purchasing common stock in this offering will suffer additional dilution when and if these options and warrants are exercised. If the options exercisable for 4,198,576 shares and warrants exercisable for 647,611 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.

SELECTED CONSOLIDATED FINANCIAL DATA

The following table presents our selected historical consolidated financial data. We derived the selected statements of operations data for the years ended June 30, 2006, 2007 and 2008 and balance sheet data as of June 30, 2007 and 2008 from our audited consolidated financial statements and related notes that are included elsewhere in this prospectus. We derived the selected consolidated statements of operations data for the years ended June 30, 2004 and 2005 and the balance sheet data as of June 30, 2004, 2005, and 2006 from our audited consolidated financial statements that do not appear in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future. 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,				
	2004	2005	2006	2007[1]	2008[1]
	(in thousands, except share and per share amounts)				
Consolidated Statements of Operations Data:					
Revenues	$	$	$	$	$ 22,177
Cost of goods sold					8,927
Gross profit					13,250
Expenses[1]:					
Selling, general and administrative	984	1,177	1,735	6,691	35,326
Research and development	3,246	2,371	3,168	8,446	16,068
Total expenses	4,230	3,548	4,903	15,137	51,394
Loss from operations	(4,230)	(3,548)	(4,903)	(15,137)	(38,144)
Other income (expense):					
Interest expense			(48)	(1,340)	(923)
Interest income	18	37	56	881	1,167
Impairment on investments					(1,267)
Total other income (expense)	18	37	8	(459)	(1,023)
Net loss	(4,212)	(3,511)	(4,895)	(15,596)	(39,167)
Accretion of redeemable convertible preferred stock[2]				(16,835)	(19,422)
Net loss available to common shareholders	$ (4,212)	$ (3,511)	$ (4,895)	$ (32,431)	$ (58,589)
Loss per common share:					
Basic and diluted[3]	$ (1.10)	$ (0.85)	$ (1.11)	$ (7.31)	$ (12.00)

Weighted average common shares used in computation:					
Basic and diluted[3]	3,839,854	4,128,530	4,416,939	4,439,157	4,882,233
Pro forma loss per common share:					
Basic and diluted					$ (3.73)
Pro forma weighted average common shares used in computation:					
Basic and diluted					10,508,095

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

	Years Ended June 30,	
	2007	**2008**
Cost of goods sold	$	$ 232
Selling, general and administrative	327	6,852
Research and development	63	297

(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.

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

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

Quarterly Results of Operations

The following table presents our unaudited quarterly results of operations for each of our last eight quarters ended June 30, 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.

	September 30, 2006	December 31, 2006	March 31, 2007	June 30, 2007	September 30, 2007	December 31, 2007	March 31, 2008	June 30, 2008
				(in thousands)				
Consolidated Statements of Operations Data:								
Revenues	$	$	$	$	$	$ 4,631	$ 7,654	$ 9,892
Gross profit (loss)					(539)	2,438	5,142	6,209
Loss from operations	(1,571)	(2,964)	(3,984)	(6,618)	(7,419)	(10,187)	(9,291)	(11,247)
Net loss	(1,328)	(3,139)	(4,187)	(6,942)	(7,441)	(9,768)	(10,611)	(11,347)
Net loss available to common shareholders[(1)]	(5,207)	(7,266)	(8,584)	(11,374)	(12,294)	(10,121)	(24,827)	(11,347)

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

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

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

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

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

As of June 30, 2008, we had an accumulated deficit of $118.3 million. We expect our losses to continue and to increase as we continue our commercialization activities, develop additional product enhancements and make further regulatory submissions. To date, we have financed our operations primarily through the private placement of equity securities.

Our consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Since our inception, we have experienced substantial operating losses and negative cash flows from operations. We had cash and cash equivalents of $7.6 million at June 30, 2008. During the years ended June 30, 2007 and 2008, net cash used in operations amounted to $12.3 million and $31.9 million, respectively. In February 2008, we were notified that recent conditions

in the global credit markets have caused insufficient demand for auction rate securities, resulting in failed auctions for $23.0 million of our auction rate securities held at June 30, 2008. These securities are currently not liquid, as we have an inability to sell the securities due to continued failed auctions. As a result, we recorded an other-than-temporary impairment loss of $1.3 million relating to these securities in our statement of operations for the year ended June 30, 2008. On March 28, 2008, we obtained a margin loan from UBS Financial Services, Inc., the entity through which we originally purchased our auction rate securities, for up to $12.0 million, which was secured by the $23.0 million par value of our auction rate securities. The outstanding balance on this loan at June 30, 2008 was $11.9 million. On August 21, 2008, we replaced this loan with a margin loan from UBS Bank USA, which increased maximum borrowings available to $23.0 million. This maximum borrowing amount is not set forth in the written agreement for the loan and may be adjusted from time to time by UBS Bank in its sole discretion. The

margin loan has a floating interest rate equal to 30-day LIBOR, plus 1.0%. The loan is due on demand and UBS Bank will require us to repay it in full from the proceeds received from a public equity offering where net proceeds exceed $50.0 million. In addition, if at any time any of our auction rate securities may be sold, exchanged, redeemed, transferred or otherwise conveyed for no less than their par value, then we must immediately effect such a transfer and the proceeds must be used to pay down outstanding borrowings under this loan. The margin requirements are determined by UBS Bank but are not included in the written loan agreement and are therefore subject to change. From August 21, 2008, the date this loan was initially funded, through the date of this prospectus, the margin requirements included maximum borrowings, including interest, of $23.0 million. If these margin requirements are not maintained, UBS Bank may require us to make a loan payment in an amount necessary to comply with the applicable margin requirements or demand repayment of the entire outstanding balance. We have maintained the margin requirements under the loans from both UBS entities. The outstanding balance on this loan at August 31, 2008 was $22.9 million.

Our ability to continue as a going concern ultimately depends on our ability to raise additional debt or equity capital prior to December 31, 2008 if we do not complete this 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.

During fiscal year 2009, we plan to continue to expand our sales and marketing efforts, conduct research and development of product improvements and increase our manufacturing capacity to support anticipated future growth. We believe the net proceeds of this offering, together with existing cash and cash equivalents 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 usually include ten single-use catheters and guidewires, along with a control unit. Reorders for single-use catheters and guidewires occur as hospitals utilize the single-use catheters.

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

Cost of Goods Sold. We assemble the single-use catheter with components purchased from third-party suppliers, as well as with components manufactured in-house. The control unit and guidewires are purchased from third-party suppliers. Our cost of goods sold consists primarily of direct labor, manufacturing overhead, purchased raw materials

and manufactured components. With the anticipated benefits of future cost reduction initiatives and increased volume and related economies of scale, we anticipate that gross margin percentages on single-use catheters that we assemble will be higher than those achieved on the control unit and guidewires that we purchase from third parties.

Selling, General and Administrative Expenses. Selling, general and administrative expenses include compensation for executive, sales, marketing, finance, information technology, human resources and administrative

personnel, including stock-based compensation. Other significant expenses include travel and marketing costs, professional fees, and patent prosecution expenses.

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

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

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

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

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

Critical Accounting Policies and Significant Judgments and Estimates

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

actual results may materially differ from these estimates.

Our significant accounting policies are described in Note 1 to our consolidated financial statements. Some of those significant accounting policies require us to make subjective or complex judgments or estimates. An accounting estimate is considered to be critical if it meets both of the following criteria: (1) the estimate requires assumptions about matters that are highly uncertain at the time the accounting estimate is made, and (2) different estimates that reasonably could have been used, or changes in the estimate that are reasonably likely to occur from

period to period, would have a material impact on the presentation of our financial condition, results of operations, or cash flows. We believe that the following are our critical accounting policies and estimates:

Revenue Recognition. We recognize revenue in accordance with SEC Staff Accounting Bulletin (SAB) No. 104, *Revenue Recognition* and EITF No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue is recognized when all of the following criteria are met: (1) persuasive evidence of an arrangement exists; (2) shipment of all components has occurred or delivery of all components has occurred if the terms specify that title and risk of loss pass when products reach their destination; (3) the sales price is fixed or determinable; and (4) collectability is reasonably assured. We have no additional post-shipment or other contractual obligations or performance requirements and do not provide any credits or other pricing adjustments affecting revenue recognition once these criteria have been met. The customer has no right of return on any component once the above criteria have been met. Payment terms are generally set at 30 days.

We derive our revenue through the sale of the Diamondback 360°, which includes single-use catheters, guidewires and control units used in the atherectomy procedure. Initial orders from all new customers require the customer to purchase the entire Diamondback 360° system, which includes multiple single-use catheters and guidewires and one control unit. Due to delays in the final FDA clearance of the new control unit and early production constraints of the new control unit, we were not able to deliver all components of the initial order. For these initial orders, we shipped and billed only for the single-use catheters and guidewires. In addition, we sent an older version of our control unit as a loaner unit with the customer s expectation that we would deliver and bill for a new control unit once it becomes available. As we have not delivered each of the individual components to all customers, we have deferred the revenue for the entire amount billed for single-use catheters and guidewires shipped to the customers that have not received the new control unit. Those billings totaled $116,000 at June 30, 2008, which amount has been deferred pending receipt of a customer purchase order and shipment of a new control unit. After the initial order, customers are not required to purchase any additional disposable products from us. Once we have delivered the new control unit to a customer, we recognize revenue that was previously deferred and revenue for subsequent reorders of single-use catheters, guidewires and additional new control units when the criteria of SAB No. 104 are met.

Investments. We classify all investments as available-for-sale. Investments are recorded at fair value and unrealized gains and losses are recorded as a separate component of shareholders deficiency until realized. Realized gains and losses are accounted for on the specific identification method. We have historically placed our investments primarily in auction rate securities, U.S. government securities, and commercial paper. These investments, a portion of which had original maturities beyond one year, were classified as short-term based on their liquid nature. The securities that had stated maturities beyond one year had certain economic characteristics of short-term investments due to a rate-setting mechanism and the ability to sell them through a Dutch auction process that occurred at pre-determined intervals, primarily every 28 days. For the years ended June 30, 2007 and 2008, the amount of gross realized gains and losses related to sales of investments were insignificant.

In February 2008, we were informed that there was insufficient demand for auction rate securities, resulting in failed auctions for $23.0 million of our auction rate securities held at June 30, 2008. 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 June 30, 2008, we have classified the fair value of the auction rate securities as a long-term asset. Starting in February 2008, interest rates on all auction rate securities were reset to temporary predetermined penalty or maximum rates. These maximum rates are generally limited to a maximum amount payable over a 12 month period equal to a rate based on the trailing 12-month average of 90-day treasury bills, plus 120 basis points. These maximum allowable rates range from 2.7% to 4.0% of par value per year. We have collected all interest due on our auction rate securities and have no reason to believe that we will not collect all interest due in the future. We do not expect to receive the principal associated with our auction rate securities until the earlier of a successful auction, their redemption by the issuer or their maturity. On March 28, 2008, we obtained a margin loan from UBS

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

sole discretion. The margin loan has a floating interest rate equal to 30-day LIBOR, plus 1.0%. The loan is due on demand and UBS Bank will require us to repay it in full from the proceeds received from a public equity offering where net proceeds exceed $50.0 million. In addition, if at any time any of our auction rate securities may be sold, exchanged, redeemed, transferred or otherwise conveyed for no less than their par value, then we must immediately effect such a transfer and the proceeds must be used to pay down outstanding borrowings under this loan. The margin requirements are determined by UBS Bank but are not included in the written loan agreement and are therefore subject to change. From August 21, 2008, the date this loan was initially funded, through the date of this prospectus, the margin requirements included maximum borrowings, including interest, of $23.0 million. If these margin requirements are not maintained, UBS Bank may require us to make a loan payment in an amount necessary to comply with the applicable margin requirements or demand repayment of the entire outstanding balance. We have maintained the margin requirements under the loans from both UBS entities. The outstanding balance on this loan at August 31, 2008 was $22.9 million.

In accordance with EITF 03-01 and FSP FAS 115-1 and 124-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments,* we review several factors to determine whether a loss is other-than-temporary. These factors include but are not limited to: (1) the length of time a security is in an unrealized loss position, (2) the extent to which fair value is less than cost, (3) the financial condition and near term prospects of the issuer, and (4) our intent and ability to hold the security for a period of time sufficient to allow for any unanticipated recovery in fair value. We recorded an other-than-temporary impairment loss of $1.3 million relating to our auction rate securities in our statement of operations for the year ended June 30, 2008. We determined the fair value of our auction rate securities and quantified the other-than-temporary impairment loss with the assistance of ValueKnowledge LLC, an independent third party valuation firm, which utilized various valuation methods and considered, among other factors, estimates of present value of the auction rate securities based upon expected cash flows, the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value, the likelihood of a return of liquidity to the market for these securities and the potential to sell the securities in secondary markets. We concluded that no weight should be given to the value indicated by the secondary markets for student loan-backed auction rate securities similar to those we hold because these markets have very low transaction volumes and consist primarily of private transactions with minimal disclosure, transactions may not be representative of the actions of typically-motivated buyers and sellers and we do not currently intend to sell in the secondary markets. However, we did consider the secondary markets for certain mortgage-backed securities but determined that these secondary markets do not provide a sufficient basis of comparison for the auction rate securities that we hold and, accordingly, attributed no weight to the values of these mortgage-backed securities indicated by the secondary markets. We attributed a weight of 66.7% to estimates of present value of the auction rate securities based upon expected cash flows and a weight of 33.3% to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or willingness of third parties to provide financing in the market against the par value of those securities. The attribution of these weights required the exercise of valuation judgment. A measure of liquidity is available from borrowing, which led to the 33.3% weight attributed to the likelihood and potential timing of issuers of the auction rate securities exercising their redemption rights at par value or the willingness of third parties to provide financing in the market against the par value of those securities. However, borrowing does not eliminate exposure to the risk of holding the securities, so the weight of 66.7% attributed to the present value of the auction rate securities based upon expected cash flows reflects the expectation that the securities are likely to be held for an uncertain period. We focused on these methodologies because no certainty exists regarding how the auction rate securities will be eventually converted to cash and these methodologies represent the most likely possible outcomes. To derive estimates of the present value of the auction rate securities based upon expected cash flows, we used the securities expected annual interest payments, ranging from 2.7% to 4.0% of par value, representing estimated maximum annual rates under the governing documents of the auction rate securities; annual market interest rates, ranging from 4.5% to 5.8%, based on observed traded, state sponsored, taxable certificates rated AAA or lower and issued between June 15 and June 30, 2008; and a range of expected terms to liquidity. Our weighting of the valuation methods indicates an implied term to liquidity of approximately 3.5 years. The implied term to liquidity of

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

securities to cash or the implied term to liquidity of approximately 3.5 years. The primary reason for the fair value being less than cost related to a lack of liquidity of the securities, rather than the financial condition and near term prospects of the issuer. Our auction rate securities include AAA rated auction rate securities issued primarily by state agencies and backed by student loans substantially guaranteed by the Federal Family Education Loan Program. These auction rate securities continue to be AAA rated auction rate securities subsequent to the failed auctions that began in February 2008. In addition to the valuation procedures described above, we considered (i) our current inability to hold these securities for a period of time sufficient to allow for an unanticipated recovery in fair value based on our current liquidity, history of operating losses, and management s estimates of required cash for continued product development and sales and marketing expenses, and (ii) failed auctions and the anticipation of continued failed auctions for all of our auction rate securities. Based on the factors described above, we recorded the entire amount of impairment loss identified for the year ended June 30, 2008 of $1.3 million as other-than-temporary. We did not identify or record any additional realized or unrealized losses for the year ended June 30, 2008. We will continue to monitor and evaluate the value of our investments each reporting period for further possible impairment or unrealized loss. Although we currently do not intend to do so, we may consider selling our auction rate securities in the secondary markets in the future, which may require a sale at a substantial discount to the stated principal value of these securities.

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

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

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

our common stock s volatility;

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

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

the risk-free rate of return; and

future dividends.

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

The absence of an active market for our common stock also requires our management and board of directors to estimate the fair value of our common stock for purposes of granting options and for determining stock-based compensation expense. In response to these requirements, our management and board of directors estimate the fair market value of common stock at each date at which options are granted based upon stock valuations and other

qualitative factors. We have conducted stock valuations using two different valuation methods: the option pricing method and the probability weighted expected return method, or PWERM. The option pricing method assumes a liquidation of a company and treats common and preferred stock as call options on the enterprise value. The option pricing method is often used when the possible outcomes for a liquidity event are deemed to have equal likelihood and when valuing securities with a high degree of uncertainty regarding potential future values. We used the option pricing method for valuations of our common stock as of July 19, 2006, December 31, 2006, June 29, 2007 and September 30, 2007, as we deemed all liquidity events to have equal likelihood at those dates. All of these valuations were conducted retrospectively. We began using the PWERM in contemporaneous valuations of our common stock as of December 31, 2007, March 31, 2008 and June 30, 2008, as of which time we had commenced significant efforts in connection with our initial public offering process and the probability of a public offering had increased. Accordingly, management and the board of directors determined that the PWERM would be more appropriate than the option pricing method. For the PWERM, we estimated the likely return to shareholders based upon our becoming a public company, being acquired or remaining a private company, and employed comparable public company, merger and acquisition transaction, and discounted cash flow analysis. These values were adjusted and weighted based on probability of occurrence. As of June 30, 2008, we assumed a 90% probability of completing an initial public offering, a 5% probability of being acquired, and a 5% probability of remaining a private company.

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

Financing Activity: Between July 19, 2006 and October 3, 2006, we sold $27.0 million in Series A convertible preferred stock at $7.99 per share; between May 16, 2007 and September 19, 2007, we sold $18.6 million in Series A-1 convertible preferred stock at $11.90 per share; and between November 13, 2007 and December 17, 2007, we sold $20.0 million in Series B convertible preferred stock at $12.95 per share. New and existing investors participated in the convertible preferred stock offerings, while certain existing investors declined the opportunity to participate. As of each valuation date, management and the board of directors considered the differences between the valuation of the common stock and the most recent price of our preferred stock and determined that such differences were reasonable and accurately reflected the anticipated time until a liquidity event, including this offering.

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 amounts assuming the conversion of the preferred stock, except the total amount to be distributed to the

preferred stock is subject to certain return on investment limitations. The aggregate liquidation preferences of our preferred stock at the dates listed below are as follows:

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

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

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

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

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

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

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. We filed the registration statement of which this prospectus is a part on January 22, 2008 and have filed several amendments.

Revenues: We recognized $22.2 million in revenues for the year ended June 30, 2008.

Our management and board of directors also considered the valuations of comparable public companies, our cash and working capital amounts, and additional objective and subjective factors relating to our business. For each valuation, our management and board of directors considered all of the factors that they considered to be relevant at the time and did not rely exclusively on any particular factors. Certain factors described with respect to each valuation represented progress in the development of our business, which reduced risk and improved the probability that we would achieve

our business plan. In addition, the order in which we have described these factors in this prospectus does not represent the relative importance or weight given to any of the factors.

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

Valuation as of July 19, 2006

This valuation estimated that the fair market value of our common stock as of July 19, 2006 was $3.40 per share, taking into consideration the sale of Series A convertible preferred stock at $7.99 per share and the hiring of

our Vice President of Sales and Vice President of Business Development to begin the process of building a sales organization in the period from July 2006 through September 2006.

Valuation as of December 31, 2006

This valuation estimated that the fair market value of our common stock as of December 31, 2006 was $3.91 per share, taking into consideration the sale of Series A convertible preferred stock at $7.99 per share, changes in the value of comparable public companies, the substantial completion of enrollment for the OASIS clinical trial, and the hiring of our Vice President of Marketing to continue building our sales and marketing function.

Valuation as of June 29, 2007

This valuation estimated that the fair market value of our common stock as of June 29, 2007 was $8.33 per share, taking into consideration the sale of Series A-1 convertible preferred stock at $11.90 per share, the completion of the OASIS clinical trial, the hiring of our Chief Executive Officer, our application for FDA 510(k) clearance for the Diamondback 360°, and the commencement of discussions with investment bankers regarding the initial public offering process.

Valuation as of September 30, 2007

This valuation estimated that the fair market value of our common stock as of September 30, 2007 was $10.30 per share, taking into consideration the sale of Series A-1 convertible preferred stock at $11.90 per share, expectation of the sale of Series B convertible preferred stock at $12.95 per share, receipt of FDA 510(k) clearance for the Diamondback 360°, continued discussions with investment bankers regarding the initial public offering process, the engagement of investment bankers to explore potential merger and acquisition opportunities, and the limited commercial launch of the Diamondback 360°.

Valuation as of December 31, 2007

This valuation estimated that the fair market value of our common stock as of December 31, 2007 was $11.82 per share, taking into consideration the sale of Series B convertible preferred stock at $12.95 per share, receipt of FDA 510(k) clearances for the updated control unit for the Diamondback 360° and for the Diamondback 360° with a solid crown, revenues of $4.6 million in revenue for the quarter ended December 31, 2007, and the holding of preparatory meetings as part of the initial public offering process.

Valuation as of March 31, 2008

This valuation estimated that the fair market value of our common stock as of March 31, 2008 was $14.38 per share, taking into consideration the sale of Series B convertible preferred stock at $12.95 per share during the quarter ending December 31, 2007, initiation of the full commercial launch of the Diamondback 360°, revenues of $12.3 million for the nine months ended March 31, 2008, and substantial completion of some of the milestones in the initial public offering process.

Valuation as of June 30, 2008

This valuation estimated that the fair market value of our common stock as of June 30, 2008 was $14.31 per share, taking into consideration revenues of $22.2 million for the year ended June 30, 2008 and substantial completion of additional milestones in the initial public offering process. This valuation also considered uncertain conditions in the public markets, which resulted in a slightly lower valuation of our common stock than the March 31, 2008 valuation.

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