CARDIOVASCULAR SYSTEMS INC
Form S-1/A
August 15, 2008

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**As filed with the Securities and Exchange Commission on August 15, 2008**
**Registration No. 333-148798**

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

**AMENDMENT NO. 5 TO**
**Form S-1**
**REGISTRATION STATEMENT**
**UNDER**
**THE SECURITIES ACT OF 1933**

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

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

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

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

*Copies to:*

**Robert K. Ranum, Esq.**
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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**.

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

**PROSPECTUS (Subject to Completion)**
**Issued August 15, 2008**

**Shares**

**Cardiovascular Systems, Inc.**

**Common Stock**

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

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

**Investing in our common stock involves risks. See Risk Factors beginning on page 9.**

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

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

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

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

**Morgan Stanley** **Citi**

**William Blair & Company**

, 2008

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

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

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

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

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

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**Market and Industry Data**

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

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## PROSPECTUS SUMMARY

*This summary highlights selected information contained in more detail later in this prospectus. This summary provides an overview of selected information and does not contain all the information you should consider. You should carefully read the entire prospectus including Risk Factors beginning on page 9 and the financial statements and related notes before making an investment decision. References in this prospectus to CSI, our company, we, us our refer to Cardiovascular Systems, Inc. and its subsidiaries, except where the context makes clear that the reference is only to Cardiovascular Systems, Inc. itself and not its subsidiaries.*

### Our Business

We are a medical device company focused on developing and commercializing interventional treatment systems for vascular disease. Our initial product, the Diamondback 360° Orbital Atherectomy System, is a minimally invasive catheter system for the treatment of peripheral arterial disease, or PAD. PAD is a common circulatory problem in which plaque deposits build up on the walls of vessels, reducing blood flow. The plaque deposits range from soft to calcified, with calcified plaque being difficult to treat with traditional interventional procedures. The Diamondback 360° is capable of treating a broad range of plaque types, including calcified vessel lesions, and addresses many of the limitations associated with existing treatment alternatives.

The Diamondback 360° removes both soft and calcified plaque in plaque-lined vessels through the orbital rotation of a diamond grit coated offset crown that is attached to a flexible drive shaft. Physicians position the crown at the site of an arterial plaque lesion and remove the plaque by causing the crown to orbit against it, creating a smooth lumen, or channel, in the vessel. The Diamondback 360° is designed to differentiate between plaque and compliant arterial tissue, a concept that we refer to as differential sanding. The particles of plaque resulting from differential sanding are generally smaller than red blood cells and are carried away by the blood stream. As the physician increases the rotational speed of the drive shaft, the crown rotates faster and centrifugal force causes the crown to orbit, creating a lumen with a diameter that is approximately twice the diameter of the device. By giving physicians the ability to create different lumen diameters by changing rotational speed, the Diamondback 360° can reduce the need to use multiple catheters of different sizes to treat a single lesion.

We have conducted three clinical trials involving 207 patients to demonstrate the safety and efficacy of the Diamondback 360° in treating PAD. In particular, our pivotal OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions. In August 2007, the U.S. Food and Drug Administration, or FDA, granted us 510(k) clearance for use of the Diamondback 360° as a therapy in patients with PAD. We were the first, and so far the only, company to conduct a prospective multi-center clinical trial with a prior investigational device exemption in support of a 510(k) clearance for an atherectomy device. We commenced a limited commercial introduction of the Diamondback 360° in the United States in September 2007. This limited commercial introduction intentionally limited the size of our sales force and the number of customers each member of the sales force served in order to focus on obtaining quality and timely product feedback on initial product usages. During the quarter ended March 31, 2008, we began our full commercial launch. We believe that the Diamondback 360° provides a platform that can be leveraged across multiple market segments. In the future, we expect to launch additional products to treat lesions in larger vessels, provided that we obtain appropriate 510(k) clearance from the FDA. We also plan to seek premarket approval from the FDA to use the Diamondback 360° to treat patients with coronary artery disease.

### Our Market

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

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

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

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

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

- difficulty treating calcified lesions, diffuse disease and lesions below the knee;
- potential safety concerns relating to damage of the arterial wall;
- the inability to create lumens larger than the catheter itself in a single insertion;
- the creation of rough, uneven lumens with deep grooves;
- the potential requirement for greater physician skill, specialized technique or multiple operators to deliver the catheter and remove plaque;
- the potential requirement for reservoirs or aspiration to capture and remove plaque;
- the potential need for ancillary distal embolization protection devices to prevent large particles of dislodged plaque from causing distal embolisms or blockages downstream;
- the potential requirement for large, expensive capital equipment used in conjunction with the procedure; and
- the potential requirement for extensive use of fluoroscopy and increased emitted radiation exposure for physicians and patients during the procedure.

**Our Solution**

The Diamondback 360° represents a new approach to the treatment of PAD that provides physicians and patients with a procedure that addresses many of the limitations of traditional treatment alternatives. We believe that the Diamondback 360° offers substantial benefits to patients, physicians, hospitals and third-party payors, including:

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

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

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

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

**Our Strategy**

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

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

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

expanding our product portfolio within the market for the treatment of peripheral arteries;

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

leveraging core technology into the coronary market; and

pursuing strategic acquisitions and partnerships.

**Patents and Intellectual Property**

Since our inception, we have filed patent applications to protect what we believe to be the most important intellectual property that we have developed. We rely on a combination of patent, copyright and other intellectual property laws, trade secrets, nondisclosure agreements and other measures to protect our proprietary rights. As of 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.

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

We may experience difficulties managing growth.

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

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

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

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

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

**Our Corporate Information**

We were incorporated in Minnesota in 1989. Our principal executive office is located at 651 Campus Drive, Saint Paul, Minnesota 55112. Our telephone number is (651) 259-1600, and our website is www.csi360.com. The information contained in or connected to our website is not incorporated by reference into, and should not be considered part of, this prospectus.

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

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## SUMMARY OF THE OFFERING

| | |
|---|---|
| Common stock offered by us | Shares |
| Common stock to be outstanding after this offering | Shares |
| Use of proceeds | We intend to use the net proceeds from this offering to repay outstanding debt with a balance of $11.9 million at June 30, 2008, plus accrued interest, and for working capital and general corporate purposes. See Use of Proceeds. |
| Risk Factors | You should read the Risk Factors section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock. |
| Proposed Nasdaq Global Market symbol | CSII |

The number of shares of our common stock that will be outstanding immediately after this offering is based on 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.

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## SUMMARY CONSOLIDATED FINANCIAL DATA

The following table summarizes our consolidated financial data. We have derived the following summary of our consolidated statements of operations data for the years ended June 30, 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: