

The background of the cover features a light blue, semi-transparent image of various medical devices, including a syringe with a needle, a long thin catheter or tube, and several vials. A dark blue rectangular box is positioned in the upper right quadrant, containing the text 'annual report 2005'.

annual report 2005

2005

Vascular Solutions, Inc.



## THE PRODUCTS WE DELIVER

**Vascular Solutions** is a medical device company that focuses on delivering unique clinical solutions within interventional cardiology and interventional radiology. As a vertically integrated medical device company, we generate ideas and create new interventional medical devices, and then we deliver those products directly to the physician through our direct domestic sales force and international distribution network.

Our focus on underserved clinical opportunities and rapid development has resulted in an expanding product portfolio. Eighty percent of Vascular Solutions' 2005 net sales came from new products introduced since 2003. Our current product lines include:

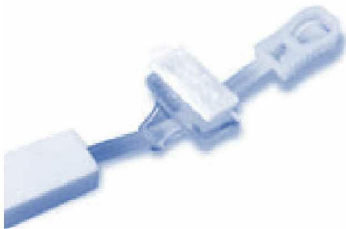
### *D-Stat® Dry Hemostatic Bandage*

The D-Stat Dry is a powerful hemostatic bandage with a simple "open and apply" solution to active bleeding. The D-Stat Dry is used following catheterization procedures to solve topical bleeding following the removal of catheters and tubes. While competitive products rely on theories of charged particles and coagulum, D-Stat Dry provides the science and proven power of thrombin.



### *D-Stat® Radial Hemostat Band*

The D-Stat Radial hemostat band utilizes a compression band together with the active hemostatic material of our D-Stat Dry to control surface bleeding. The D-Stat Radial is designed to eliminate occlusive compression of the radial artery and prevent compression of the ulnar artery following radial artery catheterization procedures.



### *Vari-Lase® Endovenous Laser Console and Procedure Kits*

The Vari-Lase endovenous laser products are designed as a complete vein care program for treatment of varicose veins. Endovenous laser therapy is a patient-friendly alternative to surgical vein-stripping for the treatment of varicose veins that can be performed in a physician's office in less than one hour.

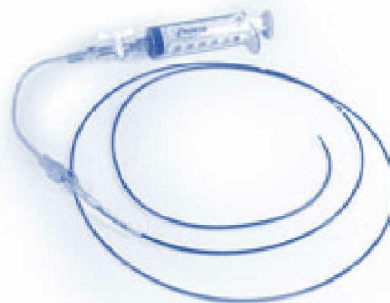


### *Pronto-Short Extraction Catheter*

The Pronto-Short extraction catheter is used to remove soft thrombus from dialysis grafts and fistulas, which are used in hemodialysis procedures and are implanted or created in a patient's forearm.

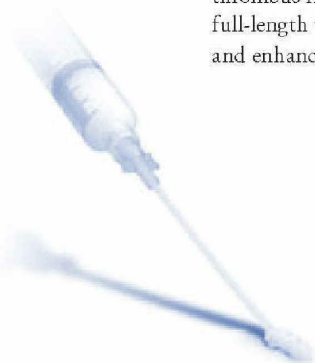
### *Pronto™ V3 Extraction Catheter*

The Pronto extraction catheter is used for the removal of soft thrombus from arteries. The newly designed V3 model includes a full-length wire braid and hydrophilic coating for ease of delivery and enhanced performance.



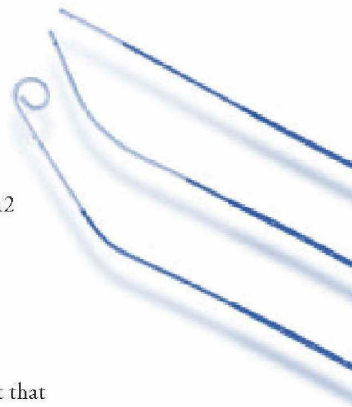
### *D-Stat® Flowable Hemostat*

The D-Stat Flowable hemostat utilizes the clinically proven procoagulant components of our original Duett product – collagen, thrombin and a buffered diluent – to provide a powerful stop to active bleeding. The thick yet flowable procoagulant controls bleeding by initiating the body's own clotting mechanisms.



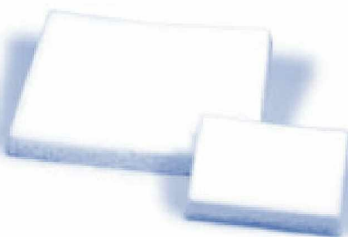
### *Langston™ Dual Lumen Catheters*

The Langston dual lumen catheters are used for measurement of intra-arterial pressure gradients. The Langston catheters deliver simultaneous pressure measurements accurately and precisely through two independent lumens in a coaxial design. There are three Langston configurations—Pigtail, Multipurpose A2 and Straight Selective—for a variety of procedural needs.



### *ThrombiGel™ Foam Hemostat*

The ThrombiGel is a unique gelatin/thrombin foam hemostat that combines a gelatin sponge and thrombin into a single composite pad. The ThrombiGel is available in multiple sizes to meet physician preferences.



### *Duett™ Pro Vascular Sealing Devices*

The Duett Pro sealing device is designed to rapidly and safely stop the bleeding and seal the arterial puncture site following percutaneous procedures such as angiography, angioplasty and stent placement. The Duett Pro is unique in its ability to quickly seal the entire puncture site with a one-size-fits-all device that leaves nothing inter-arterial.







## DEAR FELLOW SHAREHOLDERS,

On the day I am writing this report, our stock price closed at \$6.59, a new 52-week low and a 32% decrease from where it was one year ago. From this statistic alone, you might conclude that Vascular Solutions' business is shaky and that 2005 was not a successful year.

But that is simply not the case.

In 2005 we increased our net sales by 46% and set a new quarterly sales record each successive quarter. We turned the corner from a net loss to a net profit before accounting for expenses incurred in our new thrombin qualification investment. We launched three new products and set the stage for continued substantial growth each quarter for as long as we can see. I don't want to dismiss the stock market's message, because there certainly are areas we can improve in 2006 such as predicting our quarterly sales growth and meeting our projected new product launch dates. But our declining stock price doesn't mean that Vascular Solutions is moving backward. To the contrary, we've seen the anomaly of an improving business and a decreasing stock price before – most notably in 2003 when the stock market lost faith in our mission just as we started our rejuvenation.

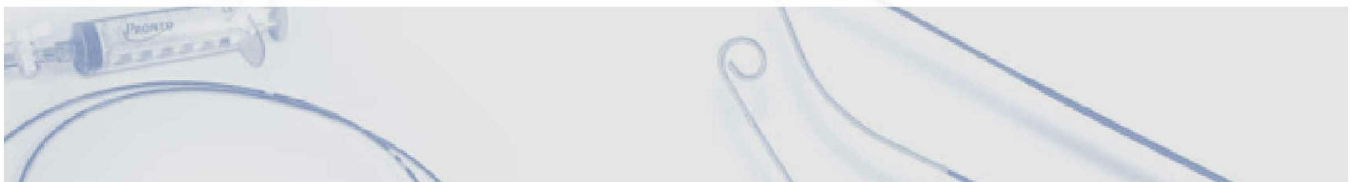
As a review, Vascular Solutions' mission is to grow a profitable medical device business focused on delivering clinically unique solutions to interventional physicians. While the large companies in our vascular device market concentrate on billion-dollar opportunities like drug eluting stents, Vascular Solutions focuses on the smaller opportunities that are often completely ignored. These opportunities are far more numerous and quicker to develop than the larger opportunities. Using our internal R&D team and our clinically-based direct sales force, we

can rapidly bring these new devices to the market and then deliver the sales and clinical results.

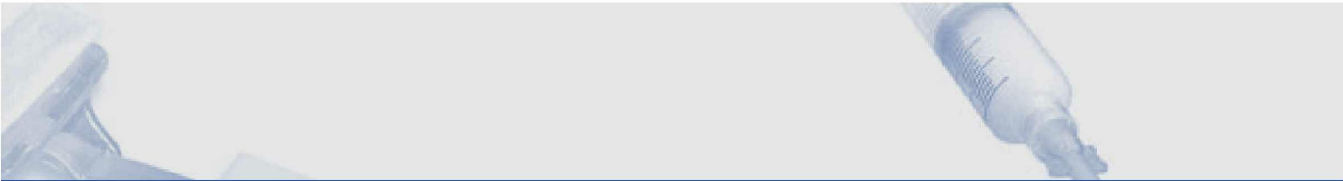
In 2005 our D-Stat Dry hemostatic bandage continued to be Vascular Solutions' top selling product, with \$13,804,000 in net sales, a 56% increase over 2004. We launched the D-Stat Dry bandage in September 2003 as a simple solution to topical bleeding following catheterization procedures. Through our proprietary blood clotting agent, the D-Stat Dry bandage has demonstrated its clinical superiority to competitive patches and has established a solid market share. While we expect growth of the original Dry product to taper off in 2006, we expect the new product line extensions in the Dry product group, including the gelatin foam-based ThrombiGel hemostat, to provide new impetus to sales growth.

The second driver of our sales growth in 2005 was our Pronto extraction catheter which is used to extract soft thrombus from within blood vessels. Pronto net sales totaled \$6,357,000 in 2005, a 108% increase over 2004. During 2005, the results of the DEAR-MI clinical study of the Pronto catheter were presented at a major medical meeting, and in 2006 we expect those results will be published in a major peer-reviewed journal. At the very end of 2005, we launched the new V3 version of the Pronto extraction catheter, which our customers have already accepted as a substantial improvement in catheter design that we think will drive Pronto sales to the next level. We also have several new versions of the Pronto catheter in development for 2006 that we expect will make the Pronto our fastest growing product line this year.

Our third major product line for 2005 was the Vari-Lase endovenous laser therapy for treating







varicose veins. Net sales of the Vari-Lase and accessory products in 2005 were \$5,009,000, an 88% increase over 2004. The endovenous laser procedure, as a simple one-hour outpatient procedure, is becoming established as the therapy of choice for treating varicose veins. Vascular Solutions' clinical based sales force has gained market share from our competitors throughout 2005, which we expect will continue throughout 2006. While this performance has caused one of our competitors to turn to litigation in an attempt to block our growth, the courts' decisions to date haven't provided them much support, and we believe our Vari-Lase sales growth will continue unabated.

Our other products include the Langston catheter, which we launched in 2004 and grew by 681% in 2005 to \$1,036,000 in net sales. Our D-Stat Flowable hemostat product also continues to be a substantial revenue generator, with net sales increasing by 45% in 2005 to \$2,083,000. With respect to our original Duett and Diagnostic Duett products, in 2005 we continued our "harvesting" of these products with net sales of \$3,954,000, which we expect will continue to decline in 2006.

In 2005 we also continued our development work on qualifying a new source of the bovine thrombin component for our existing and new hemostatic products. At the very end of 2005 we took delivery and accepted the three qualification lots of our new thrombin from our new manufacturing partner, which was a major manufacturing milestone in this project. We remain on course to qualify and bring this new thrombin source through the regulatory process by the second quarter of 2007. To fill our interim requirements, we have purchased sufficient thrombin from our former source to last us into

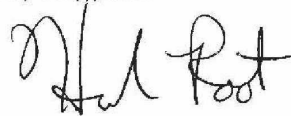
2008 according to our current sales forecasts. The obvious benefit from qualifying our new thrombin is long-term cost control, but the more substantial long-term benefit is to participate in the over \$200 million U.S. thrombin market, which we expect could occur as early as 2008.

Looking into 2006, we believe that we will continue to set new quarterly sales records each quarter throughout the year. For the entire 2006 we expect to reach between \$41 million and \$43 million in net sales. New product launches should once again provide substantial upside, with the Twin-Pass and Skyway catheters leading five new product launches planned for the year. Looking even further out, we believe that we can continue to increase our sales by at least 25% each year until we reach our next long term milestone – which is \$100 million in annual sales. After that target is reached, we expect to have our new thrombin-based surgical products launched and other larger opportunities in interventional medicine developed to take us to the next level.

Finally, if we simply continue with the progress we made in 2005, I expect that the current disconnect between our progress and our stock price will be corrected in 2006.

As always, we thank you for your continued support of our business.

Very truly yours,



Howard Root

Chief Executive Officer  
February 6, 2006



## FINANCIAL HIGHLIGHTS

### Statements of Operations Data

(in thousands)

	Year Ended December 31,				
	2005	2004	2003	2002	2001
Net sales	\$32,786	\$22,414	\$11,862	\$12,154	\$12,128
Gross profit	\$23,400	\$15,657	\$7,234	\$7,115	\$7,121
Gross profit %	71.4%	69.9%	61.0%	58.5%	58.7%
Total operating expenses	\$24,124	\$19,233	\$17,012	\$22,601	\$21,032
Operating loss	(\$724)	(\$3,576)	(\$9,778)	(\$15,486)	(\$13,911)
Net loss	(\$561)	(\$3,508)	(\$9,628)	(\$14,979)	(\$12,250)

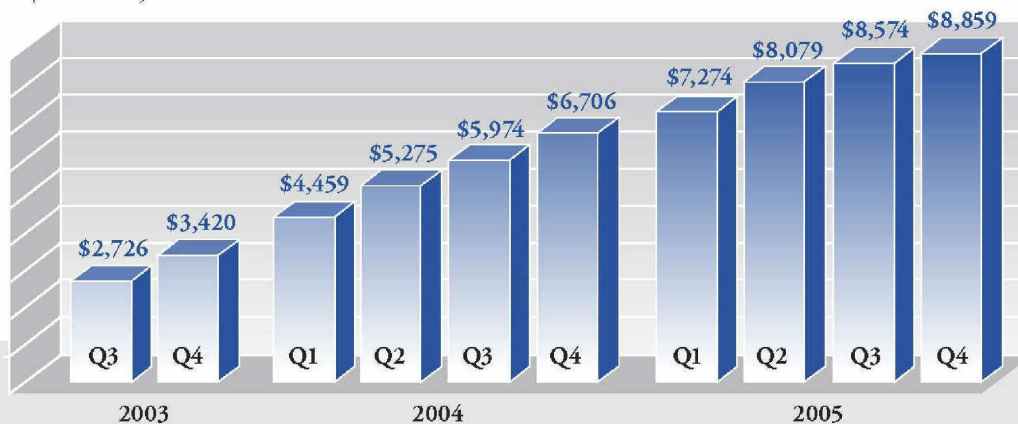
### Balance Sheet Data

(in thousands)

	December 31,	
	2005	2004
Cash and cash equivalents	\$4,282	\$7,184
Working capital	\$10,887	\$11,833
Long-term debt	\$0	\$0
Shareholder's equity	\$14,107	\$13,690
Total shares outstanding	14,642	14,351

### Quarterly Net Sales

(in thousands)



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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2005

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 0-27605

**VASCULAR SOLUTIONS, INC.**

(Exact name of registrant as specified in its charter)

**Minnesota**

(State or other jurisdiction of incorporation or organization)

**41-1859679**

(IRS Employer Identification No.)

**6464 Sycamore Court**

**Minneapolis, Minnesota 55369**

(Address of principal executive offices, including zip code)

**(763) 656-4300**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, par value \$0.01 per share**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

The aggregate market value of voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold on June 30, 2005 was \$165,065,551.

As of January 27, 2006, the number of shares outstanding of the registrant's common stock was 14,933,995.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Proxy Statement for its 2006 Annual Meeting of Shareholders to be held on April 18, 2006 are incorporated by reference in Part III of this Annual Report on Form 10-K.



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## PART I

### ITEM 1. BUSINESS

#### Overview

Vascular Solutions, Inc. (we, us or Vascular) is a medical device company focused on bringing clinically advanced solutions to interventional cardiologists and interventional radiologists worldwide. We were incorporated in the state of Minnesota in December 1996, and we began operations in February 1997. Our current product line consists of the following medical devices:

- D-Stat Dry™ hemostatic bandage, a topical pad with a bandage used to control surface bleeding,
- Pronto™ extraction catheter, a mechanical system for the removal of soft thrombus from arteries,
- Vari-Lase® endovenous laser, a laser and procedure kit used for the treatment of varicose veins,
- Duett™ sealing device, used to seal the puncture site following catheterization procedures,
- D-Stat® Flowable hemostat, a thick, yet flowable, mixture used to control bleeding,
- ThrombiGel™ hemostatic foam, a unique gelatin/thrombin foam hemostat,
- Langston™ dual lumen catheters, used to measure intravascular pressure gradients,
- MAX-Support™ abdominal retraction belt, used to allow femoral access in obese patients, and
- Acolysis® ultrasound (international only), a treatment for peripheral occlusive arterial disease.

As a vertically-integrated medical device company, we generate ideas and create new interventional medical devices, and then deliver these products directly to the physician through our direct domestic sales force and our international distribution network.

We currently have in development several additional products that leverage our existing infrastructure to bring additional solutions to the interventional cardiologist and interventional radiologist. Additional products that we expect to gain regulatory clearance and market launch before the end of 2006 in the United States include the following medical devices, each of which we believe addresses an annual market opportunity of between \$1 million and \$20 million:

- Skyway™ exchange catheter, a specialty-purpose catheter designed for guidewire support and exchange in interventional cardiology procedures,
- Twin-Pass™ dual access catheter, specialty-purpose catheter designed for dual wire access in interventional cardiology procedures,
- GuideLiner catheter, a specialty-purpose catheter designed to provide back-up support to the guide catheter in chronic total occlusion procedures,
- Gopher catheter, a low profile metal catheter used principally in chronic total occlusion cases to provide improved passage for the balloon catheter and stent, and
- Micro-Introducer Catheter, a series of catheters that combine both a diagnostic catheter and a micro-introducer kit into a single product that will be used principally by Interventional Radiologists.

#### Interventional Cardiology and Interventional Radiology Industry Background

Over 60 million Americans have one or more types of cardiovascular disease—diseases of the heart and blood vessels. Cardiovascular disease is the number one cause of death in the United States and is replacing infectious disease as the world's pre-eminent health risk. Advances in medicine have enabled physicians to perform an increasing number of diagnostic and therapeutic treatments of cardiovascular disease using minimally invasive methods, such as catheters placed inside the arteries, instead of highly invasive open surgery. Cardiologists and radiologists use diagnostic procedures, such as angiography, to confirm, and interventional procedures, such as angioplasty and stenting, to treat diseases of the coronary and peripheral arteries. Based on industry statistics, we estimate that cardiologists and radiologists performed over nine

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million diagnostic and interventional catheterization procedures worldwide in 2005. Often times, these procedures are performed to remove blood clots or plaque which have been generated and deposited inside the patient's artery and are an impediment to normal blood flow. The number of catheterization procedures performed is expected to grow by more than 5% each year for the next three years as the incidence of cardiovascular disease continues to increase. The overall interventional medical device market in 2005 exceeded \$5 billion worldwide.

Each procedure using a catheter requires a puncture in an artery, usually the femoral artery in the groin area and sometimes the radial artery in the wrist of the patient to gain access for the catheter. The catheter then is deployed through an introducer sheath and into the vessel to be diagnosed or treated. Upon completion of the procedure and removal of the catheter, the physician must seal this puncture in the artery and the tissue tract that leads from the skin surface to the artery to stop bleeding. The traditional method for sealing the puncture site has been a manual process whereby a healthcare professional applies direct pressure to the puncture site, sometimes using a sand bag or a large C-clamp, for 20 minutes to an hour in order to form a blood clot. The healthcare professional then monitors the patient, who must remain immobile in order to prevent dislodging of the clot, for an additional four to 48 hours.

Patients subjected to manual compression generally experience significant pain and discomfort during compression of the puncture site and during the period in which they are required to be immobile. Many patients report that this pain is the most uncomfortable aspect of the catheterization procedure. In addition, patients can develop a substantial coagulated mass of blood, or hematoma, around the puncture site, limiting patient mobility for up to six weeks following the procedure. Finally, the need for healthcare personnel to provide compression and the use of hospital beds during the recovery period results in substantial costs to the institution, which, under virtually all current healthcare payment systems, are not separately reimbursed.

Until 1996, manual compression was used following virtually all catheterization procedures. In late 1995, the first vascular sealing device which did not rely on compression was introduced in the United States. In addition to our Duett sealing device, five other invasive sealing devices have received approval from the Federal Drug Administration (FDA) and are currently being marketed around the world. In the aggregate, over \$400 million of the four FDA-approved invasive sealing devices were sold worldwide in 2005, compared to less than \$20 million in 1996. In addition to invasive (below the skin surface) sealing devices, starting in 2000, non-invasive "patches" had begun to be used as an assist to manual compression following catheterizations. Non-invasive patches are used by physicians who (principally due to cost, complexity or risk of complications) do not wish to use invasive sealing devices, and for those patients who are contraindicated for an invasive sealing device. Based on the number of catheterization procedures performed annually by cardiologists and radiologists, industry sources report that the total market opportunity for vascular sealing devices (invasive and non-invasive) is more than \$1 billion annually.

#### **D-Stat Dry Product Line**

In September 2003 we received regulatory clearance and commenced sales of our D-Stat Dry hemostatic bandage in the United States and international markets. The D-Stat Dry hemostatic bandage is a version of our proprietary blood clotting substance that is lyophilized (freeze-dried) into a gauze pad and combined with an adhesive bandage for application. The D-Stat Dry is used as an assistant for manual compression to manage bleeding after catheterization procedures. We believe that the market for a hemostatic pad in this indication has grown substantially since the first competitive patch was introduced in 2000, with a market size greater than \$50 million in 2005.

We believe that the D-Stat Dry has many potential uses beyond this initial application, and to date, we have developed four variations of our D-Stat Dry -- the D-Stat 2Dry, the D-Stat Clamp Accessory, the D-Stat Radial and Thrombix 3x3 trauma bandage. The D-Stat 2Dry is a convenient 2-bandage version of the D-Stat Dry used in the dialysis market. The D-Stat Clamp Accessory utilizes our D-Stat Dry pad and is configured for attachment to standard compression devices.

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The D-Stat Radial hemostat band is a specially-sized version of the D-Stat Dry that includes a compression band that allows it to be applied over the radial artery in the wrist. In approximately 5% of all catheterizations, the radial artery is used to gain arterial access in the wrist instead of the femoral artery in the groin. In these cases using the radial artery, the health care professional must control bleeding from the artery after the procedure. A variety of compression splints and tapes have been used for this purpose. The D-Stat Radial is the first device that contains an active blood clotting agent together with the compression collar for this purpose. We received regulatory clearance for the D-Stat Radial hemostat band in September 2003, and made manufacturing improvements to the product before launching it in the United States in early 2004.

At the end of the first quarter of 2004 we received regulatory clearance in the United States for the Thrombix 3x3 trauma bandage. The Thrombix bandage is designed for use in trauma indications, does not require mixing or special storage requirements and it can be quickly applied to even severely bleeding wounds. We continue our search for a potential corporate distribution partner. We also have conducted clinical evaluations at U.S. trauma centers and we have received feedback on several successful deployments, with no adverse events reported. We continue to believe that with the right partner, the Thrombix trauma bandage can be a substantial revenue generator for us in the trauma market and potentially in the military market, however until we find a suitable distribution partner the Thrombix bandage will not generate substantial revenues.

During the second quarter of 2005 we received regulatory clearance in the United States for ThrombiGel hemostatic foam. ThrombiGel version contains a gelatin foam pad (replacing the gauze pad in the original D-Stat Dry) to provide a unique, premixed, sterile, gelatin/thrombin hemostat. ThrombiGel can be used in a variety of medical procedures for the control of bleeding.

#### **Pronto Extraction Catheter Product Line**

Our Pronto product consists of an extraction catheter with a proprietary distal tip and large extraction lumen that can be delivered into arteries to mechanically remove blood clots using simple vacuum suction. The Pronto extraction catheter was initially developed by Dr. Pedro Silva of Milan, Italy, who exclusively licensed the design to us in 2002. We received CE mark approval and commenced international sales of the Pronto in August 2003, and received FDA clearance in December 2003 and commenced sales in the United States in early 2004. In the fourth quarter of 2005 we launched the third generation design of the Pronto, called the Pronto V3. We believe this new version of the Pronto incorporates several improvements that physicians have requested, and we believe there will be a substantial boost to our Pronto sales in 2006. We believe that the market size for the removal of soft thrombus is greater than \$100 million per year worldwide.

In October 2005 we announced the results of the DEAR-MI (Dethrombosis to Enhance Acute Reperfusion in Myocardial Infarction) clinical study by Dr. Pedro Silva. The DEAR-MI clinical study was a randomized evaluation of the use of the Pronto extraction for the removal of thrombus from patients presenting with ST elevated acute myocardial infarction admitted within 12 hours of symptom onset. The primary endpoints of the DEAR-MI study were a comparison of myocardial reperfusion according to ST-segment resolution and myocardial blush grade. The results showed thrombus aspiration with the Pronto was determined to be an independent predictor of myocardial reperfusion as measured by both ST resolution and mean blush grade.

We believe that the Pronto has many potential uses beyond this initial application, and to date, we have developed one additional variation of the Pronto called Pronto-Short. The Pronto-Short is designed for use in clotted dialysis grafts and was launched in August 2005. We estimate the Pronto-Short addresses a market opportunity of at least \$10 million.

#### **Vari-Lase Endovenous Laser Product Line**

Our Vari-Lase endovenous laser products consist of a laser console, procedure kits and accessories used in the treatment of reflux of the great saphenous vein, commonly referred to as varicose veins. More than one



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million people in the United States seek treatment each year for varicose veins. Left untreated, varicose veins can result in serious clinical consequences, including limited mobility and venous stasis ulcers. Historically, an invasive surgical procedure known as vein stripping was the only treatment for severe varicose veins. While vein stripping is still performed on over 100,000 patients each year in the United States, since 2002 a non-surgical procedure using endovenous laser energy to treat and close the diseased vein has become the preferred alternative. Recent clinical data on endovenous laser therapy has demonstrated excellent clinical results and outstanding patient satisfaction. During the fourth quarter of 2004 the Center for Medicare and Medicaid Services (CMS) published the Medicare Physicians Fee Schedule which established favorable reimbursement rates for the endovenous laser procedure starting January 1, 2005. Private insurance also has continued its favorable trend with coverage decisions which have caused more physicians to add this procedure to their practice. We believe the current U.S. market size for treating varicose veins using endovenous therapy is greater than \$80 million per year.

The first product we launched in our Vari-Lase product line was our Vari-Lase procedure kit in July 2003 in the United States. Our procedure kit is custom-designed for the endovenous procedure, with features supporting ease-of-use and safety, and is compatible with the competitive laser consoles already in use for this procedure. In December 2003, we received FDA clearance for our laser console, which we have manufactured to our specifications by MedArt Corporation, a subsidiary of Asah Medico, a leading Denmark-based medical laser manufacturer. During 2004 we developed and commenced sales of our Auto-Fill™ syringe and Vari-Lase procedure packs as accessory products to the Vari-Lase product line. The Auto-Fill syringe is an easy fluid delivery system for local anesthesia. The Vari-Lase Procedure Pack is a complete sterile pack of accessories designed for endovenous laser procedures. To complete our Vari-Lase product line, we sell micro-introducers and guide wires which are used as accessory items in the endovenous laser procedure as well as used in other interventional medical procedures.

#### **Duett Product Line**

The first product we brought to market, the Duett sealing device, is designed to provide a complete seal of the puncture site following catheterization procedures such as angiography, angioplasty and stenting. Our Duett sealing device combines an easy-to-use balloon catheter delivery mechanism with a biological procoagulant mixture, which we believe offers advantages over both manual compression and competitive vascular sealing devices. We began selling our Duett sealing device in Europe in February 1998 and in the United States in June 2000. Over 200,000 Duett sealing devices have been sold and deployed worldwide. In the fourth quarter of 2001 we introduced the Diagnostic Duett version of the Duett sealing device, which utilizes a lower dose of procoagulant for the less-challenging diagnostic subset of catheterization procedures. In mid-2002 we introduced the next generation “Pro” line of the Duett sealing device for improved ease-of-use. In 2003 we made the decision to reduce our focus on growing the Duett product line in order to focus on increasing sales of our new products.

We believe our Duett sealing device (1) offers a complete seal of the puncture site with nothing left behind in the artery, (2) is an easy-to-use system and (3) minimizes patient discomfort and permits early ambulation. Our product uses a balloon catheter, a device already familiar to cardiologists and radiologists, which is inserted through the introducer sheath that is already in the patient. The inflated balloon serves as a temporary mechanical seal, preventing the flow of blood from the artery. Our biological procoagulant, which is a proprietary mixture of collagen, thrombin and diluents, is then delivered to the puncture site, stimulating rapid clotting and creating a complete seal of both the arterial puncture and the tissue tract from the artery to the skin surface. The blood-clotting speed and strength of thrombin enables the use of the Duett sealing device even in the presence of powerful anti-clotting medications, such as ReoPro®, increasingly used in interventional catheterization procedures. With our Duett sealing device, nothing is left behind in the artery, so immediate reaccess of the site, if necessary, is possible, and the potential for infection is minimized.

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### **D-Stat Flowable Product Line**

The second product we developed and commercialized is the D-Stat Flowable hemostat, which we began selling worldwide in February 2002. The D-Stat Flowable hemostat is a blood clotting material that can be delivered topically and into voids and open spaces to control active bleeding. The D-Stat Flowable offers the advantage of being thick to maintain its position, yet easily deliverable. The D-Stat Flowable consists of the same collagen, thrombin and diluent components as the Duett sealing device, which has been proven effective in controlling bleeding from aggressive arterial puncture sites.

The D-Stat Flowable hemostat can be used in a wide variety of interventional procedures as an adjunct to hemostasis. An example of these uses includes sealing the access site after the removal of catheters from A-V access grafts. We believe that the D-Stat Flowable hemostat is the only hemostat available in the United States that combines the thick consistency and extremely flowable delivery that is preferred by the interventional physician in these opportunities.

We commenced sales of the D-Stat Flowable worldwide in the first quarter of 2002. Currently, the approved clinical indications for the D-Stat Flowable are limited to topical bleeding and blood "oozing" following percutaneous procedures. We believe these indications are but a small fraction of the total potential market for the D-Stat Flowable. In October 2005 we announced the results of our 269 patient clinical study of the use of the D-Stat Flowable in the hemostasis of prepectoral pockets created in pacemaker and defibrillator implantations. The primary endpoints of the Pocket Protector study were a comparison of clinically relevant pocket hematoma formation and the rate of major adverse events. The results showed a 48% reduction in hematoma formation observed in the investigation group compared to the control group and a low overall device or procedure-related major event rate. We expect to submit the premarket approval application (PMA) to the FDA during the first quarter of 2006 and we expect to obtain approval by the end of the third quarter of 2006. We estimate that the U.S. market opportunity for this prepectoral pocket indication is greater than 100,000 procedures or \$10 million annually. We also believe that the D-Stat Flowable has application for use to seal following breast biopsy and liver biopsy procedures, each of which we believe can match or exceed the prepectoral pocket market opportunity for D-Stat Flowable.

### **Catheter Product Line**

At the end of the third quarter of 2004 we received regulatory clearance in the United States for the Langston dual lumen pigtail catheter. The Langston catheter is used for the precise measurement of intravascular pressure gradients, primarily measured to diagnose aortic valve stenosis. We believe our Langston catheter is the only dual lumen pigtail catheter on the U.S. market that can be used for this intended indication. During 2005 we received approval for additional sizes and configurations of the Langston catheter product line. We believe the U.S. market opportunity for the Langston catheter product line is \$10 million annually.

At the end of the fourth quarter of 2005 we received regulatory clearance in the United States for the Twin-Pass dual access catheter and Skyway support catheter, both of which we expect to launch in the first quarter of 2006. The Twin-Pass is a two lumen catheter designed to be used in conjunction with steerable guidewires to access discrete regions of the coronary and peripheral arterial vasculature and for use during procedures utilizing two guidewires. The Skyway support catheter can be used in the support of guidewires during difficult lesion crossing procedures and in the exchange of guide wires in an interventional procedure. We believe that both of these products address market opportunities of between \$1 million and \$5 million annually within interventional cardiology.

### **Other Products**

During the first quarter of 2005 we launched the MAX-Support abdominal retraction belt. This product is a tape-free retraction system to expose the femoral artery puncture site in obese patients. Nationwide, approximately 7% of catheterization laboratory patients require taping of their belly apron to allow

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visualization of the femoral crease for the purpose of gaining access for the catheterization. The Max-Support belt is a tape-free alternative that avoids the discomfort, inefficiencies and time involved in the current practice of taping. We believe the market potential for the MAX-Support belt is approximately \$1 million annually.

During the second quarter of 2002 we acquired the Acolysis ultrasound thrombolysis system. The Acolysis system uses ultrasound energy generated by the Acolysis controller that is delivered by the disposable Acolysis probe to lyse blood clots and plaque within the artery. The Acolysis controller and probes are sold only in international markets, where it has been sold principally for the treatment of peripheral vascular disease. Upon completion of our acquisition and integration of the Acolysis business, we commenced active international sales of the Acolysis probes through our existing international distribution network in late 2002. We are in the process of working on our next generation Acolysis ultrasound thrombolysis system. Once we complete our improvement on the current system we will plan and structure a clinical study in the United States to study the effectiveness of the use of the Acolysis system to open chronic peripheral occlusions, with the study not expected to be completed before 2008.

The amount of total revenue contributed by each of our product lines for the last three fiscal years is set forth in Item 7, Part II of this Form 10-K.

### **Business Strategy**

Our primary objective is to establish ourselves as a leading supplier of clinically superior medical devices for substantial opportunities within interventional medicine. The key steps in achieving our primary objective are the following:

- *Maintain and Improve our Clinically-Oriented Direct Sales Force in the United States.* During the third quarter of 2000 we commenced sales of our Duett sealing device in the United States through a direct sales force that includes clinical specialists who train interventional cardiologists, radiologists and catheterization laboratory administrators on the use of our products. We believe that effective knowledge and training are key factors in promoting use of interventional medical devices, and we have created and will continue to work to improve an in-the-field training program for the use of our products.
- *Expand our Existing Products to Our Existing Market.* Since the end of 2002 we have received clearance for several new products to create five new line categories, all sold in the United States through our existing direct sales force to our existing markets. Each of these product lines has generated material sales, and we believe that each of these product lines has the potential to generate even more sales during 2006 and beyond.
- *Develop New Devices to be Sold Through our Direct Sales Force to our Existing Customers.* We intend to continue to leverage our direct sales force by bringing additional products to the interventional physician. During 2006 we expect to launch five new products in the United States – the Skyway, Twin-Pass, GuideLiner and Gopher catheters, the Micro-Introducer Catheter, with additional products being developed for an expected 2007 launch.
- *Explore Corporate Relationships to Augment our Direct Sales Force.* In markets for our products beyond the interventional physician (such as the trauma market for our Thrombix 3x3 product) and in other situations where synergistic sales can result, we intend to enter into corporate relationships to broaden our products' reach and increase our revenues.

### **Sales, Marketing and Distribution**

In the third quarter of 2000 we commenced sales of our Duett sealing device in the United States through our direct sales organization. As of December 31, 2005, our direct sales force consisted of approximately 72



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employees. We believe that the majority of interventional catheterization procedures in the United States are performed in high volume catheterization laboratories, and that these institutions can be served by our focused direct sales force. We also believe that our sales force is able to sell each of our new products to the same customer base.

As part of our sales strategy, our sales force is clinically trained and is able to train physicians and other healthcare personnel on the use of our products. We believe that effective training is a key factor in encouraging physicians to use interventional medical devices. We have created, and will continue to work to improve, an in-the-field training program for the use of all of our products. We also develop and maintain close working relationships with our customers to continue to receive input concerning our product development plans.

We are focused on building market awareness and acceptance of our products. Our marketing organization provides a wide range of programs, materials and events that support our sales force. These include product training, conference and trade show appearances and sales literature and promotional materials. Members of our medical advisory board also aid in marketing our products by publishing articles and making presentations at physicians' meetings and conferences.

Our international sales and marketing strategy has been to sell to interventional cardiologists and interventional radiologists through established independent distributors in major international markets, subject to required regulatory approvals. In Germany, we created our wholly-owned subsidiary Vascular Solutions GmbH to sell directly to customers in the German market beginning in the fourth quarter of 2000. In most of the other major developed markets our products are currently marketed through independent distributors. Under multi-year written distribution agreements with each of our independent distributors, we ship our products to these distributors upon receipt of purchase orders. Each of our independent distributors has the exclusive right to sell our products within a defined territory. These distributors also market other medical products, although they have agreed not to sell directly competitive products. Our independent distributors purchase our products from us at a discount from list price and resell the device to hospitals and clinics. Sales to international distributors are denominated in United States dollars. The end-user price is determined by the distributor and varies from country to country.

#### **New Product Development**

Our research and development staff is currently focused on developing new products to sell to our existing customer base through our direct sales force and on developing next generation versions of our existing products. We incurred expenses of \$3,789,000 in 2005, \$3,401,000 in 2004 and \$3,671,000 in 2003 for research and development activities. To further leverage our efficiencies, our research and development group continues to develop in-house capabilities to manufacture some of the components currently produced by outside vendors.

In addition to our normal research and development expenses, we incurred \$1,620,000 in 2005 and \$210,000 in 2004 in thrombin qualification expenses relating to our project to qualify a new source of thrombin. On October 18, 2004, we entered into a supply agreement with Sigma-Aldrich Fine Chemicals, an operating division of Sigma-Aldrich, Inc. (Sigma) for the supply of thrombin to us. Pursuant to the terms of the agreement, we will be paying for certain development costs of Sigma to allow Sigma to produce thrombin. The payments are based on certain milestones over a two year period. The initial contract term ends after ten years and is automatically extended for up to five additional successive one year terms unless one party delivers notice of termination at least one year prior to the scheduled termination of the agreement. During the term of the agreement, Sigma has agreed not to sell thrombin of the type developed for us under the agreement in or as a component of a hemostatic product for medical use. We do not have any minimum purchase requirements under the agreement; however, if we purchase less than three lots of thrombin in any year then (1) Sigma will be released from its agreement not to sell thrombin in or as a component of a hemostatic product for medical use, and (2) Sigma will have the right to terminate the agreement upon 30 days notice.

The Sigma contract is part of our plan to fully qualify a new source of thrombin and to bring the new thrombin through the regulatory process to be used in our hemostatic products starting in 2007. The payments associated with the Sigma agreement are part of our total estimated expenditures of \$6.8 million (including the payments to Sigma) to complete this project. The failure by us to complete our thrombin qualification project on time and on budget may affect our gross margins on our Duett, D-Stat Flowable and D-Stat Dry products and could therefore seriously harm our business.

The costs and purchases incurred through December 31, 2005 and the total estimated costs and purchases for the thrombin project (including costs and purchases already incurred) are as follows:

	<u>Incurred (as of December 31, 2005)</u>	<u>Total Estimated</u>
Qualification expenses.....	\$1.8 million	\$4.3 million
Capital equipment purchases.....	0.7 million	0.8 million
Thrombin inventory purchases.....	1.7 million	1.7 million
	<u>\$4.2 million</u>	<u>\$6.8 million</u>

The purchase of the \$1.7 million in thrombin is expected to be used in our hemostat products starting in 2007. Following the qualification of the Sigma thrombin for our existing products, we believe we can launch several additional new thrombin-based surgical products into the existing \$200 million annual U.S. thrombin market, which currently has only one competitor. The launch of the additional products will require additional expenses and a clinical study in 2007.

We expect our research and development activities to continue to expand to include evaluation of new concepts and products for the interventional cardiology and interventional radiology field. We believe that there are many potential new interventional products that would fit within the development, clinical, manufacturing and distribution network we have created for our existing products.

#### **Manufacturing**

We manufacture our products in our facility in a suburb of Minneapolis, Minnesota. The catheter manufacturing and packaging processes occur under a controlled clean room environment. Our manufacturing facility and processes were certified in July 1998 as compliant with the European Community's EN 13485 standards and were audited most recently in October 2005 for compliance with the FDA's quality systems regulations with no deficiencies noted.

We purchase components from various suppliers and rely on single sources for several parts of our products. In September 1998 we entered into a ten year, sole-source supply agreement with our collagen supplier, Davol Inc., that provides for a fixed price based on volume purchases which is adjusted annually for increases in the Department of Labor's employer's cost index. We purchase our requirements for thrombin (a component in the Duett and in all of the D-Stat products) under a Purchase Agreement dated June 10, 1999 with a subsidiary of King Pharmaceuticals, Inc. The agreement provides for a fixed price, with adjustments based on the supplier's manufacturing costs and the supplier's annual percentage increase in the wholesale price of thrombin. The agreement expired on May 29, 2005. Prior to the expiration of the agreement, we issued purchase orders for approximately \$3.5 million of thrombin to benefit from the pricing provisions of the agreement. We believe that these purchases will satisfy our thrombin requirements through at least the end of 2007. We have taken delivery of approximately \$1.4 million of the \$3.5 million of King thrombin through December 31, 2005 and we expect the remaining \$2.1 million of thrombin to be delivered by the end of the third quarter of 2006. To date, we have not experienced any significant adverse effects resulting from shortages of components.

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The manufacture and sale of our products entails significant risk of product liability claims. Although we have product liability insurance coverage in an amount which we consider reasonable, it may not be adequate to cover potential claims. Any product liability claims asserted against us could result in costly litigation, reduced sales and significant liabilities and divert the attention of our technical and management personnel away from the development and marketing of our products for significant periods of time.

### **Competition**

Competition in the interventional medical device industry is intense and dominated by very large and experienced companies such as Medtronic, Inc., Abbott Laboratories and Boston Scientific. We compete on the basis of our clinically differentiated products and focused opportunities within this interventional medical device market.

Our D-Stat Dry hemostatic bandage competes in the noninvasive topical patch market segment of sealing devices. These patches are applied directly over the puncture site and held in place with adjunctive manual compression for a period of 10-20 minutes. These patches include:

- The Syvek™ Patch, manufactured and marketed by Marine Polymer Technologies, Inc.
- The Closur-P.A.D.™, manufactured by Scion Cardiovascular and distributed by Medtronic, Inc.
- The Chito-Seal™, distributed by Abbott Vascular, Inc. a division of Abbott Laboratories

The Pronto extraction catheter competes in the market segment for removal of thrombus from the arterial system. There are many companies that are selling or have developed products in this segment, including Possis Medical, Medtronic, Boston Scientific and ev3.

We are aware of five companies that sell a product for the endovenous laser treatment of varicose veins. These companies are AngioDynamics, biolitec, Dornier MedTech, CoolTouch and Diomed. Each of these companies' products contains the same components for the therapy but differ in procedural training, laser wavelength, custom-designed features and customer support. In addition, VNUS Medical Technologies sells a radiofrequency alternative to the laser for the treatment of varicose veins.

Our Duett sealing device principally competes with three vascular sealing devices and manual compression. The three principal competitive vascular sealing devices are:

- The VasoSeal® device, manufactured and marketed by Datascope Corp., seals the tissue tract by placing a dry collagen plug in the tissue tract adjacent to the puncture in the artery.
- The Angio-Seal® device, sold by the Daig division of St. Jude Medical, Inc. and developed by Kensey Nash Corporation, seals the puncture site through the use of a collagen plug on the outside of the artery connected by a suture to a biodegradable anchor which is inserted into the artery.
- The Closer™ device, sold by Perclose, Inc., a subsidiary of Abbott Laboratories, seals the puncture site through the use of a suture device that enables a physician to perform a minimally invasive replication of open surgery.

There are many companies that are selling or have developed hemostats which compete generally with our D-Stat Flowable hemostat. Virtually all of these devices, however, are positioned as hemostats for the surgical market and are not designed specifically for use in interventional procedures.

In each of our product areas, we believe that several other companies are developing new devices. The medical device industry is characterized by rapid and significant technological change as well as the frequent emergence of new technologies. There are likely to be research and development projects related to these



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market areas of which we are currently unaware. A new technology or product may emerge that results in a reduced need for our products or results in a product that renders our product noncompetitive.

## **Regulatory Requirements**

### ***United States***

Our products are regulated in the United States as medical devices by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA classifies medical devices into one of three classes based upon controls the FDA considers necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls such as labeling, adherence to good manufacturing practices and maintenance of product complaint records, but are usually exempt from premarket notification requirements. Class II devices are subject to the same general controls and also are subject to special controls such as performance standards, and FDA guidelines, and may also require clinical testing prior to approval. Class III devices are subject to the highest level of controls because they are used in life-sustaining or life-supporting implantable devices. Class III devices require rigorous clinical testing prior to their approval and generally require a premarket approval (PMA) application prior to their sale.

If a medical device manufacturer can establish that a device is “substantially equivalent” to a legally marketed Class I or Class II device, or to an unclassified device, or to a Class III device for which the FDA has not called for PMAs, the manufacturer may seek clearance from the FDA to market the device by filing a 510(k) premarket notification. The 510(k) notification must be supported by appropriate data establishing the claim of substantial equivalence to the satisfaction of the FDA. Following submission of the 510(k) notification, the manufacturer may not place the device into commercial distribution in the United States until an order is issued by the FDA.

Manufacturers must file an investigated device exemption (or IDE) application if human clinical studies of a device are required and if the FDA considers experimental use of the device to represent significant risk to the patient. The IDE application must be supported by data, typically including the results of animal and mechanical testing of the device. If the IDE application is approved by the FDA, human clinical studies may begin at a specific number of investigational sites with a maximum number of patients, as approved by the FDA. The clinical studies must be conducted under the review of an independent institutional review board to ensure the protection of the patients’ rights.

Generally, upon completion of these human clinical studies, a manufacturer seeks approval of a Class III medical device from the FDA by submitting a PMA application. A PMA application must be supported by extensive data, including the results of the clinical studies, as well as literature to establish the safety and effectiveness of the device.

Our Duett sealing device is classified as a Class III device and is subject to the PMA requirements. In May 1997, the FDA determined that the review of the Duett sealing device would be delegated to the Center for Devices and Radiological Health area of the FDA, with a consulting review by the Center for Biologic Evaluation and Research. During 1998 and 1999, we received approval of our IDE application to start our feasibility clinical study, filed our IDE Supplement to begin our multi-center clinical study, completed the SEAL multi-center clinical study and filed our PMA application with the FDA. In September 1999 our manufacturing facility was audited by the FDA, with no deficiencies or non-compliances noted by the inspector. In December 1999, we received the FDA’s review letter of our PMA application, and we submitted an amendment to our PMA to the FDA in January 2000. On June 22, 2000, we received approval from the FDA of our PMA application to sell the Duett sealing device in the United States.

Our D-Stat Dry, Pronto, Vari-Lase, D-Stat Flowable, Specialty Catheter and Other product lines require clearance of a 510(k) notification by the FDA prior to being sold in the United States. Each of the devices within these product lines was subject to a 510(k) notification which was determined to be “substantially

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equivalent” to a legally marketed predicate device by the FDA, thereby allowing commercial marketing in the United States.

We also are subject to FDA regulations concerning manufacturing processes and reporting obligations. These regulations require that manufacturing steps be performed according to FDA standards and in accordance with documentation, control and testing standards. We also are subject to inspection by the FDA on an on-going basis. We are required to provide information to the FDA on adverse incidents as well as maintain a documentation and record keeping system in accordance with FDA guidelines. The advertising of our products also is subject to both FDA and Federal Trade Commission jurisdiction. If the FDA believes that we are not in compliance with any aspect of the law, it can institute proceedings to detain or seize products, issue a recall, stop future violations and assess civil and criminal penalties against us, our officers and our employees.

### ***International***

The European Union has adopted rules which require that medical products receive the right to affix the CE mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. As part of the CE mark compliance, manufacturers are required to comply with the European quality systems standards. We received the CE mark approval for our Duett sealing device and certification of our quality system in July 1998, and we received the CE mark approval for other select products within our product lines.

International sales of our products are subject to the regulatory requirements of each country in which we sell. These requirements vary from country to country but generally are much less stringent than those in the United States. We have obtained regulatory approvals where required for us to sell our products in the country. Through our Japanese distributor, in 2005 we gained regulatory approval of our Pronto extraction catheter for commercial sale in Japan.

### **Third Party Reimbursement**

In the United States, healthcare providers that purchase medical devices, generally rely on third-party payors, principally the Centers for Medicare and Medicaid Services or CMS (formerly the Health Care Financing Administration, or HCFA), and private health insurance plans, to reimburse all or part of the cost of therapeutic and diagnostic catheterization procedures. We believe that in the current United States reimbursement system, the cost of vascular sealing devices is incorporated into the overall cost of the catheter procedure. Our other products are subject to reimbursement rules depending on the specific medical procedure in which they are utilized.

Market acceptance of our products in international markets is dependent in part upon the availability of reimbursement from healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country. The main types of healthcare payment systems in international markets are government-sponsored healthcare and private insurance. Countries with government-sponsored healthcare, such as the United Kingdom, have a centralized, nationalized healthcare system. New devices are brought into the system through negotiations between departments at individual hospitals at the time of budgeting. In most foreign countries, there are also private insurance systems that may offer payments for alternative therapies.

### **Patents and Intellectual Property**

We file patent applications to protect technology, inventions and improvements that are significant to the development of our business, and use trade secrets and trademarks to protect other areas of our business. We currently have twelve United States patents issued and six additional patents pending concerning our Duett sealing device, our Pronto catheter, our Langston dual lumen pigtail catheter, our MAX-Support abdominal retraction belt, our Acolysis ultrasound product and our D-Stat Dry product. We also have pursued

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international patent applications, which designate the key developed nations with substantive patent protection systems.

The interventional medical device market in general, and the vascular sealing device and endovenous laser therapy fields in particular, are characterized by frequent and substantial intellectual property litigation. Each of the vascular sealing products currently on the U.S. market, including our Duett sealing device, has been subject to infringement litigation. In addition, two of our competitors in the endovenous laser therapy market (Diomed & VNUS) have brought eight separate intellectual property lawsuits against their competitors, including us. (See "Legal Proceedings" in Item 3 of Part I of this Form 10-K.) The interpretation of patents involves complex and evolving legal and factual questions. Intellectual property litigation in recent years has proven to be complex and expensive, and the outcome of such litigation is difficult to predict.

We may become the subject of additional intellectual property claims in the future related to our products. Our defense of any intellectual property claims filed in the future, regardless of the merits of the complaint, could divert the attention of our technical and management personnel away from the development and marketing of our products for significant periods of time. The costs incurred to defend future claims could be substantial and adversely affect us, even if we are ultimately successful.

We also rely on trade secret protection for certain aspects of our technology. We typically require our employees, consultants and vendors for major components to execute confidentiality agreements upon their commencing services with us or before the disclosure of confidential information to them. These agreements generally provide that all confidential information developed or made known to the other party during the course of that party's relationship with us is to be kept confidential and not disclosed to third parties, except in special circumstances. The agreements with our employees also provide that all inventions conceived or developed in the course of providing services to us shall be our exclusive property.

We also register the trademarks and trade names through which we conduct our business. To date, we have registered the trademarks "D-Stat," and "Vari-Lase," and have applied for registration in the United States of the marks "Vascular Solutions Duett," "Pronto," "MAX-Support," "Langston," "Twin-Pass," "Skyway," "Langton," "Thrombi-Gel," and the Duett stylized logo. We acquired the registered trademark "Acolysis" in connection with our acquisition of the Acolysis therapeutic ultrasound business in 2002. U.S. trademark registrations are generally for a term of 10 years, renewable every 10 years as long as the trademark is used in the regular course of trade.

#### **Employees**

As of December 31, 2005, we had 179 full time employees. Of these employees, 42 were in manufacturing activities, 90 were in sales and marketing activities, 15 were in research and development activities, 19 were in regulatory, quality assurance and clinical research activities and 13 were in general and administrative functions. We have never had a work stoppage and none of our employees are covered by collective bargaining agreements. We believe our employee relations are good.

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## Executive Officers of the Registrant

Our executive officers as of January 31, 2006 are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Howard Root	45	Chief Executive Officer and Director
James Hennen	33	Chief Financial Officer, Vice President of Finance and Corporate Secretary
Deborah Neymark	49	Vice President of Regulatory Affairs, Clinical Research and Quality Systems
James Quackenbush	47	Vice President of Manufacturing
Gregg Sutton	46	Vice President of Research and Development
Fred Reuning	50	Vice President of Marketing

**Howard Root** has served as our Chief Executive Officer and a director since he co-founded Vascular Solutions, Inc. in February 1997. From 1990 to 1995, Mr. Root was employed by ATS Medical, Inc., a mechanical heart valve company, most recently as Vice President and General Counsel. Prior to joining ATS Medical, Mr. Root practiced corporate law, specializing in representing emerging growth companies, at the law firm of Dorsey & Whitney for over five years. Mr. Root received his B.S. in Economics and J.D. from the University of Minnesota.

**James Hennen** has served as our Chief Financial Officer since January 2004. Mr. Hennen served as our Controller & Director of Finance from February 2002 through December 2003. Prior to joining us, Mr. Hennen served in various accounting positions, most recently as International Controller with WAM!NET, Inc., a globally networked information technology company for media transfer, where he worked since December 1997. From October 1995 through December 1997, Mr. Hennen was a Senior Auditor for Ernst & Young, LLP. Mr. Hennen received a B.S. in Business/Accounting from the University of Minnesota. Mr. Hennen is a Certified Public Accountant.

**Deborah Neymark** has served as our Vice President of Regulatory Affairs, Clinical Affairs and Quality Systems since October 2000. Mrs. Neymark served as the Corporate Compliance Officer and Vice President of Regulatory Affairs, Clinical Research and Quality Systems for Empi, Inc. from October 1995 to October 2000. From May 1993 to October 1995, Mrs. Neymark was employed as a Regulatory Affairs Manager for Boston Scientific's Scimed division. Prior to May 1993, Mrs. Neymark held regulatory affairs, clinical research and quality assurance positions at Medtronic and Lifecore Biomedical. She received her B.S. in Biology from Valparaiso University.

**James Quackenbush** has served as our Vice President of Manufacturing since March 1999. Prior to joining us, Mr. Quackenbush served as Vice President of Manufacturing and Operations with Optical Sensors, Inc., a diagnostic medical device company, where he worked since October 1992. From March 1989 through October 1992, Mr. Quackenbush served as operations manager with Schneider USA's stent division. Prior to this time, he was an advanced project engineer with the 3M Medical Products Division. Mr. Quackenbush received a B.S. in Industrial Engineering from Iowa State University.

**Gregg Sutton** has served as our Vice President of Research & Development since October 2004. Prior to joining us, Mr. Sutton served as Vice President of Research & Development with AtriTech, Inc., a development stage interventional medical device company, since January 2000. From 1998 to 2000, he was Vice President of Research & Development of AngioGuard, Inc., an interventional medical device company that was acquired by Johnson & Johnson in 2000. In 1990, Mr. Sutton co-founded Navarre Biomedical, Inc., a manufacturer of interventional radiology products that was acquired by CR Bard in 1997. Prior to 1990 Mr. Sutton held product engineering positions at St. Jude Medical, Claris Medical and Daig Corporation. Mr. Sutton received a B.S. in Mechanical Engineering from the University of Minnesota.

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**Fred Reuning** has served as our Vice President of Marketing since July 2005. Prior to joining us, Mr. Reuning worked at Smiths Medical, a medical device company, where he was Director of Marketing for the Vascular Access division from November 2001 to July 2005 and Senior Product Manager from January 2000 to November 2001. From 1987 to 2000, he worked for Novartis Nutrition, a medical nutrition company, in product management for medical devices with his last position as Group Manager, Medical Devices from November 1997 to December 1999. Mr. Reuning received a B.A. in history from Washington and Lee University and a M.A. in international studies from Johns Hopkins School of Advanced International Studies.

There are no family relationships among any of our executive officers.

#### Available Information

We make available free of charge on or through our internet website at <http://www.vascularolutions.com> our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the Exchange Act) as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

#### ITEM IA. RISK FACTORS

*The risks and uncertainties described below are not the only ones facing our company. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the following risks occur, our business, financial condition or results of operations could be seriously harmed.*

*We will not be successful if the interventional medical device community does not adopt our new products*

During the third quarter of 2000 we commenced sales of our first product, the Duett sealing device, in the United States, which we believe represents the largest market for interventional medical devices. We have not become profitable with our sales of the Duett. In the second half of 2003, we received clearance to commence sales of four new interventional products in the United States. Our success will depend on the medical community's acceptance of our new products. We cannot predict how quickly, if at all, the medical community will accept our new products, or, if accepted, the extent of their use. Our potential customers must:

- believe that our products offer benefits compared to the methodologies and/or devices that they are currently using;
- use our products and obtain acceptable clinical outcomes;
- believe that our products are worth the price that they will be asked to pay; and
- be willing to commit the time and resources required to change their current methodology.

Because we have only limited experience with sales of our new products, we have no ability to predict the level of growth in sales of these products. If we encounter difficulties in growing our sales of our new medical devices in the United States, our business will be seriously harmed.

*We have limited working capital to pursue our business*

On December 31, 2005, we had \$4.3 million in cash and cash equivalents and a working capital of \$10.9 million. During 2005, our operating activities resulted in the use of \$1.7 million of cash. There can be no assurance that our existing working capital will be sufficient to satisfy our working capital needs. If our sales



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do not increase, or if we encounter unexpected expenses, we will need to raise additional working capital. We have no commitments for additional funding and so our ability to meet our long-term liquidity needs is uncertain. If we raise additional funds through the issuance of equity securities, our shareholders may experience significant dilution. Furthermore, additional financing may not be available when needed or, if available, financing may not be on terms favorable to us or our shareholders. If financing is not available when required or is not available on acceptable terms, we may be unable to develop or market our products or unable to take advantage of business opportunities, or we may be required to significantly curtail our business operations.

*We have incurred losses and we may not be profitable in the future*

Since we commenced operations in February 1997, we have incurred net losses primarily from costs relating to the development and commercialization of our Duett sealing device and new products. At December 31, 2005, we had an accumulated deficit of \$63.8 million. We expect to continue to significantly invest in our sales and marketing, and research and development activities. Because of our plans to introduce new products and expand our commercialization, we expect to incur net losses through at least the second quarter of 2006. Our business strategies may not be successful, and we may not become profitable in any future period or at all. If we do become profitable, we cannot be certain that we can sustain or increase profitability on a quarterly or annual basis.

*We may face additional intellectual property claims in the future which could prevent us from manufacturing and selling our products or result in our incurring substantial costs and liabilities*

The interventional medical device industry is characterized by numerous patent filings and frequent and substantial intellectual property litigation. Companies in the interventional medical device industry have employed intellectual property litigation in an attempt to gain a competitive advantage. We have been subject to two intellectual property lawsuits concerning our Duett sealing device. Although we have settled both of these intellectual property lawsuits, it is possible that additional claims relating to the Duett could be brought in the future. We also are the subject of three intellectual property lawsuits concerning our Vari-Lase products. In addition, while we do not believe that any of our new products infringes any existing patent, it is highly likely that we will become subject to intellectual property claims with respect to our new products in the future. Intellectual property litigation in recent years has proven to be very complex, and the outcome of such litigation is difficult to predict.

An adverse determination in any intellectual property litigation or interference proceedings could prohibit us from selling a product, subject us to significant liabilities to third parties or require us to seek licenses from third parties. The costs associated with these license arrangements may be substantial and could include ongoing royalties. Furthermore, the necessary licenses may not be available to us on satisfactory terms, if at all. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling a product.

Our defense of intellectual property claims filed in the future, regardless of the merits of the complaint, could divert the attention of our technical and management personnel away from the development and marketing of our products for significant periods of time. The costs incurred to future claims could be substantial and seriously harm us, even if our defense is ultimately successful.

*The loss of, or interruption of supply from, key vendors, including our single source supplier of thrombin, could limit our ability to manufacture our products*

We purchase components used in our products from various suppliers and rely on a single source for the thrombin component of our Duett sealing device and D-Stat products. There are currently no FDA-approved alternative suppliers of thrombin. Our current supply agreement with our thrombin vendor terminated in May 2005. Because it requires FDA approval, establishing our new supplier for thrombin requires a lead-time of at least two years and involves significant additional costs. The failure by us to complete our thrombin

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qualification project on time and on budget, or the loss of any other key vendor, may limit our ability to manufacture our Duett, D-Stat Flowable and D-Stat Dry products and could therefore seriously harm our business.

*We have purchased a substantial amount of thrombin inventory, and failure to both qualify our new source of thrombin and sell an increasing amount of our thrombin-based products could cause a substantial inventory write-off.*

The principal component in all of our hemostatic products is thrombin. Under a previous supply agreement with our original thrombin supplier we issued substantial purchase orders prior to its expiration in 2005. As of December 31, 2005, we had approximately \$1.4 million of thrombin from this original source in inventory. Currently we are in the process of qualifying a new source of thrombin, which has required us to purchase and hold in inventory approximately \$1.7 million of additional thrombin as of December 31, 2005. We must complete our qualification work and receive FDA clearance before we can utilize this new source of thrombin as a component in our hemostatic products. If we do not achieve this FDA clearance, we will not be able to sell this thrombin and will be required to write-off our inventory. In addition, if any of our inventory of thrombin from the original source or the new source is destroyed or otherwise degraded, we could be exposed to substantial losses.

*Our future operating results are difficult to predict and may vary significantly from quarter to quarter, which may adversely affect the price of our common stock*

The limited history of our sales and our history of losses make prediction of future operating results difficult. You should not rely on our past revenue growth as any indication of future growth rates or operating results. The price of our common stock will likely fall in the event that our operating results do not meet the expectations of analysts and investors. Comparisons of our quarterly operating results are an unreliable indication of our future performance because they are likely to vary significantly based on many factors, including:

- the level of sales of our products in the United States market;
- our ability to introduce new products and enhancements in a timely manner;
- the demand for and acceptance of our products;
- the success of our competition and the introduction of alternative products;
- our ability to command favorable pricing for our products;
- the growth of the market for our devices;
- the expansion and rate of success of our direct sales force in the United States and our independent distributors internationally;
- actions relating to ongoing FDA compliance;
- the effect of intellectual property disputes;
- the size and timing of orders from independent distributors or customers;
- the attraction and retention of key personnel, particularly in sales and marketing, regulatory, manufacturing and research and development;
- unanticipated delays or an inability to control costs;

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- general economic conditions as well as those specific to our customers and markets; and
  - seasonal fluctuations in revenue due to the elective nature of some procedures.

*We may face product liability claims that could result in costly litigation and significant liabilities*

The manufacture and sale of medical products entail significant risk of product liability claims. The medical device industry in general has been subject to significant medical malpractice litigation. Any product liability claims, with or without merit, could result in costly litigation, reduced sales, cause us to incur significant liabilities and divert our management's time, attention and resources. Because of our limited operating history and lack of experience with these claims, we cannot be sure that our product liability insurance coverage is adequate or that it will continue to be available to us on acceptable terms, if at all.

*The market for interventional medical devices is highly competitive and will likely become more competitive, and our competitors may be able to respond more quickly to new or emerging technologies and changes in customer requirements that may render our products obsolete*

The existing market for interventional medical devices is intensely competitive. We expect competition to increase further as companies develop new products and/or modify their existing products to compete directly with ours. Each of our products encounters competition from at least several medical device companies, including Medtronic Inc., Abbot Laboratories, St. Jude Medical and Datascope. Each of these companies has:

- better name recognition;
- broader product lines;
- greater sales, marketing and distribution capabilities;
- significantly greater financial resources;
- larger research and development staffs and facilities; and
- existing relationships with some of our potential customers.

We may not be able to effectively compete with these companies. In addition, broad product lines may allow our competitors to negotiate exclusive, long-term supply contracts and offer comprehensive pricing for their products. Broader product lines may also provide our competitors with a significant advantage in marketing competing products to group purchasing organizations and other managed care organizations that are increasingly seeking to reduce costs through centralized purchasing. Greater financial resources and product development capabilities may allow our competitors to respond more quickly to new or emerging technologies and changes in customer requirements that may render our products obsolete.

*Our international sales are subject to a number of risks that could seriously harm our ability to successfully commercialize our products in any international market*

Our international sales are subject to several risks, including:

- the ability of our independent distributors to sell our products;
- the impact of recessions in economies outside the United States;
- greater difficulty in collecting accounts receivable and longer collection periods;

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- unexpected changes in regulatory requirements, tariffs or other trade barriers;
  - weaker intellectual property rights protection in some countries;
  - potentially adverse tax consequences; and
  - political and economic instability.

The occurrence of any of these events could seriously harm our future international sales and our ability to successfully commercialize our products in any international market.

*We have limited manufacturing experience and may encounter difficulties in our manufacturing operations which could seriously harm our business*

We have limited experience in manufacturing our products. In particular, we have limited experience in lyophilization, which is a key manufacturing step for our D-Stat Dry hemostatic bandage. We believe our facilities are adequate for our projected production of our products for the foreseeable future, but future facility requirements will depend largely on future sales of our products in the United States. We may encounter unforeseen difficulties in expanding our production of our new products, including problems involving production yields, quality control and assurance, component supply and shortages of qualified personnel, compliance with FDA regulations and requirements regarding good manufacturing practices, and the need for further regulatory approval of new manufacturing processes. Difficulties encountered by us in expanding and maintaining our manufacturing capabilities could seriously harm our business.

*Our business and results of operations may be seriously harmed by changes in third-party reimbursement policies*

We could be seriously harmed by changes in reimbursement policies of governmental or private healthcare payors, particularly to the extent any changes affect reimbursement for catheterization procedures in which our products are used. Failure by physicians, hospitals and other users of our products to obtain sufficient reimbursement from healthcare payors for procedures in which our products are used or adverse changes in governmental and private third-party payors' policies toward reimbursement for such procedures would seriously harm our business.

In the United States, healthcare providers, including hospitals and clinics that purchase medical devices such as our products, generally rely on third-party payors, principally federal Medicare, state Medicaid and private health insurance plans, to reimburse all or part of the cost of catheterization procedures. Any changes in this reimbursement system could seriously harm our business.

In international markets, acceptance of our products is dependent in part upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country. Our failure to receive international reimbursement approvals could have a negative impact on market acceptance of our products in the markets in which these approvals are sought.

*Our products and our manufacturing activities are subject to extensive governmental regulation that could prevent us from selling our products in the United States or introducing new and improved products*

Our products and our manufacturing activities are subject to extensive regulation by a number of governmental agencies, including the FDA and comparable international agencies. We are required to:

- obtain the clearance of the FDA and international agencies before we can market and sell our products;

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- satisfy these agencies' content requirements for all of our labeling, sales and promotional materials; and
  - undergo rigorous inspections by these agencies.

Compliance with the regulations of these agencies may delay or prevent us from introducing any new model of our existing products or other new products. Furthermore, we may be subject to sanctions, including temporary or permanent suspension of operations, product recalls and marketing restrictions if we fail to comply with the laws and regulations pertaining to our business.

We are also required to demonstrate compliance with the FDA's quality system regulations. The FDA enforces its quality system regulations through pre-approval and periodic post-approval inspections. These regulations relate to product testing, vendor qualification, design control and quality assurance, as well as the maintenance of records and documentation. If we are unable to conform to these regulations, the FDA may take actions which could seriously harm our business. In addition, government regulation may be established that could prevent, delay, modify or rescind regulatory clearance or approval of our products.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

Our offices are in approximately 43,000 square feet of leased space in a suburb of Minneapolis, Minnesota. These facilities include approximately 12,600 square feet used for manufacturing activities and approximately 3,500 square feet used for research and laboratory activities, with the remainder used for general purpose office space. Our lease for these facilities expires in September 2008. We believe that we may require additional space for our expanding operations before the expiration of this lease. We believe that there is suitable space available in the local market (although not in our current facility) at reasonable rates that are available to us if we need expansion space prior to the end of our lease.

#### **ITEM 3. LEGAL PROCEEDINGS**

On December 11, 2003, we and one of our non-officer employees were named as defendants in a lawsuit brought by Diomed, Inc. in the United States District Court for the District of Massachusetts. The complaint alleges that in marketing our Vari-Lase endovenous laser procedure kit we engaged in false advertising and infringed a registered trademark of Diomed. The complaint also alleges that the non-officer employee, who previously worked for a company that conducted business with Diomed, improperly utilized trade secrets of Diomed in developing our Vari-Lase procedure kit. The complaint requests monetary damages and an injunction on the sale of our Vari-Lase procedure kit. We believe that the allegations included in the complaint are wholly without merit. On July 13, 2005, the court held a hearing on our motion for summary judgment, in which we sought dismissal of all claims. On January 31, 2006, the Court granted our motion for summary judgment dismissing all counts of Diomed's complaint with the exception of one trade secret misappropriation count and a portion of two other counts to the extent they are based on alleged trade secret misappropriation. Our counterclaim against Diomed was not dismissed. The Court has scheduled a status conference for this case on March 2, 2006. Our insurance carrier initially accepted our tender of this claim and has paid for the expenses incurred in defending this lawsuit. After the summary judgment hearing, the insurance company notified us that they were withdrawing coverage prospectively, effective November 6, 2005. It is not possible to predict the timing or outcome of this litigation, including whether it will affect our ability to sell our Vari-Lase procedure kit, or to estimate the amount or range of potential loss.

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On March 4, 2004, we were named as the defendant in an intellectual property lawsuit brought by Diomed, Inc. in the United States District Court for the District of Massachusetts. The complaint requested a judgment that our Vari-Lase procedure kit and Vari-Lase laser console infringe on a single patent held by Diomed, Inc. and asked for relief in the form of an injunction that would prevent us from selling our Vari-Lase products, compensatory and treble damages caused by the manufacture and sale of our product, and other costs, disbursements and attorneys' fees. On April 12, 2005, the Judge entered a Memorandum and Order on Claims Construction from the Markman hearing phase of the litigation. In the Order, the Judge held that in order to violate the Diomed patent, a competing method must deliberately put the tip of the laser fiber in physical contact with the wall of the vein, must drain blood from the vein, must compress the vein and must maintain vein wall contact as the laser energy is delivered. We believe that our Vari-Lase products are not used in this method, and thus we do not believe the litigation has merit. On December 21, 2005, we filed our motion for summary judgment, in which we seek dismissal of all claims. It is not possible to predict the timing or outcome of this litigation, including whether it will affect our ability to sell their Vari-Lase products, or to estimate the amount or range of potential loss.

On October 13, 2005, we were named as one of three defendants in an intellectual property lawsuit brought by VNUS Medical Technologies, Inc. in the United States District Court for the Northern District of California. The complaint requested a judgment that our Vari-Lase procedure kit and Vari-Lase laser console infringes on four patents held by VNUS Medical Technologies, Inc. and asked for relief in the form of an injunction that would prevent us from selling our Vari-Lase products, compensatory and treble damages caused by the manufacture and sale of the Company's product, and other costs, disbursements and attorneys' fees. We believe that our Vari-Lase products do not violate these patents, and thus we do not believe the litigation has merit. It is not possible to predict the timing or outcome of this litigation, including whether it will affect our ability to sell our Vari-Lase products, or to estimate the amount or range of potential loss.

From time to time we are involved in legal proceedings arising in the normal course of our business. As of the date of this report we are not a party to any legal proceeding not described in this section in which an adverse outcome would reasonably be expected to have a material adverse effect on our results of operations or financial condition.

#### **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

No matters were submitted to a vote of security holders during the quarter ended December 31, 2005.



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**PART II**

**ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES**

Our common stock began trading on the NASDAQ National Market under the symbol "VASC" on July 20, 2000. The following table sets forth, for the periods indicated, the range of high and low last sale prices for the common stock as reported by the NASDAQ National Market.

	<u>High</u>	<u>Low</u>
<b>2005</b>		
First Quarter .....	10.200	8.030
Second Quarter .....	12.470	9.070
Third Quarter .....	13.360	9.270
Fourth Quarter .....	9.940	6.750
<b>2004</b>		
First Quarter .....	10.690	5.090
Second Quarter .....	14.740	8.900
Third Quarter .....	11.100	7.000
Fourth Quarter .....	10.750	7.730

**Holders**

As of December 31, 2005, we had 196 shareholders of record. Such number of record holders does not reflect shareholders who beneficially own common stock in nominee or street name.

**Dividends**

We have paid no cash dividends on our common stock, and do not intend to pay cash dividends on our common stock in the future.

**ITEM 6. SELECTED FINANCIAL DATA**

The following selected financial data as of December 31, 2005 and 2004 and for the three years ended December 31, 2005, 2004 and 2003 are derived from, and should be read together with, our financial statements included elsewhere in this Form 10-K. The following selected financial data as of December 31, 2003, 2002 and 2001 and for the fiscal years ended December 31, 2002 and 2001 are derived from financial statements not included herein. The information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," the Consolidated Financial Statements and Notes thereto and other financial information included elsewhere in this Form 10-K.

	<b>Year Ended December 31,</b>				
	<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
	<b>(in thousands, except per share amounts)</b>				
<b>Statements of Operations Data:</b>					
Net sales .....	\$ 32,786	\$ 22,414	\$ 11,862	\$ 12,154	\$ 12,128
Cost of sales .....	9,386	6,757	4,628	5,039	5,007
Gross profit .....	23,400	15,657	7,234	7,115	7,121
<b>Operating expenses:</b>					
Research and development.....	3,789	3,401	3,671	3,227	4,124
Clinical and regulatory .....	2,006	1,906	1,536	1,348	1,288
Sales and marketing .....	13,681	11,360	9,646	11,964	12,772
General and administrative.....	2,810	2,138	1,942	2,167	2,498
Thrombin qualification .....	1,620	210	-	-	-
Legal settlement.....	-	-	-	3,750	350
Amortization of purchased technology....	218	218	217	145	-
Total operating expenses .....	24,124	19,233	17,012	22,601	21,032
Operating loss .....	(724)	(3,576)	(9,778)	(15,486)	(13,911)
Interest income .....	163	68	150	507	1,661
Net loss .....	\$ (561)	\$ (3,508)	\$ (9,628)	\$ (14,979)	\$ (12,250)
<b>Net loss per common share –</b>					
Basic and diluted .....	\$ (0.04)	\$ (0.25)	\$ (0.75)	\$ (1.13)	\$ (0.93)
Weighted average number of common shares outstanding .....	14,515	13,952	12,859	13,276	13,217
	<b>As of December 31,</b>				
	<b>2005</b>	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>
	<b>(in thousands)</b>				
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and available-for-sale securities .....	\$ 4,282	\$ 7,184	\$ 5,885	\$ 16,750	\$ 33,318
Working capital .....	10,887	11,833	9,223	18,656	34,712
Total assets .....	19,896	16,822	12,992	22,280	37,593
Long-term debt .....	-	-	-	-	-
Total shareholders' equity .....	14,107	13,690	10,873	20,369	35,630

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## ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with our Consolidated Financial Statements and Notes thereto, and the other financial information included elsewhere in this Form 10-K Report. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains descriptions of our expectations regarding future trends affecting our business. These forward-looking statements and other forward-looking statements made elsewhere in this document are made in reliance upon safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Item 1A of Part I of this Form 10-K sets forth certain factors we believe could cause actual results to differ materially from those contemplated by the forward looking statements.

### Overview

We are a medical device company focused on bringing solutions to interventional cardiologists and interventional radiologists. As a vertically-integrated medical device company, we generate ideas and create new interventional medical devices, and then deliver those products directly to the physician through our direct domestic sales force and international distribution network. We continue to develop new products and applications for our existing products.

Since 2003, we have launched four substantial product lines:

- *D-Stat Dry Product Line.* We launched the D-Stat Dry Hemostatic Bandage in September 2003. The D-Stat Dry hemostatic bandage consists of a freeze-dried pad of our D-Stat procoagulant which can be applied to topical bleeding with a custom adhesive bandage. Other products included in the D-Stat Dry product line include D-Stat 2Dry, the D-Stat Clamp, the D-Stat Radial and Thrombix trauma bandage (formerly D-Stat Dry 3x3).
- *Pronto Extraction Catheter Product Line.* We launched the Pronto Extraction Catheter in international markets at the end of the third quarter of 2003, and received regulatory clearance for United States sales in December 2003. The Pronto extraction catheter consists of a catheter with a proprietary atraumatic distal tip and large extraction lumen for the removal of soft thrombus from arteries. Pronto-Short is also included in the Pronto product line.
- *Vari-Lase Product Line.* We launched the Vari-Lase Procedure Kit in the third quarter of 2003 and the Vari-Lase Laser Console in the first quarter of 2004. The Vari-Lase product is a treatment for superficial venous reflux, otherwise known as varicose veins. Other products included in the Vari-Lase product line include Auto-Fill, Procedure Packs, MicroIntroducers and GuideWires.
- *Specialty Catheter Product Line.* We received regulatory clearance for the Langston Dual Lumen Pigtail Catheter in September 2004 and launched this product in the fourth quarter of 2004. The Langston catheter is used to measure the precise measurement of aortic stenosis.

We believe these four new product lines together with sales of our existing Duett product line, D-Stat Flowable product line and Other Products, will result in continued substantial revenue growth in the range of 25% to 40% for 2006. We also believe our gross margin percent will be approximately 68% to 70% during 2006.

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## Results of Operations

### *Year ended December 31, 2005 compared to year ended December 31, 2004*

Net sales increased to \$32,786,000 for the year ended December 31, 2005 from \$22,414,000 for the year ended December 31, 2004. Approximately 89% of our net sales for the year ended December 31, 2005 were to customers in the United States and 11% of the net sales were to customers in international markets. Net sales by product category were as follows:

- Net sales of the D-Stat Dry product line were \$13,804,000 for the year ended December 31, 2005 compared to \$8,831,000 for the year ended December 31, 2004. Through December 31, 2005, we have sold our D-Stat Dry to 904 of the estimated 3,000 cardiac and interventional radiology labs in the United States.
- Net sales of the Pronto product line were \$6,357,000 for the year ended December 31, 2005 compared to \$3,051,000 for the year ended December 31, 2004. We have sold our Pronto to 807 accounts in the United States through December 31, 2005.
- Net sales of the Vari-Lase product line were \$5,008,000 for the year ended December 31, 2005 compared to \$2,662,000 for the year ended December 31, 2004. We have sold our Vari-Lase kits to 316 accounts in the United States through December 31, 2005.
- Net sales of the Duett product line were \$3,954,000 for the year ended December 31, 2005 compared to \$5,973,000 for the year ended December 31, 2004. We expect Duett sales to continue to decline at a rate of 20% to 30%, year over year, as we continue to harvest this product and focus on our new higher margin products.
- Net sales of the D-Stat Flowable product line increased to \$2,083,000 for the year ended December 31, 2005 compared to \$1,441,000 for the year ended December 31, 2004, a 45% increase. We have sold our D-Stat Flowable to 753 accounts in the United States through December 31, 2005.
- Net sales of the Specialty Catheter product line were \$1,036,000 for the year ended December 31, 2005 compared to \$133,000 for the year ended December 31, 2004. In September 2004 we launched the Langston dual lumen pigtail catheter and we have sold it to 487 accounts in the United States through December 31, 2005.
- Net sales of Other Products were \$544,000 for the year ended December 31, 2005 compared to \$323,000 for the year ended December 31, 2004. Other Products include Acolysis, MAX Support Belt and freight. Acolysis is sold only in international markets.

Gross profit as a percentage of net sales increased to 71% for the year ended December 31, 2005 from 70% for the year ended December 31, 2004. Our selling mix continues to change to our higher margin products such as our D-Stat Dry, which has gross margins greater than 80%. We expect gross margins to be in the range of 67% to 70% in 2006 as our selling mix continues to change and our new V3 version of the Pronto has higher manufacturing costs than the original Pronto.

Research and development expenses increased 11% to \$3,789,000 for the year ended December 31, 2005 from \$3,401,000 for the year ended December 31, 2004. The increase was the result of our increased investment in research and development as well as our increase in head count to 15 employees at December 31, 2005 versus 12 at December 31, 2004. We expect our normal research and development expenses to be approximately 10% to 12% of sales per quarter in 2006 as we continue to pursue additional new products at an expected rate of approximately two new products per year and we continue to move our longer term

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development projects forward. Research and development expenses will decline as a percent of sales throughout 2006 as our sales increase.

Clinical and regulatory expenses increased 5% to \$2,006,000 for the year ended December 31, 2005 from \$1,906,000 for the year ended December 31, 2004. The increase was the result of increased clinical study activity, increased FDA fees and increased number of employees compared to 2004. During 2005 our clinical studies consisted of the "Pocket Protector" study for a new indication of our D-Stat Flowable product and the D-Stat Dry study to obtain clinical data to support growing sales of the D-Stat Dry. Clinical and regulatory expenses fluctuate due to the timing of clinical and marketing studies. We expect clinical and regulatory expenses to be approximately 6% to 8% of sales per quarter in 2006 as we continue to pursue additional new products at an expected rate of approximately two new products per year and we continue to move our longer term development projects forward. Clinical and regulatory expenses will decline as a percent of sales throughout 2006 as our sales increase.

Sales and marketing expenses increased 20% to \$13,681,000 for the year ended December 31, 2005 from \$11,360,000 for the year ended December 31, 2004. The increase in sales and marketing expenses is the direct result of our increase in our direct sales force to 72 employees at the end of 2005 compared to 57 as of December 31, 2004. We expect to add approximately 10 field sales employees during 2006 to complete our geographic coverage of the United States. As a result, we expect our sales and marketing expenses to be between 38% and 45% of sales per quarter in 2006. Sales and marketing expenses are expected to decline as a percent of sales throughout 2006 as our sales increase.

General and administrative expenses increased 31% to \$2,810,000 for the year ended December 31, 2005 from \$2,138,000 for the year ended December 31, 2004. The increase was primarily the result of higher legal fees relating to the Diomed litigation (see "Legal Proceedings" in Item 3 of Part I of this Form 10-K) along with higher business insurance and accounting fees in 2005 compared to 2004. We expect general and administrative expenses to be approximately 8% to 10% of sales per quarter in 2006.

Thrombin qualification project expenses were \$1,620,000 for the year ended December 31, 2005 compared to \$210,000 for the year ended December 31, 2004. We expect the total remaining expenses associated with our qualification of the new source of thrombin to be approximately \$2.5 million in 2006.

Amortization of purchased technology was \$218,000 for each of the years ended December 31, 2005 and 2004. The amortization resulted from our acquisition of the Acolysis assets from the secured creditors of Angiosonics, Inc. We allocated \$870,000 from the acquisition to purchased technology and are amortizing the amount over four years.

Interest income increased to \$163,000 for the year ended December 31, 2005 from \$68,000 for the year ended December 31, 2004 primarily as a result of higher interest rates.

## **Results of Operations**

### ***Year ended December 31, 2004 compared to year ended December 31, 2003***

Net sales increased to \$22,414,000 for the year ended December 31, 2004 from \$11,862,000 for the year ended December 31, 2003. Approximately 89% of our net sales for the year ended December 31, 2004 were to customers in the United States and 11% of the net sales were to customers in international markets. Net sales by product category were as follows:

- Net sales of the D-Stat Dry product line were \$8,831,000 for the year ended December 31, 2004 compared to \$1,085,000 for the year ended December 31, 2003. Our D-Stat Dry product was launched at the end of the third quarter of 2003.

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- Net sales of the Pronto product line were \$3,051,000 for the year ended December 31, 2004 compared to \$97,000 for the year ended December 31, 2003. Our Pronto product was launched at the end of the third quarter of 2003 in international markets, and we received FDA approval in December 2003 but did not commence sales in the United States until 2004.
  - Net sales of the Vari-Lase product line were \$2,662,000 for the year ended December 31, 2004 compared to \$255,000 for the year ended December 31, 2003. Our Vari-Lase procedure kit was launched during the third quarter of 2003, and our Vari-Lase laser console was launched during the first quarter of 2004.
  - Net sales of the Duett product line were \$5,973,000 for the year ended December 31, 2004 compared to \$8,995,000 for the year ended December 31, 2003. We expect Duett sales to continue to decline at a rate of between 20% to 30%, year over year, as we continue to harvest this product and focus on our new higher margin products.
  - Net sales of the D-Stat Flowable product line increased to \$1,441,000 for the year ended December 31, 2004 compared to \$1,187,000 for the year ended December 31, 2003, a 21% increase.
  - Net sales of the Specialty Catheter product line were \$133,000 for the year ended December 31, 2004 compared to no sales for the year ended December 31, 2003. In September 2004 we launched the Langston dual lumen pigtail catheter.
  - Net sales of Other Products were \$323,000 for the year ended December 31, 2004 compared to \$243,000 for the year ended December 31, 2003. The increase in Other Products was due to increased freight revenue, which is the result of increased shipments.

Gross profit as a percentage of net sales increased to 70% for the year ended December 31, 2004 from 61% for the year ended December 31, 2003. The selling mix changed in 2004 to the higher margin products such as our D-Stat Dry, which had gross margins greater than 80%, and our Pronto, which had gross margins in excess of 75%.

Research and development expenses decreased 7% to \$3,401,000 for the year ended December 31, 2004 from \$3,671,000 for the year ended December 31, 2003. The decrease was related to less outside project spending in 2004 compared to 2003.

Clinical and regulatory expenses increased 24% to \$1,906,000 for the year ended December 31, 2004 from \$1,536,000 for the year ended December 31, 2003. The increase was the result of increased clinical study activity, increased FDA fees and increased number of employees compared to 2003. During 2004 our clinical studies consisted of the "Pocket Protector" study for a new indication of our D-Stat Flowable product and the D-Stat Dry study to obtain clinical data to support growing sales of the D-Stat Dry. Clinical and regulatory expenses fluctuate due to the timing of clinical and marketing studies.

Sales and marketing expenses increased 18% to \$11,360,000 for the year ended December 31, 2004 from \$9,646,000 for the year ended December 31, 2003. The increase in sales and marketing expenses is the direct result of our increase in our direct sales force to 57 employees at the end of 2004 compared to 47 as of December 31, 2003.

General and administrative expenses increased 10% to \$2,138,000 for the year ended December 31, 2004 from \$1,942,000 for the year ended December 31, 2003. The increase was primarily the result of higher legal fees relating to the Diomed litigation (see "Legal Proceedings" in Item 3 of Part I of this Form 10-K) along with higher business insurance in 2004 compared to 2003.

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Thrombin qualification project expenses were \$210,000 for the year ended December 31, 2004 compared to no expenses for the year ended December 31, 2003.

Amortization of purchased technology was \$218,000 for the year ended December 31, 2004 and \$217,000 for the year ended December 31, 2003. The amortization resulted from our acquisition of the Acolysis assets from the secured creditors of Angiosonics, Inc.

Interest income decreased to \$68,000 for the year ended December 31, 2004 from \$150,000 for the year ended December 31, 2003 primarily as a result of lower interest rates and lower cash balances.

#### **Income Taxes**

We have not generated any fiscal year pre-tax income to date and therefore have not paid any federal income taxes since our inception in December 1996. No provision or benefit for federal and state income taxes has been recorded for net operating losses incurred in any period since our inception.

As of December 31, 2005, we had approximately \$58.2 million of federal net operating loss carryforwards available to offset future taxable income which begin to expire in the year 2013. As of December 31, 2005, we also had federal and state research and development tax credit carryforwards of approximately \$2.1 million which begin to expire in the year 2013. As of December 31, 2005, we also had a foreign tax loss carryforward of approximately \$2.5 million, which does not expire. Under the United States Tax Reform Act of 1986, the amounts of and benefits from net operating loss carryforwards may be impaired or limited in certain circumstances, including significant changes in ownership interests. Future use of our existing net operating loss carryforwards may be restricted due to changes in ownership or from future tax legislation. We performed a section 382 "change in ownership" study during the third quarter 2005 on our federal net operating loss carryforward, and we concluded that we will have no limitations on the net operating loss carryforward.

#### **Liquidity and Capital Resources**

We have financed all of our operations since inception through the issuance of equity securities and, to a lesser extent, sales of our products. Through December 31, 2005, we have sold capital stock generating aggregate net proceeds of approximately \$78 million. At December 31, 2005, we had \$4,282,000 in cash and cash equivalents on-hand compared to \$7,184,000 at December 31, 2004.

During the year ended December 31, 2005, we used \$1,729,000 in cash as a result of operating activities, we incurred capital expenditures in the amount of \$2,200,000, and we generated \$1,108,000 in financing activities through the sale of common stock upon the exercise of outstanding stock options and issuances under employee stock plans. Our capital expenditures included equipment related to our thrombin qualification process, leasehold improvements and manufacturing equipment. Our operating cash usage was primarily the result of our planned build up of thrombin from our current supplier as well as our required purchase from our new supplier to qualify our new source of thrombin.

We purchase our requirements for thrombin (a component in the Duett and in all of the D-Stat products) under a Purchase Agreement dated June 10, 1999 with a subsidiary of King Pharmaceuticals, Inc. The agreement provides for a fixed price, with adjustments based on the supplier's manufacturing costs and the supplier's annual percentage increase in the wholesale price of thrombin. The agreement expired on May 29, 2005. Prior to the expiration of the agreement, we issued purchase orders for approximately \$3.5 million of thrombin to benefit from the pricing provisions of the agreement, which thrombin we expect to be delivered through the third quarter of 2006. We believe that these purchases will satisfy our thrombin requirements through at least the end of 2007. We have taken delivery of approximately \$1.4 million of the \$3.5 million of King thrombin through December 31, 2005. We have executed a supply agreement for a new source of thrombin, which we plan to fully qualify and bring through the regulatory process by the second quarter of 2007 at a cumulative cost of approximately \$4.3 million in development and qualification expenditures, of



which approximately \$2.5 million of the expenses remain and are projected to be incurred in 2006. We have purchased \$700,000 in capital expenditures out of our total planned capital expenditures of \$800,000. We also have purchased \$1.7 million of thrombin from our new supplier as of the end of 2005, which fulfills our thrombin purchase requirement. With the thrombin already purchased and our planned additional King thrombin purchases, we expect our inventory to peak at approximately \$8.8 million at the end of the third quarter of 2006, and then decrease throughout the remainder of 2006 and 2007 as the King thrombin is used in our products. This investment, while substantial, is within our projected capital resources and we expect will allow us to introduce new thrombin-based products as well as control our long-term cost of thrombin. The failure by us to complete our thrombin qualification project on time and on budget may affect our gross margins on our Duett, D-Stat Flowable and D-Stat Dry products and could therefore seriously harm our business.

We currently have a \$7 million credit facility with Silicon Valley Bank. The \$5 million revolving line of credit has a 12 month term, bears interest at the rate of prime plus 0.5% and is secured by a first security interest on all of our assets. The \$2 million equipment line of credit has a 36 month term, bears interest at the rate of prime plus 1.5% and is secured by a first security interest on all of our assets. The credit facility includes two covenants: minimum tangible net worth of \$11,000,000 through August 31, 2006, \$12,000,000 through November 30, 2006, and \$13,000,000 thereafter, and liquidity coverage of not less than 1.25 to 1.00. We were in compliance with these covenants at December 31, 2005. As of December 31, 2005, we had no outstanding balance on the \$7 million credit facility and the availability of the \$5 million revolving line of credit was \$4.0 million. On January 6, 2006, we drew down \$2 million of the equipment line.

The following table summarizes our contractual cash commitments as of December 31, 2005:

Contractual Obligations	Total	Payments Due by Period			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Facility Operating Leases	\$ 937,000	\$ 335,000	\$ 602,000	\$ -	\$ -
Sigma Contract Commitment	130,000	130,000	-	-	-
King Pharmaceutical Thrombin Purchases	2,113,000	2,113,000	-	-	-
Total Contractual Cash Obligations	\$3,180,000	\$ 2,578,000	\$602,000	\$ -	\$ -

We do not have any other significant cash commitments related to supply agreements, nor do we have any significant commitments for capital expenditures.

We currently anticipate that we will continue to experience positive cash flow from our normal operating activities, excluding requirements associated with our new supply of thrombin. We currently believe that our working capital of \$10,887,000 at December 31, 2005, our recent \$2 million equipment advance and our anticipated cash from product sales will be sufficient to meet all of our operating and capital requirements, including our thrombin inventory purchases under our current thrombin supply contract and our costs associated with the new supply of thrombin. However, our actual liquidity and capital requirements will depend upon numerous factors, including the costs and timing of expansion of sales and marketing activities; the amount of revenues from sales of our existing and new products; the cost of maintaining, enforcing and defending patents and other intellectual property rights; competing technological and market developments; developments related to regulatory and third party reimbursement matters; the cost and progress of our research and development efforts; and other factors.

If cash generated from operations is insufficient to satisfy our cash needs, we may be required to raise additional funds. In the event that additional financing is needed, and depending on market conditions, we may seek to raise additional funds for working capital purposes through the sale of equity or debt securities.

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## Critical Accounting Policies

Management's Discussion and Analysis of Financial Condition and Results of Operations addresses our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate these estimates and judgments. We base our estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our accounting policies are described in Note 2 to the financial statements. We set forth below those material accounting policies that we believe are the most critical to an investor's understanding of our financial results and condition, and require complex management judgment.

### *Inventory*

We state our inventory at the lower of cost (first-in, first-out method) or market. The estimated value of excess, obsolete and slow-moving inventory as well as inventory with a carrying value in excess of its net realizable value is established by us on a quarterly basis through review of inventory on hand and assessment of future demand, anticipated release of new products into the market, historical experience and product expiration. Our stated value of inventory could be materially different if demand for our products decreased because of competitive conditions or market acceptance, or if products become obsolete because of advancements in the industry.

### *Revenue Recognition*

We recognize revenue in accordance with generally accepted accounting principles as outlined in the SEC's Staff Accounting Bulletin No. 104 "Revenue Recognition," which requires that four basic criteria be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) the price is fixed or determinable; (iii) collectibility is reasonably assured; and (iv) product delivery has occurred or services have been rendered. We recognize revenue as products are shipped based on FOB shipping point terms when title passes to customers. We negotiate credit terms on a customer-by-customer basis and products are shipped at an agreed upon price. All product returns must be pre-approved and, if approved, customers are subject to a 20% restocking charge.

We analyze the rate of historical returns when evaluating the adequacy of the allowance for sales returns, which is included with the allowance for doubtful accounts on our balance sheet. At December 31, 2005, this reserve was \$30,000 compared to \$20,000 at December 31, 2004. If the historical data we use to calculate these estimates does not properly reflect future returns, revenue could be overstated.

### *Allowance for Doubtful Accounts*

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is regularly evaluated by us for adequacy by taking into consideration factors such as past experience, credit quality of the customer base, age of the receivable balances, both individually and in the aggregate, and current economic conditions that may affect a customer's ability to pay. At December 31, 2005, this reserve was \$110,000 compared to \$160,000 at December 31, 2004. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required.

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#### *Warranty Costs*

We provide a warranty for certain products against defects in material and workmanship for periods of up to 24 months. We record a liability for warranty claims at the time of sale. The amount of the liability is based on the amount we are charged by our original equipment manufacturer to cover the warranty period. The original equipment manufacturer includes a year warranty with each product sold to us. We record a liability for the uncovered warranty period offered to a customer, provided the warranty period offered exceeds the initial one year warranty period covered by the original equipment manufacturer. At December 31, 2005, this warranty provision was \$50,000 compared to \$33,000 at December 31, 2004. If the assumptions used in calculating the provision were to materially change, resulting in more defects than anticipated, an additional provision may be required.

#### *Income Taxes*

The carrying value of our net deferred tax assets assumes that we will be able to generate sufficient taxable income in the United States and, to a lesser extent, Germany, based on estimates and assumptions. We record a valuation allowance to reduce the carrying value of our net deferred tax asset to the amount that is more likely than not to be realized. For the year ended December 31, 2005, we recorded a \$27.1 million valuation allowance related to our net deferred tax assets of \$27.1 million. In the event we were to determine that we would be able to realize our deferred tax assets in the future, an adjustment to the deferred tax asset would increase net income in the period such determination is made. On a quarterly basis, we evaluate the realizability of our deferred tax assets and assess the requirement for a valuation allowance.

#### *New Accounting Pronouncements*

The Financial Accounting Standards Board (FASB) has issued Statement No. 123R, *Share-Based Payment* (SFAS 123R), which requires companies to measure and recognize compensation expense for all stock-based payments at fair value. SFAS 123R is effective for us starting with the quarter ending March 31, 2006. Early adoption is encouraged and retroactive application of the provisions of SFAS 123R to the beginning of the fiscal year that includes the effective date is permitted, but not required. We estimate the expense associated with SFAS 123R will be in the range of \$1.3 million to \$1.7 million in 2006. See the Stock-Based Compensation discussion in Note 2 of our financial statements for information related to the pro forma effects on our reported net income (loss) and net income (loss) per common share of applying the fair value recognition provisions of the previous Statement of Financial Accounting Standards (SFAS) 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Financial instruments that potentially subject us to concentrations of credit risk consist primarily of cash and cash equivalents and accounts receivables. We maintain our accounts for cash and cash equivalents principally at one major bank and one investment firm in the United States. We have a formal written investment policy that restricts the placement of investments to issuers evaluated as creditworthy. We have not experienced any losses on our deposits of our cash and cash equivalents.

With respect to accounts receivable, we perform credit evaluations of our customers and do not require collateral. There have been no material losses on accounts receivables.

In the United States and Germany, we sell our products directly to hospitals and clinics in the local currency.

In all other international markets, we sell our products to independent distributors who, in turn, sell to medical clinics. We sell our product in these countries through independent distributors denominated in United States dollars. Loss, termination or ineffectiveness of distributors to effectively promote our product would have a material adverse effect on our financial condition and results of operations.

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We do not believe our operations are currently subject to significant market risks for interest rates, foreign currency exchange rates, commodity prices or other relevant market price risks of a material nature.

We did not have any indebtedness as of December 31, 2005. If we were to borrow from our revolving credit or equipment line, we would be exposed to changes in interest rates, see note 17. Advances under our revolving and equipment lines of credit bear interest at an annual rate indexed to prime. We will thus be exposed to interest rate risk with respect to these lines of credit to the extent that interest rates rise when there are amounts outstanding under these lines of credit. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes.

#### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The Consolidated Financial Statements and Notes thereto required pursuant to this Item begin on page 39 of this Annual Report on Form 10-K.

#### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None.

#### **ITEM 9A. CONTROLS AND PROCEDURES**

##### **Evaluation of Disclosure Controls and Procedures.**

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act. Based upon that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

##### **Changes in Internal Controls.**

During the fiscal quarter ended December 31, 2005, there has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

##### **Management's Report on Internal Control Over Financial Reporting.**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework in *Internal Control - Integrated Framework*, our management concluded that our internal control over financial reporting was effective as of December 31, 2005.

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Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2005 has been audited by Virchow, Krause & Company, LLP, an independent registered public accounting firm, as stated in their report which is included herein on page 43.

**ITEM 9B. OTHER INFORMATION**

No information was required to be disclosed in a report on Form 8-K in the fourth quarter that was not so disclosed.

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### PART III

#### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Incorporated herein by reference to the Sections under the headings "Election of Directors," "Committees of the Board of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" contained in the Proxy Statement for our Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the close of the year ended December 31, 2005.

See Item 1 of Part I hereof for information regarding our executive officers.

We have adopted a code of ethics that applies to all of our directors, officers (including our chief executive officer, chief financial officer, chief accounting officer, and any person performing similar functions) and employees. We have made our Code of Ethics available by filing it as Exhibit 14 with our 2003 Annual Report on Form 10-K.

#### ITEM 11. EXECUTIVE COMPENSATION

Incorporated herein by reference to the Sections under the headings "Director Compensation," "Employment Agreements" and "Executive Compensation and Other Information" contained in the Proxy Statement for our Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the close of the year ended December 31, 2005.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS

Incorporated herein by reference to the Section under the heading "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" contained in the Proxy Statement for our Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the close of the year ended December 31, 2005.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

None.

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Incorporated herein by reference to the Section under the heading "Additional Information about our Independent Auditor" contained in the Proxy Statement for our Annual Meeting of Shareholders to be filed with the Securities and Exchange Commission within 120 days of the close of the year ended December 31, 2005.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this Report.

(1) The following financial statements are filed herewith in Item 8 in Part II.

- (i) Reports of Independent Registered Public Accounting Firms
- (ii) Consolidated Balance Sheets
- (iii) Consolidated Statements of Operations
- (iv) Consolidated Statements of Changes in Shareholders' Equity
- (v) Consolidated Statements of Cash Flows
- (vi) Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

Schedule II – Valuation and Qualifying Accounts. Such schedule should be read in conjunction with the consolidated financial statements. All other supplemental schedules are omitted because of the absence of conditions under which they are required.

(3) Exhibits

<u>Exhibit Number</u>	<u>Description</u>
3.1	Amended and Restated Articles of Incorporation of Vascular Solutions, Inc. (incorporated by reference to Exhibit 3.1 to Vascular Solutions' Form 10-Q for the quarter ended September 30, 2000).
3.2	Bylaws of Vascular Solutions, Inc. (incorporated by reference to Exhibit 3.2 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)).
4.1	Specimen of Common Stock certificate (incorporated by reference to Exhibit 4.1 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)).
4.2	Form of warrant dated January 31 and February 14, 1997 issued to representatives of Miller, Johnson & Kuehn, Incorporated (incorporated by reference to Exhibit 4.2 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)).
4.3	Form of warrant dated December 29, 1997 issued to representatives of Miller, Johnson & Kuehn, Incorporated (incorporated by reference to Exhibit 4.3 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)).
4.4	Amended and Restated Investors' Rights Agreement dated December 9, 1998, by and between Vascular Solutions, Inc. and the purchasers of Series A and Series B preferred stock (incorporated by reference to Exhibit 4.4 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)).
10.1	Lease Agreement dated August 30, 2002 by and between First Industrial, L.P. as Landlord and Vascular Solutions, Inc. as Tenant (incorporated by reference to Exhibit 10.1 of Vascular Solutions' Form 10-Q for the quarter ended September 30, 2002).
10.2	Sublease Agreement dated March 31, 2005 by and between Insignia Systems, Inc. and Vascular Solutions, Inc. (incorporated by reference to Exhibit 10.1 of Vascular Solutions' Form 10-Q for the quarter ended March 31, 2005).



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- 10.3 Consent Agreement dated March 31, 2005 by and between IRET – Plymouth, LLC as Landlord, Insignia Systems, Inc. as Tenant and Vascular Solutions, Inc. as Subtenant (incorporated by reference to Exhibit 10.2 of Vascular Solutions’ Form 10-Q for the quarter ended March 31, 2005).
- 10.4 Mutual and General Release dated November 9, 1998 by and between Vascular Solutions, Inc., Dr. Gary Gershony and B. Braun Medical, Inc. (incorporated by reference to Exhibit 10.5 of Vascular Solutions’ Registration Statement on Form S-1 (File No. 333-84089)).
- 10.5 Purchase and Sale Agreement dated September 17, 1998 by and between Vascular Solutions, Inc. and Davol Inc. (incorporated by reference to Exhibit 10.8 of Vascular Solutions’ Registration Statement on Form S-1 (File No. 333-84089)).
- 10.6 Purchase Agreement dated June 10, 1999 by and between GenTrac, Inc. and Vascular Solutions, Inc. (incorporated by reference to Exhibit 10.9 of Vascular Solutions’ Registration Statement on Form S-1 (File No. 333-84089)).
- 10.7\* Form of Employment Agreement by and between Vascular Solutions, Inc. and each of its executive officers (incorporated by reference to Exhibit 10.5 of Vascular Solutions’ Form 10-Q for the quarter ended March 31, 2004).
- 10.8 Form of Distribution Agreement (incorporated by reference to Exhibit 10.12 of Vascular Solutions’ Registration Statement on Form S-1 (File No. 333-84089)).
- 10.9\* Vascular Solutions, Inc. Employee Stock Purchase Plan, as amended (incorporated by reference to Exhibit 10.14 to Vascular Solutions’ Form 10-K for the year ended December 31, 2000).
- 10.10\* Stock Option and Stock Award Plan as Amended December 9, 2005 (incorporated by reference to Exhibit 10.1 of Vascular Solutions’ Form 8-K dated December 9, 2005).
- 10.11\*\* Supply Agreement dated October 18, 2004 by and between Vascular Solutions and Sigma-Aldrich Fine Chemicals, an operating division of Sigma-Aldrich, Inc (incorporated by reference to Exhibit 10.12 to Vascular Solutions’ Form 10-K for the year ended December 31, 2004).
- 10.12\*\* Private Label Purchase Agreement dated September 22, 2003 by and between Vascular Solutions and MedArt Corporation (incorporated by reference to Exhibit 10.18 of Vascular Solutions’ Form 10-Q for the quarter ended September 30, 2003).
- 10.13 Loan and Security Agreement dated December 31, 2003 by and between Vascular Solutions and Silicon Valley Bank (incorporated by reference to Exhibit 10.14 of Vascular Solutions’ Form 10-K for the year ended December 31, 2003).
- 10.14 Amendment to Loan Agreement dated December 29, 2005 by and between Vascular Solutions and Silicon Valley Bank.
- 10.15\* Form of Incentive Stock Option Agreement (Plan) (incorporated by reference to Exhibit 10.1 of Vascular Solutions’ Form 8-K dated September 22, 2004).
- 10.16\* Form of Nonqualified Stock Option Agreement (Plan) (incorporated by reference to Exhibit 10.2 of Vascular Solutions’ Form 8-K dated September 22, 2004).
- 10.17\* Form of Board of Directors Stock Option Agreement (Plan), as amended December 9, 2005 (incorporated by reference to Exhibit 10.2 of Vascular Solutions’ Form 8-K dated December 9, 2005).
- 10.18\* Form of Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.3 of Vascular Solutions’ Form 8-K dated December 9, 2005).
- 14 Code of Ethics (incorporated by reference to Exhibit 14 of Vascular Solutions’ Form 10-K for the year ended December 31, 2003).
- 21 List of Subsidiaries
- 23.1 Consent of Virchow, Krause & Company, LLP.
- 23.2 Consent of Ernst & Young LLP.
- 24.1 Power of Attorney (included on signature page).
- 31.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

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- 32.1 Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2 Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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\* Management contract or compensatory plan or arrangement required to be filed as an Exhibit to this Form 10-K.

\*\* Pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended, confidential portions of these exhibits have been deleted and filed separately with the Securities and Exchange Commission pursuant to a request for confidential treatment.

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**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on the 31st day of January, 2006.

VASCULAR SOLUTIONS, INC.

By: /s/ Howard Root  
Howard Root  
Chief Executive Officer and Director

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Howard Root and James Hennen (with full power to act alone), as his true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to the Annual Report on Form 10-K of Vascular Solutions, Inc., and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on the 31st day of January, 2006, by the following persons in the capacities indicated.

<u>Signature</u>	<u>Title</u>
<u>/s/ Howard Root</u> Howard Root	Chief Executive Officer and Director <i>(principal executive officer)</i>
<u>/s/ James Hennen</u> James Hennen	Vice President, Finance and Chief Financial Officer <i>(principal financial officer)</i>
<u>/s/ Timothy Slayton</u> Timothy Slayton	Controller <i>(principal accounting officer)</i>
<u>/s/ Robert Paulson.</u> Robert Paulson	Director
<u>/s/ Richard Nigon</u> Richard Nigon	Director
<u>/s/ Michael Kopp</u> Michael Kopp	Director
<u>/s/ Paul O'Connell</u> Paul O'Connell	Director
<u>/s/ John Erb</u> John Erb	Director
<u>/s/ Dr. Gary Dorfman</u> Dr. Gary Dorfman	Director

**SCHEDULE II**  
**VALUATION AND QUALIFYING ACCOUNTS**  
**YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003**

Description	Balance at Beginning of Year	Additions Charged to Costs and Expenses	Less Deductions	Balance at End of Year
YEAR ENDED DECEMBER 31, 2005:				
Sales return allowance .....	\$ 20,000	\$ 56,000	\$ 46,000	\$ 30,000
Allowance for doubtful accounts .....	<u>160,000</u>	<u>(41,000)</u>	<u>9,000</u>	<u>110,000</u>
Total .....	<u>\$ 180,000</u>	<u>\$ 15,000</u>	<u>\$ 55,000</u>	<u>\$ 140,000</u>
YEAR ENDED DECEMBER 31, 2004:				
Sales return allowance .....	\$ 20,000	\$ 20,000	\$ 20,000	\$ 20,000
Allowance for doubtful accounts .....	<u>140,000</u>	<u>34,000</u>	<u>14,000</u>	<u>160,000</u>
Total .....	<u>\$ 160,000</u>	<u>\$ 54,000</u>	<u>\$ 34,000</u>	<u>\$ 180,000</u>
YEAR ENDED DECEMBER 31, 2003:				
Sales return allowance .....	\$ 40,000	\$ (13,000)	\$ 7,000	\$ 20,000
Allowance for doubtful accounts .....	<u>90,000</u>	<u>69,000</u>	<u>19,000</u>	<u>140,000</u>
Total .....	<u>\$ 130,000</u>	<u>\$ 56,000</u>	<u>\$ 26,000</u>	<u>\$ 160,000</u>

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders  
Vascular Solutions, Inc.

We have audited the accompanying consolidated balance sheets of Vascular Solutions, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the years ended December 31, 2005 and 2004. These consolidated financial statements are the responsibility of the company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Vascular Solutions, Inc. as of December 31, 2005 and 2004 and the results of their operations and their cash flows for the years ended December 31, 2005 and 2004, in conformity with U.S. generally accepted accounting principles.

/s/ Virchow, Krause & Company, LLP

Minneapolis, Minnesota  
January 20, 2006

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders  
Vascular Solutions, Inc.

We have audited the consolidated statements of operations, changes in shareholders' equity, and cash flows for the year ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal controls over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows of Vascular Solutions, Inc. for the year ended December 31, 2003, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Minneapolis, Minnesota  
January 16, 2004

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders  
Vascular Solutions, Inc.

Under date of January 20, 2006, we reported on the consolidated balance sheets of Vascular Solutions, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, changes in shareholders' equity, and cash flows for the years ended December 31, 2005 and 2004, as contained in the annual report on Form 10-K for the year ended December 31, 2005. In connection with our audits of the aforementioned consolidated financial statements, we have also audited the related financial statement schedule as listed in the accompanying index. This financial statement schedule is the responsibility of the Company's management. Our responsibility is to express an opinion on this financial statement schedule based on our audits.

In our opinion, such financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ Virchow, Krause & Company LLP

Minneapolis, Minnesota  
January 20, 2006

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**Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders  
Vascular Solutions, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting appearing under Item 9A, that Vascular Solutions, Inc. (the "Company") maintained effective internal control over financial reporting as of December 31, 2005, based on the criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Vascular Solutions, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provide a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

In our opinion, management's assessment that Vascular Solutions, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also in our opinion, Vascular Solutions, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the accompanying consolidated balance sheets of Vascular Solutions, Inc. as of December 31, 2005 and 2004 and the related consolidated statements of operations, changes in shareholder's equity and cash flows for the years ended December 31, 2005 and 2004, and our report dated January 20, 2006, expresses an unqualified opinion on those consolidated financial statements.

/s/ Virchow, Krause & Company, LLP

Minneapolis, Minnesota  
January 20, 2006



Vascular Solutions, Inc.

Consolidated Balance Sheets

	December 31	
	2005	2004
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 4,282,000	\$ 7,184,000
Accounts receivable, net of reserves of \$140,000 and \$180,000 at December 31, 2005 and 2004, respectively	4,854,000	3,534,000
Inventories	6,962,000	3,659,000
Prepaid expenses	578,000	588,000
Total current assets	<u>16,676,000</u>	<u>14,965,000</u>
Property and equipment, net	2,955,000	1,374,000
Intangible assets, net	265,000	483,000
Total assets	<u>\$19,896,000</u>	<u>\$16,822,000</u>
<b>Liabilities and shareholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,898,000	\$ 857,000
Accrued compensation	1,196,000	1,612,000
Accrued expenses	1,695,000	663,000
Total current liabilities	<u>5,789,000</u>	<u>3,132,000</u>
Commitments		
Shareholders' equity:		
Common stock, \$0.01 par value:		
Authorized shares – 40,000,000		
Issued and outstanding shares – 14,642,225 – 2005;		
14,350,937 – 2004	147,000	144,000
Additional paid-in capital	77,793,000	76,675,000
Other	(42,000)	101,000
Accumulated deficit	(63,791,000)	(63,230,000)
Total shareholders' equity	<u>14,107,000</u>	<u>13,690,000</u>
Total liabilities and shareholders' equity	<u>\$19,896,000</u>	<u>\$16,822,000</u>

*See accompanying notes*

Vascular Solutions, Inc.

Consolidated Statements of Operations

	Year Ended December 31		
	2005	2004	2003
Net sales	\$ 32,786,000	\$ 22,414,000	\$ 11,862,000
Cost of goods sold	9,386,000	6,757,000	4,628,000
Gross profit	23,400,000	15,657,000	7,234,000
Operating expenses:			
Research and development	3,789,000	3,401,000	3,671,000
Clinical and regulatory	2,006,000	1,906,000	1,536,000
Sales and marketing	13,681,000	11,360,000	9,646,000
General and administrative	2,810,000	2,138,000	1,942,000
Thrombin qualification	1,620,000	210,000	–
Amortization of purchased technology	218,000	218,000	217,000
Total operating expenses	24,124,000	19,233,000	17,012,000
Operating loss	(724,000)	(3,576,000)	(9,778,000)
Interest income	163,000	68,000	150,000
Net loss	\$ (561,000)	\$ (3,508,000)	\$ (9,628,000)
Basic and diluted net loss per common share	\$ (0.04)	\$ (0.25)	\$ (0.75)
Shares used in computing basic and diluted net loss per common share	14,515,524	13,952,278	12,858,765

*See accompanying notes*

Vascular Solutions, Inc.

Consolidated Statements of Changes in Shareholders' Equity

	Common Stock		Additional Paid-In Capital	Other	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2002	12,880,839	\$129,000	\$70,355,000	\$ (21,000)	\$(50,094,000)	\$20,369,000
Exercise of stock options	65,855	1,000	82,000	—	—	83,000
Issuance of common stock under the Employee Stock Purchase Plan	195,876	2,000	124,000	—	—	126,000
Stock repurchase program	(153,400)	(2,000)	(138,000)	—	—	(140,000)
Amortization of deferred compensation	—	—	—	41,000	—	41,000
Comprehensive loss:						
Net loss	—	—	—	—	(9,628,000)	(9,628,000)
Translation adjustment	—	—	—	22,000	—	22,000
Total comprehensive loss						(9,606,000)
Balance at December 31, 2003	12,989,170	\$130,000	\$70,423,000	\$ 42,000	\$(59,722,000)	\$10,873,000
Exercise of stock options	227,300	2,000	341,000	—	—	343,000
Issuance of common stock under the Employee Stock Purchase Plan	245,567	3,000	273,000	—	—	276,000
Sale of common stock in private placement at \$6.75 per share in March 2004, net of offering costs	888,900	9,000	5,584,000	—	—	5,593,000
Deferred compensation related to option grants	—	—	54,000	(54,000)	—	—
Amortization of deferred compensation	—	—	—	12,000	—	12,000
Comprehensive loss:						
Net loss	—	—	—	—	(3,508,000)	(3,508,000)
Translation adjustment	—	—	—	101,000	—	101,000
Total comprehensive loss						(3,407,000)
Balance at December 31, 2004	14,350,937	\$144,000	\$76,675,000	\$101,000	\$(63,230,000)	\$13,690,000
Exercise of stock options	191,750	2,000	594,000	—	—	596,000
Issuance of common stock under the Employee Stock Purchase Plan	99,538	1,000	511,000	—	—	512,000
Deferred compensation related to option grants	—	—	13,000	(13,000)	—	—
Amortization of deferred compensation	—	—	—	22,000	—	22,000
Comprehensive loss:						
Net loss	—	—	—	—	(561,000)	(561,000)
Translation adjustment	—	—	—	(152,000)	—	(152,000)
Total comprehensive loss						(713,000)
Balance at December 31, 2005	<b>14,642,225</b>	<b>\$147,000</b>	<b>\$77,793,000</b>	<b>\$(42,000)</b>	<b>\$(63,791,000)</b>	<b>\$14,107,000</b>

See accompanying notes.

Vascular Solutions, Inc.

Consolidated Statements of Cash Flows

	Year Ended December 31		
	2005	2004	2003
<b>Operating activities</b>			
Net loss	<b>\$(561,000)</b>	\$(3,508,000)	\$(9,628,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	<b>596,000</b>	474,000	386,000
Amortization	<b>218,000</b>	218,000	217,000
Deferred compensation expense	<b>22,000</b>	12,000	41,000
Change in allowance for doubtful accounts	<b>(40,000)</b>	20,000	30,000
Changes in operating assets and liabilities:			
Accounts receivable	<b>(1,304,000)</b>	(1,744,000)	(483,000)
Inventories	<b>(3,328,000)</b>	(473,000)	(1,054,000)
Prepaid expenses	<b>5,000</b>	(126,000)	(135,000)
Accounts payable	<b>2,043,000</b>	106,000	(20,000)
Accrued compensation and expenses	<b>620,000</b>	906,000	229,000
Net cash used in operating activities	<b>(1,729,000)</b>	(4,115,000)	(10,417,000)
<b>Investing activities</b>			
Purchase of property and equipment, net	<b>(2,200,000)</b>	(900,000)	(539,000)
Purchase of securities	<b>—</b>	—	(10,695,000)
Proceeds from sales of securities	<b>—</b>	3,020,000	22,590,000
Net cash provided by (used in) investing activities	<b>(2,200,000)</b>	2,120,000	11,356,000
<b>Financing activities</b>			
Proceeds from exercise of stock options	<b>596,000</b>	343,000	83,000
Net proceeds from sale of common stock	<b>512,000</b>	5,869,000	126,000
Repurchase of common stock	<b>—</b>	—	(140,000)
Net cash provided by financing activities	<b>1,108,000</b>	6,212,000	69,000
Effect of exchange rate changes on cash and cash equivalents	<b>(81,000)</b>	102,000	22,000
Increase (decrease) in cash and cash equivalents	<b>(2,902,000)</b>	4,319,000	1,030,000
Cash and cash equivalents at beginning of year	<b>7,184,000</b>	2,865,000	1,835,000
Cash and cash equivalents at end of year	<b>\$ 4,282,000</b>	\$ 7,184,000	\$ 2,865,000

See accompanying notes.

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## 1. Description of Business

Vascular Solutions, Inc. (the Company) is a medical device company focused on bringing solutions to interventional cardiologists and interventional radiologists. The Company's current principle product lines consist of the following medical devices:

- D-Stat Dry™ hemostatic bandage, a topical pad with a bandage used to control surface bleeding,
- Pronto™ extraction catheter, a mechanical system for the removal of soft thrombus from arteries,
- Vari-Lase® endovenous laser, a laser and procedure kit used for the treatment of varicose veins,
- Duett™ sealing device, used to seal the puncture site following catheterization procedures,
- D-Stat® Flowable hemostat, a thick, yet flowable, mixture used to control bleeding,
- ThrombiGel™ hemostatic foam, a unique gelatin/thrombin foam hemostat,
- Langston™ dual lumen catheters, used to measure intravascular pressure gradients,
- MAX-Support™ abdominal retraction belt, used to allow femoral access in obese patients, and
- Acolysis® ultrasound (international only), a treatment for peripheral occlusive arterial disease.

As a vertically-integrated medical device company, the Company generates ideas and creates new interventional medical devices, and then delivers the products directly to the physician through a direct domestic sales force and an international distribution network. The Company was incorporated in the state of Minnesota in December 1996 and began operations in February 1997.

## 2. Summary of Significant Accounting Policies

### *Basis of Consolidation*

The consolidated financial statements include the accounts of Vascular Solutions, Inc. and its wholly owned subsidiary, Vascular Solutions GmbH, after elimination of intercompany accounts and transactions.

### *Segment Reporting*

A business segment is a distinguishable component of an enterprise that is engaged in providing an individual product or service or a group of related products or services and that is subject to risks and returns that are different from those of other business segments. The Company's segments have similar economic characteristics and are similar in the nature of the products sold, type of customers, methods used to distribute the Company's products and regulatory environment. Management believes that the Company meets the criteria for aggregating its operating segments into a single reporting segment.

### *Foreign Currency Translation and Transactions*

Vascular Solutions, GmbH accounts for its transactions in its functional currency the Euro. Foreign assets and liabilities are translated into U.S. dollars using the year-end exchange rates. Equity is translated at average historical exchange rates. Results of operations are translated using the average exchange rates throughout the year. Translation gains or losses are accumulated as a separate component of shareholders' equity.

### *Comprehensive Loss*

The components of comprehensive loss are net loss and the effects of foreign currency translation adjustments. The accumulated other comprehensive income (loss) for the foreign currency translation adjustment at December 31, 2005 and 2004 was \$(8,000) and \$144,000, respectively.

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## 2. Summary of Significant Accounting Policies (Continued)

### *Fair Value of Financial Instruments*

The carrying amount for cash and cash equivalents, accounts receivable, accounts payable, and accrued expenses approximates fair value due to the immediate or short-term maturity of these financial instruments.

### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

### *Cash and Cash Equivalents*

The Company classifies all highly liquid investments with initial maturities of three months or less as cash equivalents. Cash equivalents consist of cash and money market funds and are stated at cost, which approximates market value. The Company deposits its cash in high quality financial institutions. The balances, at times may exceed federally insured limits.

### *Credit risk and allowance for doubtful accounts*

The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. This allowance is regularly evaluated by the Company for adequacy by taking into consideration factors such as past experience, credit quality of the customer base, age of the receivable balances, both individually and in the aggregate, and current economic conditions that may affect a customer's ability to pay. Accounts receivable over 60 days past due are considered past due. The Company does not accrue interest on past due accounts receivable. Receivables are written off only after all collection attempts have failed and are based on individual credit evaluation and the specific circumstances of the customer. At December 31, 2005 and 2004, the allowance for doubtful accounts was \$110,000 and \$160,000, respectively.

All product returns must be pre-approved and, if approved, customers are subject to a 20% restocking charge. The Company analyzes the rate of historical returns when evaluating the adequacy of the allowance for sales returns, which is included with the allowance for doubtful accounts on our balance sheet. At December 31, 2005 and 2004, the sales and return allowance was \$30,000 and \$20,000, respectively.

Accounts receivable are shown net of the combined total of the allowance for doubtful accounts and allowance for sales returns of \$140,000 and \$180,000 at December 31, 2005 and 2004, respectively.

### *Inventories*

Inventories are stated at the lower of cost (first-in, first-out method) or market. Appropriate consideration is given to deterioration, obsolescence and other factors in evaluating net realizable value. Inventories are comprised of the following at December 31:

	<u>2005</u>	<u>2004</u>
Raw materials	\$4,965,000	\$2,379,000
Work-in-process	834,000	221,000
Finished goods	1,163,000	1,059,000
	<u>\$6,962,000</u>	<u>\$3,659,000</u>

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## 2. Summary of Significant Accounting Policies (Continued)

### *Property and Equipment*

Property and equipment are stated at cost. Depreciation is provided on a straight-line basis over the estimated useful lives of the assets as follows:

Manufacturing equipment	1 to 7 years
Office and computer equipment	1 to 5 years
Furniture and fixtures	3 to 5 years
Leasehold improvements	Remaining term of the lease
Research and development equipment	3 to 7 years

### *Impairment of Long-Lived Assets*

The Company will record impairment losses on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amount. The amount of impairment loss recorded will be measured as the amount by which the carrying value of the assets exceeds the fair value of the assets. To date, the Company has determined that no impairment of long-lived assets exists.

### *Revenue Recognition*

In the United States and Germany, the Company sells its products directly to hospitals and clinics. Revenue is recognized in accordance with generally accepted accounting principles as outlined in the Security and Exchange Commission's Staff Accounting Bulletin No. 104, *Revenue Recognition*, which requires that four basic criteria be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) the price is fixed or determinable; (iii) collectibility is reasonably assured; and (iv) product delivery has occurred or services have been rendered. The Company recognizes revenue as products are shipped based on FOB shipping point terms when title passes to customers. The Company negotiates credit terms on a customer-by-customer basis and products are shipped at an agreed upon price. All product returns must be pre-approved and, if approved, customers are subject to a 20% restocking charge.

In all other international markets, the Company sells its products to international distributors which subsequently resell the products to hospitals and clinics. The Company has agreements with each of its distributors which provide that title and risk of loss pass to the distributor upon shipment of the products to the distributor. The Company warrants that its products are free from manufacturing defects at the time of shipment to the distributor. Revenue is recognized upon shipment of products to distributors following the receipt and acceptance of a distributor's purchase order. Allowances are provided for estimated returns and warranty costs at the time of shipment.

### *Shipping and handling costs*

In accordance with the Emerging Issues Task Force (EITF) issue 00-10, "Accounting for Shipping and Handling Fees and Costs," the Company includes shipping and handling revenues in net sales and shipping and handling costs in cost of sales.

### *Research and Development Costs*

All research and development costs are charged to operations as incurred.

## 2. Summary of Significant Accounting Policies (Continued)

### Warranty Costs

Certain of the Company's products are covered by warranties against defects in material and workmanship for periods of up to 24 months. The Company records a liability for warranty claims at the time of sale. The amount of the liability is based on the amount the Company is charged from their original equipment manufacturer to cover the warranty period. The original equipment manufacturer includes a year warranty with each product sold to the Company. The Company records a liability for the uncovered warranty period offered to a customer, provided the warranty period offered exceeds the initial one year warranty period covered by the original equipment manufacturer.

Warranty provisions and claims for the years ended December 31, 2005 and 2004, were as follows:

	2005	2004
Beginning balance	\$33,000	\$ -
Warranty provisions	21,000	33,000
Warranty claims	(4,000)	-
Ending balance	<u>\$50,000</u>	<u>\$33,000</u>

### Stock-Based Compensation

At December 31, 2005, the Company had a stock-based employee compensation plan, which is described more fully in Note 9. The Company accounts for the plan under the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. No stock-based employee compensation cost is reflected in net loss, as all options granted under the plan had exercise prices equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS 123R to stock-based employee compensation.

	Year Ended December 31		
	2005	2004	2003
Net loss, as reported	\$(561,000)	\$(3,508,000)	\$(9,628,000)
Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards	(1,377,000)	(1,231,000)	(573,000)
Pro forma net loss	<u>\$(1,938,000)</u>	<u>\$(4,739,000)</u>	<u>\$(10,201,000)</u>
Net loss per common share:			
Basic and diluted – as reported	<u>\$(0.04)</u>	<u>\$(0.25)</u>	<u>\$(0.75)</u>
Basic and diluted – pro forma	<u>\$(0.13)</u>	<u>\$(0.34)</u>	<u>\$(0.79)</u>

For purposes of calculating the above-required disclosure, the fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The fair value of the Company's stock options was estimated assuming no expected dividends and the following weighted average assumptions:

	2005	2004	2003
Expected life (years)	5.50	6.50	6.38
Expected volatility	58%	94%	98%
Risk-free interest rate	4.34%	3.85%	3.54%



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## 2. Summary of Significant Accounting Policies (Continued)

The weighted average fair value of options granted with an exercise price equal to the deemed stock price on the date of grant during 2005, 2004 and 2003 was \$5.64, \$5.77 and \$0.71, respectively.

### *Income Taxes*

Income taxes are accounted for under the liability method. Deferred income taxes are provided for temporary differences between the financial reporting and the tax bases of assets and liabilities. Deferred tax assets are reduced by a valuation allowance to the extent that realization of the related deferred tax asset is not assured.

### *Net Loss Per Common Share*

In accordance with SFAS No. 128, *Earnings Per Share*, basic net loss per common share is computed by dividing net loss by the weighted average common shares outstanding during the periods presented. Diluted net loss per common share is computed by dividing net loss by the weighted average common and potential dilutive common shares outstanding computed in accordance with the treasury stock method. For all periods presented, diluted loss per share is the same as basic loss per common share because the effect of outstanding options and warrants is antidilutive.

### *Goodwill and Other Intangible Assets*

In fiscal 2002, the Company adopted SFAS No. 142, *Goodwill and Other Intangible Assets*. Goodwill is tested for impairment annually in the fourth quarter or more frequently if changes in circumstances or the occurrence of events suggest impairment exists. The Company has concluded that no impairment of goodwill exists as of December 31, 2005.

Other intangible assets consist of purchased technology. Purchased technology is amortized using the straight-line method over its estimated useful life of four years. The Company reviews intangible assets for impairment as changes in circumstances or the occurrence of events suggest the remaining value is not recoverable.

### *New Accounting Pronouncements*

The Financial Accounting Standards Board (FASB) has issued Statement No. 123R, *Share-Based Payment* (SFAS 123R), which requires companies to measure and recognize compensation expense for all stock-based payments at fair value. SFAS 123R is effective for the Company starting with the quarter ending March 31, 2006. Early adoption is encouraged and retroactive application of the provisions of SFAS 123R to the beginning of the fiscal year that includes the effective date is permitted, but not required. The Company estimates the expense associated with SFAS 123R will be in the range of \$1.3 million to \$1.7 million in 2006. See the Stock Based Compensation discussion above for information related to the pro forma effects on the Company's reported net income (loss) and net income (loss) per common share of applying the fair value recognition provisions of the previous Statement of Financial Accounting Standards (SFAS) 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

### *Reclassification*

Certain 2004 and 2003 amounts have been reclassified to conform to the 2005 presentation.

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### 3. Goodwill and Other Intangible Assets

As discussed in Note 2 above, the Company has adopted SFAS No. 141 and determined that the developed technology the Company acquired from Angiosonics, Inc. in April 2002 would be amortized over its useful life of four years. The goodwill acquired will not be amortized. The Company expects the future annual amortization expense for its acquired purchased development to be approximately \$72,000 in 2006.

Balances of acquired intangible assets as of December 31, 2005 were as follows:

	<b>Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net</b>
Amortizing intangibles:			
Purchased technology	\$ 870,000	\$798,000	\$72,000
Non-amortizing intangibles:			
Goodwill	193,000	-	193,000
	<u>\$1,063,000</u>	<u>\$798,000</u>	<u>\$265,000</u>

Balances of acquired intangible assets as of December 31, 2004 were as follows:

	<b>Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net</b>
Amortizing intangibles:			
Purchased technology	\$ 870,000	\$580,000	\$290,000
Non-amortizing intangibles:			
Goodwill	193,000	-	193,000
	<u>\$1,063,000</u>	<u>\$580,000</u>	<u>\$483,000</u>

### 4. Property and Equipment

Property and equipment consists of the following at December 31:

	<b>2005</b>	<b>2004</b>
Property and equipment:		
Manufacturing equipment	\$ 3,083,000	\$ 1,565,000
Office and computer equipment	1,153,000	923,000
Furniture and fixtures	303,000	242,000
Leasehold improvements	462,000	206,000
Research and development equipment	367,000	328,000
	<u>5,368,000</u>	<u>3,264,000</u>
Less accumulated depreciation	<u>(2,413,000)</u>	<u>(1,890,000)</u>
Net property and equipment	<u>\$ 2,955,000</u>	<u>\$ 1,374,000</u>

### 5. Private Placement

On March 9, 2004, the Company sold 888,900 shares of our common stock at an offering price of \$6.75 per share for net proceeds of \$5,593,000 in a private placement.

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## 6. Lines of Credit

On December 29, 2005, the Company modified and extended the secured asset-based loan and security agreement dated December 31, 2003. In addition to the operating line of credit, the Company added an equipment line of credit. The operating line of credit is a one-year, \$5,000,000 facility with availability based primarily on eligible customer receivables and inventory. The interest rate is prime plus 0.5%. As of December 31, 2005, the Company had no outstanding loan balance against the facility. Based on the Company's eligible customer receivables, inventory and cash balances, \$4,001,000 was available for borrowing as of December 31, 2005. The operating line of credit also requires a one time facility fee of \$25,000.

The equipment line of credit is a three-year, \$2,000,000 facility with an interest rate of prime plus 1.5%. As of December 31, 2005, the Company had no outstanding loan balance against the facility. As part of the equipment line of credit agreement, the Company must borrow a minimum of \$1,000,000 on or before January 6, 2006. See additional discussion in Note 17 below.

These lines of credit include two covenants: minimum tangible net worth of \$11,000,000 through August 31, 2006, \$12,000,000 through November 30, 2006, and \$13,000,000 thereafter, and liquidity coverage of not less than 1.25 to 1.00. The Company was in compliance with these covenants at December 31, 2005.

## 7. Leases

The Company leases a 43,000 square-foot office and manufacturing facility under an operating lease agreement, which expires in September 2008. Rent expense related to the operating lease was approximately \$402,000, \$343,000 and \$336,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

Future minimum lease commitments under this operating lease as of December 31, 2005 are as follows:

2006	\$ 335,000
2007	344,000
2008	<u>258,000</u>
	<u>\$ 937,000</u>

## 8. Income Taxes

At December 31, 2005, the Company had net operating loss carryforwards of approximately \$58,175,000 for federal income tax purposes that are available to offset future taxable income and begin to expire in the year 2013. Included in the U.S. amount are approximately \$2.2 million of deductions resulting from disqualifying dispositions of stock options. When these deductions from disqualifying dispositions are realized for financial statement purposes they will not result in a reduction in income tax expense, rather the benefit will be recorded as additional paid-in-capital. At December 31, 2005, the Company also had federal and Minnesota research and development tax credit carryforwards of approximately \$2,086,000, which begin to expire in the year 2013. At December 31, 2005, the Company has foreign tax loss carryforwards of approximately \$2,467,000 that do not expire. No benefit has been recorded for any loss or credit carryforwards, and utilization in future years may be limited under Sections 382 and 383 of the Internal Revenue Code if significant ownership changes have occurred or from future tax legislation changes. The Company performed a section 382 study during the third quarter 2005 on their federal net operating loss carryforward and the Company concluded that they will have no limitations on the net operating loss carryforward.

## 8. Income Taxes (Continued)

The components of the Company's deferred tax assets and liabilities as of December 31, 2005 and 2004 are as follows:

	2005	2004
Deferred tax assets:		
Net operating loss carryforwards	\$24,257,000	\$24,089,000
Tax credit carryforwards	2,086,000	1,598,000
Depreciation and amortization	249,000	231,000
Accrued compensation	210,000	213,000
Inventory reserve	180,000	172,000
Other	102,000	114,000
	<u>27,084,000</u>	<u>26,417,000</u>
Less valuation allowances	(27,084,000)	(26,417,000)
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

The Company records a valuation allowance to reduce the carrying value of the net deferred taxes to an amount that is more likely than not to be realized. The increase in the valuation allowance was \$667,000, \$2,196,000 and \$4,150,000 for the years ending December 31, 2005, 2004 and 2003, respectively.

Reconciliation of the statutory federal income tax rate to the Company's effective tax rate is as follows:

	2005	2004	2003
Tax at statutory rate	(34.0)%	(34.0)%	(34.0)%
State income taxes, net of federal benefit	(5.0)	(6.0)	(6.0)
Meals and entertainment	19.0	3.0	1.0
Impact of net operating loss carryforward	20.0	37.0	39.0
Effective income tax rate	<u>-%</u>	<u>-%</u>	<u>-%</u>

## 9. Stock Options and Warrants

### *Stock Option Plan*

The Company has a stock option and stock award plan (the Stock Option Plan) which provides for the granting of incentive stock options to employees and nonqualified stock options to employees, directors, and consultants. As of December 31, 2005, the Company had reserved 3,900,000 shares of common stock under the Stock Option Plan. Under the Stock Option Plan, incentive stock options must be granted at an exercise price not less than the fair market value of the Company's common stock on the grant date. The exercise price of a nonqualified option granted under the Stock Option Plan must not be less than 50% of the fair market value of the Company's common stock on the grant date. Prior to the initial public offering in July 2000, the Board of Directors determined the fair value of the common shares underlying options by assessing the business progress of the Company as well as the market conditions for medical device companies and other external factors. The options expire on the date determined by the Board of Directors but may not extend more than ten years from the grant date. The Stock Option Plan also permits the granting of stock appreciation rights, restricted stock, and other stock-based awards. The incentive stock options generally become exercisable over a four-year period and the nonqualified stock options generally become exercisable over a two-year period. Unexercised options are canceled 90 days after termination of employment and become available under the Stock Option Plan.

## 9. Stock Options and Warrants (Continued)

In the third quarter of 2002, the Company offered to exchange for its current employees, other than the Chief Executive Officer, any outstanding options to purchase shares of the Company's common stock under the Stock Option Plan with an exercise price of at least \$3.00 per share for new options the Company would grant under the plan. The new options were granted on February 18, 2003, which was six months and two business days after the date the options were exchanged. The Company granted 429,000 new options under the Stock Option Plan at an exercise price of \$0.84. The number of shares granted to each participating option holder was the number of shares subject to the eligible options tendered by such option holder. A stock option holder had to be employed by the Company through February 18, 2003 in order to be eligible to receive the new options. As a result of this exchange of options, 467,000 options with an average price of \$6.80 were canceled.

Option activity is summarized as follows:

	Shares Available for Grant	Plan Options Outstanding	Exercise Price	Weighted Average Exercise Price
Balance at December 31, 2002	1,214,000	901,000	\$0.81– \$16.50	\$3.94
Shares reserved	500,000	–	–	–
Granted	(889,000)	889,000	0.78– 5.74	0.89
Exercised	–	(66,000)	0.78– 2.70	1.25
Canceled	219,000	(219,000)	0.81– 16.50	2.49
Balance at December 31, 2003	1,044,000	1,505,000	0.78– 12.00	2.50
Shares reserved	500,000	–	–	–
Granted	(357,000)	357,000	6.74– 10.89	7.75
Exercised	–	(167,000)	0.78– 7.31	2.03
Canceled	50,000	(50,000)	0.84– 7.48	2.92
Balance at December 31, 2004	1,237,000	1,645,000	0.78– 12.00	3.68
Shares reserved	500,000	–	–	–
Granted	(344,000)	344,000	8.90– 11.62	9.74
Exercised	–	(181,000)	0.78– 10.89	3.20
Canceled	93,000	(93,000)	0.81– 9.46	5.74
Balance at December 31, 2005	<b>1,486,000</b>	<b>1,715,000</b>	<b>\$0.78–\$12.00</b>	<b>\$4.83</b>

The following table summarizes information about stock options outstanding at December 31, 2005:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Outstanding as of December 31, 2005	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Exercisable as of December 31, 2005	Weighted Average Exercise Price
\$ 0.78–\$ 0.83	61,000	7.1	\$ 0.79	59,000	\$ 0.79
0.84– 0.84	528,000	7.1	0.84	458,000	0.84
0.85– 2.51	184,000	5.0	2.25	181,000	2.26
2.52– 6.00	255,000	4.0	5.69	253,000	5.70
6.01– 7.00	199,000	8.0	6.73	107,000	6.72
7.01– 12.00	488,000	8.4	9.40	201,000	9.32
	<b>1,715,000</b>	<b>6.9</b>	<b>\$4.83</b>	<b>1,259,000</b>	<b>\$3.88</b>

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## 9. Stock Options and Warrants (Continued)

### *Deferred Compensation*

In 2005, 2004, and 2003, the Company recorded \$13,000, \$54,000 and \$-0-, respectively, of deferred compensation in connection with certain nonqualified stock options granted to medical advisory board members. The weighted average fair value of these options was \$4.18. The deferred compensation recorded is amortized ratably over the period that the options vest and is adjusted for options which have been canceled. Deferred compensation expense was \$22,000, \$12,000 and \$41,000 for the years ended December 31, 2005, 2004, and 2003, respectively.

### *Warrants*

As of December 31, 2005, the Company had the following warrants outstanding and exercisable:

<u>Exercise Price</u>	<u>Outstanding as of December 31, 2005</u>	<u>Expiration Date</u>
1.50	70,000	January 31, 2007
1.50	14,000	February 14, 2007
3.00	68,000	December 29, 2007
<u>\$2.17</u>	<u>152,000</u>	

## 10. Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan (the Purchase Plan) under which 1,300,000 shares of common stock have been reserved for issuance. Eligible employees may contribute 1% to 10% of their compensation to purchase shares of the Company's common stock at a discount of 15% of the market value at certain plan-defined dates up to a maximum of 2,000 shares per purchasing period. The Purchase Plan terminates in May 2010. In fiscal 2005, 2004 and 2003, 99,500 shares, 245,600 shares, and 195,900 shares, respectively, were issued under the Purchase Plan. At December 31, 2005, 516,000 shares were available for issuance under the Purchase Plan.

## 11. Employee Retirement Savings Plan

The Company has an employee 401(k) retirement savings plan (the Plan). The Plan provides eligible employees with an opportunity to make tax-deferred contributions into a long-term investment and savings program. All employees over the age of 21 are eligible to participate in the Plan beginning with the first quarterly open enrollment date following start of employment. Through December 31, 2001, the Plan allowed eligible employees to contribute up to 18% of their annual compensation. Effective January 1, 2002, the employee contribution limit was increased to 50% of their annual compensation, subject to a maximum limit determined by the Internal Revenue Service, with the Company contributing an amount equal to 25% of the first 5% contributed to the Plan. The Company recorded an expense of \$89,000, \$73,000 and \$74,000 for contributions to the Plan for the years ended December 31, 2005, 2004, and 2003, respectively.

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## 12. Concentrations of Credit and Other Risks

In the United States and Germany, the Company sells its products directly to hospitals and clinics. In all other international markets, the Company sells its products to distributors who, in turn, sell to medical clinics. Loss, termination, or ineffectiveness of distributors to effectively promote the Company's product could have a material adverse effect on the Company's financial condition and results of operations.

No customers were more than 5% of net sales for the years ended December 31, 2005, 2004 and 2003.

With respect to accounts receivable, the Company performs credit evaluations of its customers and does not require collateral. No customers were more than 5% of gross accounts receivable as of December 31, 2005 and 2004. There have been no material losses on customer receivables.

Sales by geographic destination as a percentage of total net sales were as follows for the years ended December 31:

	2005	2004	2003
Domestic	89%	89%	87%
Foreign	11	11	13

## 13. Related Party Sales

In fiscal 2005, 2004 and 2003, the Company sold \$419,000, \$279,000 and \$0- of product to a company in which a board member of the Company is a Vice President. As of December 31, 2005 and 2004, the Company had an accounts receivable balance due of \$70,000 and \$57,000 from this related party company.

## 14. Dependence on Key Suppliers

### King Pharmaceuticals

The Company purchases certain key components from single-source suppliers. Any significant component delay or interruption could require the Company to qualify new sources of supply, if available, and could have a material adverse effect on the Company's financial condition and results of operations. The Company purchases their requirements for thrombin (a component in the Duett and D-Stat products) under a Purchase Agreement dated June 10, 1999 with a subsidiary of King Pharmaceuticals, Inc. (King). The agreement provides for a fixed price, with adjustments based on the supplier's manufacturing costs and the supplier's annual percentage increase in the wholesale price of thrombin. The agreement expired on May 29, 2005. In anticipation of the agreement expiring, the Company submitted purchase orders to King for approximately \$3.5 million of thrombin to benefit from the pricing provisions of the agreement. The Company expects the final lots of thrombin totaling \$2.1 million to be delivered during the third quarter of 2006. The Company believes that these purchases will satisfy its thrombin requirements through at least the end of 2007.

### Sigma

On October 18, 2004, the Company entered into a supply agreement with Sigma-Aldrich Fine Chemicals, an operating division of Sigma-Aldrich, Inc. (Sigma) for the supply of thrombin to the Company. Pursuant to the terms of the agreement, the Company will be paying for certain development costs of Sigma to allow Sigma to produce thrombin. The payments are based on achievement of certain milestones over a two year period. The contract terminates after ten years and is automatically extended for up to five additional successive one year terms unless one party delivers notice of termination at least one year prior to the scheduled termination of the

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#### 14. Dependence on Key Suppliers (Continued)

agreement. During the term of the contract, Sigma has agreed not to sell thrombin of the type developed for the Company under the contract in or as a component of a hemostatic product for medical use. The Company does not have any minimum purchase requirements under the contract; however, if the Company purchases less than three lots of thrombin in any year then (i) Sigma will be released from its agreement not to sell thrombin in or as a component of a hemostatic product for medical use, and (ii) Sigma will have the right to terminate the contract on 30 days notice.

The Sigma contract is the start of the Company's plan to fully qualify a new source of thrombin and to bring the new thrombin through the regulatory process to be used in the Company's hemostatic products starting in 2007. The cost associated with the Sigma agreement are part of the Company's total estimated expenditures of \$6.8 million (including the payments to Sigma) to complete the thrombin qualification project. The failure by the Company to complete the thrombin qualification project on time and on budget may affect the Company's gross margins on the Duett, D-Stat Flowable and D-Stat Dry products and could therefore seriously harm the Company's business.

The costs and purchases incurred through December 31, 2005 and the total estimated costs and purchases for the thrombin project (including costs and purchases already incurred) are as follows:

	<u>Incurred (as of December 31, 2005)</u>	<u>Total Estimated</u>
Qualification expenses.....	\$1.8 million	\$4.3 million
Capital equipment purchases .....	0.7 million	0.8 million
Thrombin inventory purchases .....	1.7 million	1.7 million
	<u>\$4.2 million</u>	<u>\$6.8 million</u>

#### 15. Commitments and Contingencies

All legal cost related to litigation are charged to operations as incurred.

##### Diomed Litigation

On December 11, 2003, the Company and a non-officer employee of the Company were named as defendants in a lawsuit brought by Diomed, Inc. in the United States District Court for the District of Massachusetts. The complaint alleges that in marketing the Company's Vari-Lase endovenous laser procedure kit the Company engaged in false advertising and infringed a registered trademark of Diomed. The complaint also alleges that the non-officer employee, who previously worked for a company that conducted business with Diomed, improperly utilized trade secrets of Diomed in developing the Company's Vari-Lase procedure kit. The complaint requests monetary damages and an injunction on the sale of the Company's Vari-Lase procedure kit. The Company believes that the allegations included in the complaint are wholly without merit. On July 13, 2005, the court held a hearing on the Company's motion for summary judgment, in which the Company sought dismissal of all claims. On January 31, 2006, the Court granted the Company's motion for summary judgment dismissing all counts of Diomed's complaint with the exception of one trade secret misappropriation count and a portion of two other counts to the extent they are based on alleged trade secret misappropriation. The Company's counterclaim against Diomed was not dismissed. The Court has scheduled a status conference for this case on March 2, 2006. The Company's insurance carrier initially accepted the Company's tender of this claim and has paid for the expenses incurred in defending this lawsuit. After the summary judgment hearing, the insurance company notified the



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## 15. Commitments and Contingencies (continued)

Company that they were withdrawing coverage prospectively, effective November 6, 2005. It is not possible to predict the timing or outcome of this litigation, including whether it will affect the Company's ability to sell our Vari-Lase procedure kit, or to estimate the amount or range of potential loss.

On March 4, 2004, the Company was named as the defendant in an intellectual property lawsuit brought by Diomed, Inc. in the United States District Court for the District of Massachusetts. The complaint requested a judgment that the Company's Vari-Lase procedure kit and Vari-Lase laser console infringe on a single patent held by Diomed, Inc. and asked for relief in the form of an injunction that would prevent the Company from selling their Vari-Lase products, compensatory and treble damages caused by the manufacture and sale of the Company's product, and other costs, disbursements and attorneys' fees. On April 12, 2005, the Judge entered a Memorandum and Order on Claims Construction from the Markman hearing phase of the litigation. In the Order, the Judge held that in order to violate the Diomed patent, a competing method must deliberately put the tip of the laser fiber in physical contact with the wall of the vein, must drain blood from the vein, must compress the vein and must maintain vein wall contact as the laser energy is delivered. The Company believes that their Vari-Lase products are not used in this method, and thus the Company does not believe the litigation has merit. It is not possible to predict the timing or outcome of this litigation, including whether it will affect the Company's ability to sell their Vari-Lase products, or to estimate the amount or range of potential loss.

### VNUS Medical Technologies Litigation

On October 13, 2005, the Company was named as one of three defendants in an intellectual property lawsuit brought by VNUS Medical Technologies, Inc. in the United States District Court for the Northern District of California. The complaint requested a judgment that the Company's Vari-Lase procedure kit and Vari-Lase laser console infringes on four patents held by VNUS Medical Technologies, Inc. and asked for relief in the form of an injunction that would prevent the Company from selling their Vari-Lase products, compensatory and treble damages caused by the manufacture and sale of the Company's product, and other costs, disbursements and attorneys' fees. The Company believes its Vari-Lase products do not violate these patents, and thus the Company does not believe the litigation has merit. It is not possible to predict the timing or outcome of this litigation, including whether it will affect the Company's ability to sell their Vari-Lase products, or to estimate the amount or range of potential loss.

### MedArt Purchase Commitment

The Company signed a purchase agreement with MedArt Corporation on September 22, 2003. Under that agreement, the Company was obligated to purchase laser consoles with an aggregate purchase price of \$1,197,000 for its Vari-Lase business during the first year of the agreement, which commenced in December 2003. The Company fulfilled its laser console purchase requirement of \$1,197,000 during 2004.

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**16. Quarterly Financial Data (Unaudited, in Thousands, Except per Share Data)**

<b>2005</b>	<b>Fourth Quarter</b>	<b>Third Quarter</b>	<b>Second Quarter</b>	<b>First Quarter</b>
Net sales	\$8,859	\$8,574	\$8,079	\$7,274
Gross profit	6,169	6,244	5,771	5,216
Operating income (loss)	(450)	16	33	(323)
Net income (loss)	(407)	60	75	(289)
Basic and diluted net income (loss) per share	\$(0.03)	\$0.00	\$0.00	\$(0.02)
<b>2004</b>				
Net sales	\$6,706	\$5,974	\$5,275	\$4,459
Gross profit	4,651	4,290	3,673	3,043
Operating loss	(599)	(445)	(1,021)	(1,511)
Net loss	(573)	(437)	(999)	(1,499)
Basic and diluted net loss per share	\$(0.04)	\$(0.03)	\$(0.07)	\$(0.11)

**17. Subsequent Event**

On January 6, 2006, the Company executed a \$2,000,000 advance on the equipment line of credit, discussed above in Note 6. The advance is secured by various equipment acquired by the Company during the year ended December 31, 2005.

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## CORPORATE INFORMATION

### *Directors*

**Michael Kopp**  
Medical Device Industry Consultant

**Richard Nigon**  
Director of Equity Corporate Finance,  
Miller Johnson Steichen Kinnard

**Paul O'Connell**  
Vice President,  
Vascular Interventional Products Group,  
B. Braun Medical, Inc.

**John Erb**  
Chief Executive Officer, CHF Solutions, Inc.

**Dr. Gary Dorfman**  
President, General Vascular Devices, Ltd.

**J. Robert Paulson, Jr.**  
Chief Executive Officer, Restore Medical, Inc.

**Howard Root**  
Chief Executive Officer, Vascular Solutions, Inc.

### *Officers*

**Howard Root**  
Chief Executive Officer

**Deborah Neymark**  
Vice President of Regulatory Affairs, Quality  
Systems and Clinical Affairs

**James Quackenbush**  
Vice President, Manufacturing

**Gregg Sutton**  
Vice President, Research & Development

**Frederick Reuning**  
Vice President, Marketing

**James Hennen**  
Vice President of Finance, Chief Financial  
Officer and Secretary

### *Investor Relations*

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### *Transfer Agent and Registrar*

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161 North Concord Exchange Street  
South Saint Paul, Minnesota 55075  
Telephone: 651-450-4064

### *Independent Auditors*

Virchow Krause & Company, LLP  
Minneapolis, Minnesota

### *Legal Counsel*

Dorsey & Whitney LLP  
Minneapolis, Minnesota

### *Annual Meeting*

The Company's Annual Meeting of  
Shareholders will be held on Tuesday,  
April 18, 2006, 3:30 p.m. at:

Radisson Hotel and Convention Center  
3131 Campus Drive  
Plymouth, Minnesota 55441

### *Additional Information*

A copy of Vascular Solutions' filings with  
the Securities and Exchange Commission  
are available upon request by contacting  
Investor Relations or by accessing the  
Securities and Exchange Commission's  
web site at [www.sec.gov](http://www.sec.gov).

### *Stock Exchange Listing*

NASDAQ National Market System  
Symbol: VASC





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