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# Vascular SOLUTIONS

2002 Annual Report

## Overview of Vascular Solutions

Vascular Solutions is a medical device company focused on bringing solutions to interventional cardiologists and interventional radiologists. Our rapidly expanding product line includes the Duett sealing device, the D-Stat flowable hemostat and the Acolysis therapeutic ultrasound system. 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 international distribution network.

## Duett™ Pro Vascular Sealing Device


The Duett Pro sealing device is used by interventional cardiologists and interventional radiologists to seal the arterial puncture site following percutaneous procedures such as angiography, angioplasty and stent placement. Using a dual approach – a balloon catheter and procoagulant – the Duett Pro sealing device is designed to rapidly and safely stop the bleeding.

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 rigid behind which could interfere with re-access or potentiate an infection. This results in a "quiet" groin and improved patient comfort.

During 2002, we launched the next generation "Pro" line of the Duett sealing device. The Pro line enhances the Duett catheter by simplifying the device deployment steps. For the less-challenging diagnostic catheterization procedures, we also offer the Diagnostic Duett Pro, a version which contains a lower dose of procoagulant that can provide the same clinical benefits, but at a more economical price.

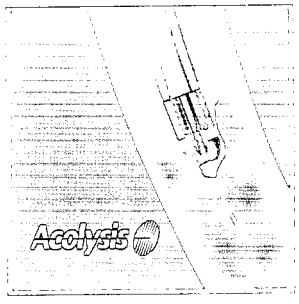
## D-Stat™ Flowable Hemostat


Simply put, the D-Stat delivers control of active bleeding.

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

We launched the D-Stat worldwide in February 2002. Initial clinical applications of the D-Stat have been numerous, stretching anywhere active topical bleeding exists in interventional medical procedures. Additional clinical uses of the D-Stat are being evaluated.

## Acolysis® Ultrasound Thrombolysis System

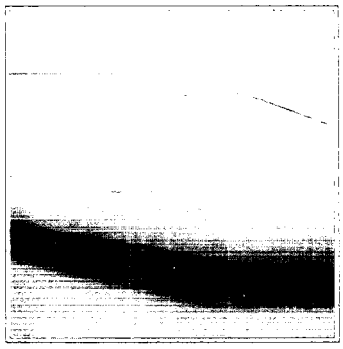



During 2002 we acquired the Acolysis ultrasound thrombolysis system. The Acolysis system uses ultrasound energy generated by the Acolysis controller delivered intravascularly by the disposable probe to lyse blood clots and plaque. The Acolysis system is sold only in international markets, where it has been sold principally for the treatment of peripheral vascular disease for more than two years.

The therapeutic principle of the Acolysis system is to generate ultrasound thrombolysis by the selective disruption of the fibrin matrix of the thrombus. Cavitation produces subcapillary-sized particles, resulting in a debulking of the arterial lesion. Peripheral vascular disease, the initial market opportunity, affects over 8 million people worldwide.

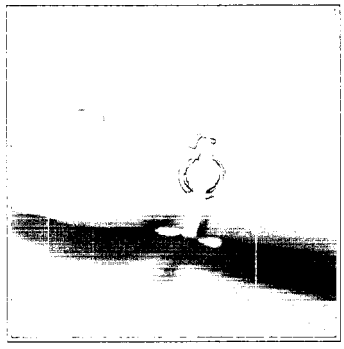
# New Products Expected in 2003

## D-Stat Dry Hemostatic Bandage



The D-Stat Dry is a freeze-dried pad of D-Stat procoagulant combined with an adhesive bandage for a powerful, yet low cost solution to topical active bleeding. Initial potential uses of the D-Stat Dry include sealing following a wide variety of arterial punctures and radiology procedures. Additional applications of the D-Stat Dry are being explored in hemodialysis clinics, military applications and emergency medical use. We expect to launch the D-Stat Dry worldwide in the second half of 2003.

## D-Stat Radial



Approximately 5% of all catheterization procedures (over 400,000 annually) utilize the radial artery in the wrist rather than the femoral artery in the groin to gain arterial access. Currently there are no radial sealing devices, only compression devices, splints and patches. The D-Stat Radial is a specially designed version of the D-Stat Dry that can be applied quickly to the radial puncture to deliver the hemostatic power of the D-Stat procoagulant. We expect to launch the D-Stat Radial worldwide in the second half of 2003.

## Pronto™ Extraction Catheter

Working with Dr. Pedro Silva of Milan, Italy, we have developed the Pronto extraction catheter. The Pronto features a proprietary atraumatic distal tip and large extraction lumen to quickly remove soft thrombus from arteries. We anticipate receiving regulatory clearance for a worldwide launch of the Pronto extraction catheter in the second half of 2003.

## Varicose Vein Treatment

Varicose veins affect over one million people worldwide and, when severe, are treated by surgical vein stripping. Recently, new interventional tools have been developed to intravascularly treat and close superficial varicose veins as a replacement for invasive vein stripping. Vascular Solutions has developed a product that furthers this shift to interventional treatments in a clinically-efficient and cost-effective manner. We anticipate launching our varicose vein treatment worldwide in the second half of 2003.

# To Our Shareholders

2002 was a year in which Vascular Solutions weathered the storm and established its foundation for future growth and profitability. In a very challenging competitive environment, during 2002 we maintained and modestly increased our sales while reducing our operating expenses. Throughout the year we focused our efforts and our capital on bringing substantial new products to our current markets using our existing infrastructure. As the result of these efforts, at the beginning of 2003 we have a solid base of business, a vertically integrated operation and four new substantial interventional medical devices that we expect to launch worldwide in the second half of 2003.

We entered 2002 as a single product medical device company focused on our Duett sealing device. In the intensely competitive sealing device market, we realized that spending increasing amounts of our capital to accelerate the introduction of our Duett sealing device was unlikely to generate an acceptable return on our investment. Instead, we made the decision to focus our efforts on maintaining our Duett customers, growing our Duett usage within our customer base, and developing additional clinically advanced medical devices that we could sell through our existing infrastructure into our current markets. We believe that the leverage we apply to new products using our existing organization and our existing direct sales force can make our investment extremely efficient.

The results of our strategic direction were as expected. We modestly increased our net sales in 2002 over 2001 in spite of a continuing reduction in sales and marketing expenses. Our cost reduction efforts culminated in a 24% year-over-year decrease in sales and marketing expenses in the fourth quarter of 2002. Other operating expenses also decreased in 2002 over 2001 with the exception of our legal expenses. Even with respect to our legal expenses, however, at the end of 2002 we settled our intellectual property litigation with no continuing financial obligations past 2002. Again, we enter 2003 with a clean balance sheet, a solid financial position and substantial opportunities for growth.

Our excitement in 2002 came from our development of new products. The first new product to launch from this pipeline was the D-Stat flowable hemostat, which we began to sell worldwide in February 2002. The D-Stat is a thick yet flowable blood clotting mixture that leverages the procoagulant technology we developed for the Duett. Even with only initial limited approved clinical uses of the D-Stat, we achieved annualized net sales of almost $1 million in the fourth quarter of 2002. In 2003 we expect to expand these D-Stat clinical uses, first with a clinical study on the use of D-Stat following pacemaker and defibrillator implantations, and then D-Stat use in conjunction with breast biopsies and liver biopsies. Each of these potential markets of the D-Stat we believe to be larger than our existing approved indications, and have the added benefit of very limited competitive products.

Our next new product to launch from our pipeline was the Acolysis therapeutic ultrasound system. The Acolysis system uses ultrasound energy generated by the Acolysis controller and delivered intravascularly by the single use, disposable Acolysis probe for lysing blood clots and plaque. We acquired the Acolysis business for $1.5 million in April 2002, and we integrated the Acolysis business into our existing operations and manufacturing facility during the remainder of 2002. The Acolysis product is currently being sold in international markets, principally to treat chronic total occlusions in peripheral arteries. The first long term data from this clinical use of our Acolysis product is beginning to be reported, with very favorable indications for the long term success of this product.

Looking into 2003, our new product pipeline includes four new products that are scheduled for worldwide launch in the second half of the year. The D-Stat Dry hemostatic bandage is our version of an adhesive bandage, using a

lyophilized pad of our proprietary procoagulant technology to greatly increase the speed to clotting. We believe that the D-Stat Dry bandage will be the most effective, simple and cost-effective topical solution to hemostasis available to the physician. Substantial market opportunities for the D-Stat Dry exist in our current interventional cardiology and radiology markets that we can reach with our existing sales force. Other opportunities for the D-Stat Dry in emergency medicine, hemodialysis clinics and military uses are expected to be addressed through corporate partnerships. We are in the process of completing our regulatory submission for the D-Stat Dry and anticipate a worldwide launch in the second half of 2003.

Again building off our procoagulant technology, we also developed the D-Stat Radial hemostat band. The D-Stat Radial is a customized band to achieve hemostasis following catheterization procedures utilizing the radial artery in the wrist. While there are a number of femoral artery sealing devices such as our Duett, there are no existing radial artery sealing devices other than simple compression bandages. We believe the D-Stat Radial will be a very effective solution to this opportunity, with a worldwide market potential in excess of $10 million annually. Like the D-Stat Dry, we are in the process of completing our regulatory submissions for the D-Stat Radial and anticipate a worldwide launch in the second half of 2003.

Our third new product for 2003 is expected to be the Pronto extraction catheter. This product was developed in conjunction with Dr. Pedro Silva of Milan, Italy. The Pronto is designed to mechanically remove soft thrombus from arteries using a very simple, yet proprietary syringe extraction system. The market opportunity for the Pronto extraction catheter also is quite substantial, centered on the prompt treatment of patients presenting with acute myocardial infarctions, or heart attacks. We also are expecting to launch the Pronto extraction catheter worldwide in the second half of 2003.

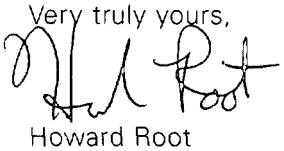
Finally, during 2002 we internally developed a product for the treatment of superficial venous reflux, otherwise known as varicose veins. Interventional radiologists have treated severe varicose veins with an archaic procedure known as vein stripping. Recently, new endovascular procedures utilizing either radiofrequency energy or laser energy have begun to grow as alternatives to vein stripping. Our product in this area furthers this shift to interventional, rather than surgical, treatment of varicose veins.

The D-Stat Dry, D-Stat Radial, Pronto extraction catheter and varicose vein treatment each represent potential revenues substantially in excess of $1 million per quarter to Vascular Solutions upon full commercialization in 2004. Beyond these products, we are working on a next generation Mechancial Duett device which could substantially improve our competitive position in the market for vascular sealing devices, and we are planning our regulatory work to bring the Acolysis system into the United States. Entering 2003, our organization is fully staffed to make these projects a reality.

With our currently available working capital, we are well positioned to bring these products to market, grow our sales, and become profitable before the end of 2004. That is our focus, and 2002 was a large step in that direction. Along the way we constantly evaluate our alternatives and assess our plans and results to make sure that we are setting a course that maximizes shareholder value. We understand the disappointment reflected in our current stock price, and we will continue to take the actions necessary to resume a fast path to success.

Thank you again for your support in our mission.

Very truly yours,



Howard Root
Chief Executive Officer February 10, 2003

# FINANCIAL HIGHLIGHTS

## Statements of Operations Data

*(in thousands)*

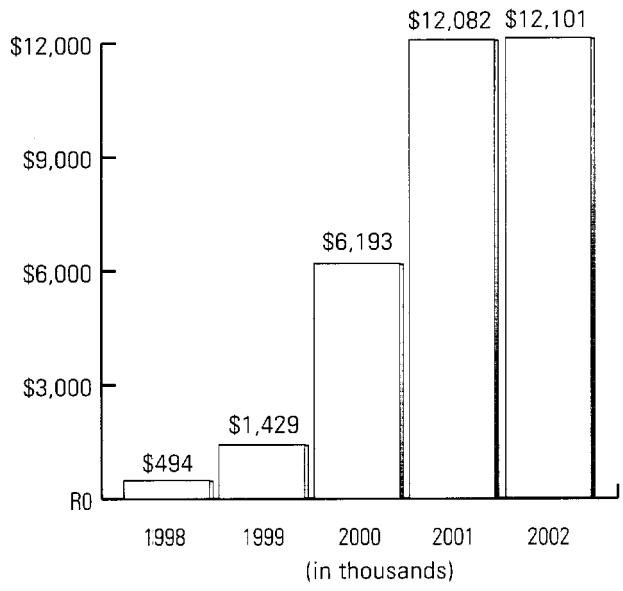
| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2002 | 2001 | 2000 | 1999 | 1998 |
| Net sales | $12,101 | $12,082 | $6,193 | $1,429 | $494 |
| Gross profit | $7,115 | $7,121 | $3,492 | $364 | $52 |
| Gross profit % | 58.8% | 58.9% | 56.4% | 25.5% | 10.4% |
| Total operating expenses | $22,601 | $21,032 | $13,154 | $8,597 | $5,467 |
| Operating loss | ($15,486) | ($13,911) | ($9,662) | ($8,233) | ($5,415) |
| Net loss | ($14,979) | ($12,250) | ($8,209) | ($7,862) | ($5,141) |

## Balance Sheet Data

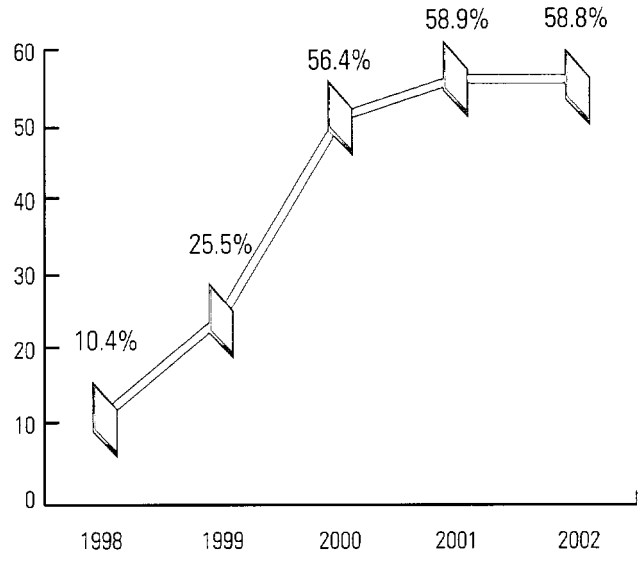
*(in thousands)*

| | December 31, | |
|---|---|---|
| | 2002 | 2001 |
| Cash, cash equivalents and available-for-sale securities | $16,750 | $33,318 |
| Working capital | $18,656 | $34,712 |
| Long-term debt | $0 | $0 |
| Shareholder's equity | $20,369 | $35,630 |
| Total shares outstanding | 12,881 | 13,327 |

## Annual Net Sales




## Gross Profit



# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

## FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2002

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 | 41-1859679 |
|---|---|
| (State of Incorporation) | (IRS Employer Identification No.) |

6464 Sycamore Court
Minneapolis, Minnesota 55369
(Address of Principal Executive Offices)

(763) 656-4300
(Registrant's telephone number, including are 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 $.01 per share**

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 [ X ] 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. [ X ]

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 February 15, 2003 was $8,321,000.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act). Yes [ ] No [ X ]

As of February 15, 2003, the number of shares outstanding of the registrant's common stock was 12,850,239.

## DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for its 2003 Annual Meeting of Shareholders to be held on April 15, 2003 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

We are a medical device company focused on bringing clinically advanced solutions to interventional cardiologists and interventional radiologists worldwide. Our current product line includes the Duett™ sealing device, the D-Stat™ flowable hemostat and the Acolysis® therapeutic ultrasound system. 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 international distribution network.

Our principal product, 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 150,000 Duett sealing devices have been sold and deployed worldwide, and we achieved over $10 million in net sales of the Duett sealing device in its first year on the United States market. In the fourth quarter of 2001 we introduced the Diagnostic Duett version of the Duett sealing device, which utilizes a lower dose of progcoagulant 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, and we are currently working on future generations of the Duett product line.

The second product we have developed and commercialized is the D-Stat flowable hemostat, which we began selling worldwide in February 2002. The D-Stat utilizes the clinically proven procoagulant components of the Duett sealing device to provide a powerful stop to active bleeding. The thick, yet flowable procoagulant controls active bleeding by initiating the body's own clotting mechanisms in the same manner as the Duett procoagulant. The D-Stat has clinical use in a multitude of interventional procedures, and substantial extension market opportunities in other medical practice areas.

During the second quarter of 2002 we acquired the Acolysis ultrasound thrombolysis system. The Acolysis system uses ultrasound energy generated by the controller that is delivered intravascularly by the disposable probe to lyse blood clots and plaque. The Acolysis system is 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, we commenced active international sales of the Acolysis probes through our existing international distribution network in late 2002.

We are developing several additional products that leverage our existing infrastructure to bring additional solutions to the interventional cardiologist and radiologist. Additional interventional medical devices that we expect to gain regulatory clearance and market launch in the second half of 2003 include the D-Stat Dry hemostatic bandage, the D-Stat Radial hemostat band, the Pronto extraction catheter and a minimally invasive varicose vein treatment device.

### 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. Peripheral vascular disease affects over 8 million people

worldwide. 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 9 million diagnostic and interventional catheterization procedures worldwide in 2002. 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 2002 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 usually develop a substantial coagulated mass of blood, or hemotoma, 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 the Duett sealing device, four devices have received FDA approval and are currently being marketed around the world. In aggregate, approximately $320 million of the four FDA-approved devices were sold worldwide in 2002 compared to less than $20 million in 1996. 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 is more than $1 billion. Accordingly, the market opportunity for vascular sealing devices is less than 20% penetrated.

### The Vascular Solutions Duett Sealing Device

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 diluent, 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.

We commenced sales of a new version of our Duett sealing device, the Diagnostic Duett sealing device, for a subset of catheterization patients in the fourth quarter of 2001. The Diagnostic Duett is tailored specifically for treating diagnostic patients. Because the Duett sealing device is a one-size-fits-all device, the procoagulant is dosed appropriately for the most challenging catheterization patients. We developed the Diagnostic Duett with a lower dose of procoagulant that is tailored specifically for the less-challenging diagnostic patients where substantial blood-thinning drugs are less frequently used. All other components of the Diagnostic Duett, including the balloon catheter, are identical to the original Duett sealing device. This results in the Diagnostic Duett having identical deployment steps, but being less expensive and yet fully effective for the over 2.5 million diagnostic procedures that occur each year in the United States.

In July 2002 we launched the next generation "Pro" line of the Duett sealing device. The Pro line enhances the Duett catheter by improving its robustness and simplifying the device deployment steps.

**The D-Stat Flowable Hemostat**

Our second product, the D-Stat flowable hemostat, is a blood clotting gel that can be delivered topically and into voids and open spaces to seal against active bleeding. The D-Stat offers the advantage of being thick to maintain its position, yet easily deliverable. The D-Stat 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. After a simple reconstitution step, the D-Stat hemostat can be applied directly to a wide variety of bleeding surfaces using one of the three included applicator tips. Since the D-Stat is applied locally, no special catheter delivery system is required. The D-Stat hemostat is shelf stable and can be prepared up to three hours before use.

The D-Stat flowable hemostat can be used in a wide variety of interventional procedures as an adjunct to hemostasis. Examples of these uses include sealing the access site after the removal of catheters from A-V access grafts, sealing very small punctures of the femoral artery, and sealing following venous punctures. 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 worldwide in the first quarter of 2002, and by the end of the fourth quarter of 2002 we reached nearly $1 million in annualized net sales of the D-Stat. We achieved this revenue with limited approved clinical indications for the D-Stat, which initially has been limited to topical bleeding and blood "oozing." We believe these indications are but a small fraction of the total potential market for the D-Stat. We recently filed for regulatory approval for a clinical study to confirm our next clinical use of the D-Stat in the hemostasis of prepectoral pockets created in pacemaker and defribrillator implantations. We estimate that the U.S. market opportunity for this prepectoral pocket indication is greater than 100,000 procedures each year. Following the prepectoral pockets study, we expect to perform clinical studies on the use of D-Stat 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.

**The Acolysis Ultrasound Thrombolysis System**

Our third product, the Acolysis ultrasound thrombolysis system, uses high energy, low frequency ultrasound to lyse thrombus into subcapillary particles without damaging vessel walls. The therapeutic principle of the Acolysis system is to generate ultrasound thrombolysis by the selective disruption of the fibrin matrix of the thrombus. Cavitation produces subcapillary-sized particles, resulting in a debulking of the arterial lesion. Peripheral vascular disease, the initial market opportunity, affects over 8 million people worldwide. We believe

the Acolysis System represents a breakthrough in both therapy and technology, and initial clinical experience and one-year follow-up with the product has been favorable.

Our international sales efforts on the Acolysis therapeutic ultrasound product began in earnest during the fourth quarter of 2002. Our first indication for this product is to open chronic total occlusions in peripheral arteries. Currently, in Germany we have approximately 10 Acolysis controllers placed in the field generating a mix of clinical evaluations and sales. We are in the process of planning and structuring a clinical study to confirm the effectiveness of the use of the Acolysis system to open chronic total occlusions. We expect to commence a U.S. clinical study of the Acolysis product in 2004.

**Business Strategy**

Our primary objective is to establish ourselves as a leading supplier of clinically superior medical devices for substantial opportunites within interventional medicine. Starting with our Duett sealing device in the large vascular sealing device market, the key steps in achieving our primary objective are the following:

- *Establish 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 training is a key factor in promoting use of interventional medical devices. We have created and will continue to work to improve an in-the-field training and certification program for the use of our products. As of December 31, 2002, our United States direct sales force consisted of approximately 50 employees.

- *Continue to Promote the Duett Sealing Device's Benefits Compared to Manual Compression and Other Devices.* We believe that the primary benefits of the Duett sealing device are improved patient outcomes and provider efficiencies. We intend to continue to use our existing and growing body of clinical results to initiate use of our Duett sealing device by physicians currently using manual compression and to convert physicians from other vascular sealing devices to our product.

- *Leverage Future Devices through our Direct Sales Force to our Existing Customers.* We intend to leverage our direct sales force by bringing additional products to the interventional physician. The D-Stat is our first product that takes advantage of this strategy, and the Acolysis product in international markets is the second product in our pipeline. Our research and development team is working on four additional substantial medical devices for the interventional physician that we expect to launch through our existing distribution network in the second half of 2003.

**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, 2002, our direct sales force consisted of approximately 50 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 will be able to sell our new products to the same customer base.

As part of our sales force, we have hired clinical specialists 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 and certification 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 radiologists through established independent distributors in major international markets, subject to required regulatory approvals. In Germany, we established a direct sales organization by creating Vascular Solutions GmbH and began selling directly to customers in the German market in the fourth quarter of 2000. Our products are currently marketed through independent distributors in Norway, Italy, Austria, the United Kingdom, Ireland, Denmark, Switzerland, Finland, Sweden, Greece, Belgium, Spain, the Netherlands, South Africa, China and Portugal. We intend to add independent distributors in other countries as our sales and marketing efforts are expanded. 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 other vascular sealing devices. 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.

Substantially all of our revenues from inception until our FDA approval on June 22, 2000 were derived from sales to international distributors, primarily in Europe, none of which is affiliated with us. Sales in Europe constituted 11%, 10%, 33% and 93% of our net sales for the years ended December 31, 2002, 2001, 2000 and 1999.

**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 Duett sealing device. We incurred expenses of $3,227,538 in 2002, $4,123,883 in 2001 and $3,117,339 in 2000 for research and development activities. To further reduce our costs, our research and development group continues to develop in-house capabilities to manufacture some of the components currently produced by outside vendors.

We have developed four new products that we expect to launch in the second half of 2003 through our existing distribution network to the interventional cardiology and interventional radiology market:

- *D-Stat Dry Hemostatic Bandage.* The D-Stat Dry bandage consists of a freeze-dried pad of the D-Stat procoagulant which can be applied to topical bleeding with a custom adhesive bandage. Initial potential uses of the D-Stat Dry include sealing following arterial interventional punctures and a variety of radiology procedures. We believe that the D-Stat Dry bandage will be the most effective, simple and cost-effective topical solution to hemostasis available to the interventional physician.

- *D-Stat Radial Hemostat Band.* The D-Stat Radial hemostat band is a customized compression device with the power of the D-Stat procoagulant for sealing the arterial puncture following catheterization procedures utilizing the radial artery in the wrist. Currently, only compression devices are used to seal the puncture of the radial artery, which is the source of arterial puncture in approximately 5% of all

catheterizations. We believe that the D-Stat Radial will lessen the time to hemostasis, and thereby lower the risk of complications resulting from compression of the radial artery following catheterization procedures.

- *Pronto Extraction Catheter.* We have licensed from Dr. Pedro Silva of Milan, Italy a patented design of an extraction catheter for the removal of soft thrombus from arteries. The Pronto catheter consists of an extraction catheter with a proprietary atraumatic distal tip and large extraction lumen that can be placed in arteries and easily extract soft thrombus. A user-friendly syringe extraction system allows for a single operator deployment with total preparation and deployment time of less than one minute. Principal clinical uses of the Pronto extraction catheter are expected to include the removal of thrombus burden from acute myocardial infarction (heart attack) cases.

- *Varicose Vein Treatment.* During 2002 we internally generated a product that addresses the substantial market for the treatment of superficial venous reflux, otherwise known as varicose veins. Varicose veins affect over one million people worldwide and, when severe, are treated by the archaic practice of surgical vein stripping. Recently, new interventional tools have been developed to intravascularly treat and close superficial varicose veins as a replacement for invasive vein stripping. We have developed a product that furthers this shift to interventional treatments in a clinically-efficient and cost-effective manner.

We are also working on next generation versions of the Duett sealing device. We have developed and performed pre-clinical testing of the Mechanical Duett, a concept that utilizes an immediate and complete mechanical seal of the arterial puncture to obtain hemostasis. To develop the Mechanical Duett, we have entered into a development and manufacturing agreement with Tepha, Inc. to supply us with the bioresorbable component of the Mechanical Duett. Initial international clinical studies of the Mechanical Duett are expected to occur in the middle of 2003.

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 46001 standards and were audited in September 1999 and June 2000 for compliance with the FDA's quality systems regulations with no deficiencies noted. Upon expiration of our existing lease, in March 2003 we will move to a new facility, also located in a suburb of Minneapolis, Minnesota which will require recertification by the FDA.

We purchase components from various suppliers and rely on single sources for several parts of the Duett sealing device and D-Stat flowable hemostat. 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. In June 1999, we entered into a five year, sole-source, supply agreement with our thrombin supplier, GenTrac, Inc., a subsidiary of King Pharmaceuticals, Inc., that provides for a fixed price with a price adjustment formula based on increased costs and wholesale price increases. To date, we have not experienced any significant adverse effects resulting from shortages of components.

The manufacture and sale of our products entail 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 Duett sealing device competes with four vascular sealing devices and manual compression. Because the substantial majority of vascular sealing is performed through manual compression, this represents our primary competition. Manual compression usually requires a healthcare professional to manually apply pressure to the puncture site for 20 minutes to one hour following which the patient is confined to bed rest for between four and 48 hours. Often manual compression involves the use of mechanical devices, including C-clamps and sandbags, or pneumatic devices. Manual compression is considered to be uncomfortable for the patient.

The four 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 mechanical device that enables a physician to perform a minimally invasive replication of open surgery.

- The QuickSeal™ device, manufactured by SubQ, Inc. and distributed by Boston Scientific, Inc., mechanically seals the puncture site through use of a hydrated gelatin plug placed in the tissue tract adjacent to the puncture in the artery.

We believe that several other companies are developing arterial closure 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 vascular sealing devices of which we are currently unaware. A new technology or product may emerge that results in a reduced need for vascular sealing devices or results in a product that renders our product noncompetitive.

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 open surgical market and are not designed specifically for use in interventional procedures. There are likely to be new products, or modifications of existing products, that will compete with our D-Stat flowable hemostat in the interventional segment of the hemostat market, and these new products may render our product noncompetitive.

Topical patches and pads, which have recently been introduced to the market, are designed to treat bleeding at arterial puncture sites. Our D-Stat Dry hemostatic bandage will compete in this market segment. 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 Acolysis therapeutic ultrasound system and the Pronto extraction catheter compete, and are expected to compete, in the highly competitive market segment for removal of thrombus and plaque from the arterial system. There are many companies that are selling or have developed products in this segment, including Possis Medical, Inc., Boston Scientific and Endicor. We believe that several other companies are developing other technologies that will compete with our Acolysis System, and these new technologies may render 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, or FDC, 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, premarket notification and adherence to good manufacturing practices. Class II devices are subject to the same general controls and also are subject to special controls such as performance standards, postmarket surveillance, patient registries 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 may need to 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 device presents what the FDA considers to be a significant risk. 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 board at the hospital performing the clinical study.

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 IDE 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 flowable hemostat also is regulated in the United States as a medical device by the FDA and required clearance of our 510(k) application by the FDA prior to being sold in the United States. Our D-Stat flowable hemostat was the subject of a 510(k) application which was determined to be "substantially equivalent" to a legally marketed predicate device by the FDA, thereby allowing commercial marketing in the United States. In January 2002, our 510(k) application for the D-Stat flowable hemostat was cleared by the FDA, and we commenced sales in the United States in February 2002.

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 compliance, manufacturers are required to comply with the ISO 9000 series of standards for quality operations. We received the CE mark approval for our Duett sealing device and ISO 9001 certification in July 1998, we received the CE mark approval for our D-Stat flowable hemostat in October 2001 and we purchased the Acolysis system, which previously had obtained the CE mark, in April 2002.

International sales of the Duett sealing device, D-Stat and the Acolysis System are subject to the regulatory requirements of each country in which we sell our product. These requirements vary from country to country but generally are much less stringent than those in the United States. Our products are currently marketed in Germany, Norway, Italy, Austria, the United Kingdom, Ireland, Denmark, Switzerland, Finland, Sweden, Greece, Belgium, Spain, the Netherlands, South Africa, China and Portugal. We have obtained regulatory approvals where required. Through our Japanese distributor, we are pursuing the regulatory approval of our Duett sealing device for commercial sale in Japan.

**Third Party Reimbursement**

In the United States, healthcare providers that purchase medical devices, such as vascular sealing 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. We have performed analyses to establish the cost benefit of the Duett sealing device, relying on shortened hospital stays and decreased use of healthcare professionals, to justify the increased cost of using our Duett sealing device in the United States.

During 2000, CMS implemented a new Medicare prospective payment system for hospital outpatient services. One aspect of the new system recognized new technology items and services as discrete payment groups under the prospective payment system. Under this system, hospitals receive separate payments for the use of new medical devices that are recognized by CMS. The Duett sealing device was issued a transitional pass through code by CMS in 2000. Effective January 1, 2003, CMS incorporated the payment for the Duett sealing device and all vascular sealing devices into the overall payment for the diagnostic catheterization procedure. The net effect is an overall increase in the 2003 hospital payment for a diagnostic procedure, with no separate reimbursement for the sealing device. Currently there is no separate reimbursement for our D-Stat flowable hemostat.

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. Prior to the formation of our company, Dr. Gary Gershony filed a number of patent applications in the United States and other countries directed to proprietary technology used in our Duett sealing device. Upon the commencement of our operations in February 1997, Dr. Gershony assigned all patents and patent applications relating to the Duett sealing device to us on a worldwide, perpetual, royalty-free basis. At the time of assignment, there existed one United States patent issued that is directed to a balloon catheter sealing device and method and which expires in May 2013, three United States patents pending and an international patent application pending which designated numerous foreign countries and regions.

Since commencing operations, we have continued the prosecution of the pending United States patent applications and filed new patent applications. A second United States patent was issued that is directed to a balloon catheter and procoagulant sealing device and method and which expires in October 2015. A third United States patent was issued that contains method claims concerning the use of a balloon catheter and flowable procoagulant and which expires in October 2015. A fourth United States patent was issued concerning the procoagulant mixture and which expires in October 2015. A fifth United States patent was issued concerning a balloon catheter sealing device and which expires in May 2013. A sixth United States patent was issued concerning a balloon catheter and procoagulant sealing device and which expires in October 2015. A seventh

United States patent was issued concerning a balloon catheter sealing device and which expires in October 2015. We currently have 5 additional United States patents pending concerning aspects of our Duett sealing device and other interventional products. We also have pursued international patent applications, which designate the key developed nations with substantive patent protection systems.

The interventional cardiology market in general, and the vascular sealing device field in particular, is characterized by numerous patent filings and 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. (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 Duett sealing device or other 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 applied for registration in the United States of the marks "Vascular Solutions Duett," "D-Stat," "Pronto" and the Duett stylized logo. We acquired the registered trademark "Acolysis" in connection with our acquisition of the Acolysis therapeutic ultrasound business in 2002.

**Employees**

As of December 31, 2002, we had 127 full time employees. Of these employees, 31 were in manufacturing activities, 62 were in sales and marketing activities, 8 were in research and development activities, 15 were in regulatory, quality assurance and clinical research activities and 11 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.

**Executive Officers of the Registrant**

The executive officers of the Company as of February 15, 2003 are as follows:

| Name | Age | Position |
|---|---|---|
| Howard Root | 42 | Chief Executive Officer, Acting Chief Financial Officer and Director |
| Michael Nagel | 40 | Vice President of Sales & Marketing and Secretary |
| Deborah Jensen | 46 | Vice President of Regulatory Affairs |
| James Quackenbush | 44 | Vice President of Manufacturing |

*Howard Root* has served as our Chief Executive Officer and a director since he co-founded Vascular Solutions 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. degrees from the University of Minnesota.

*Michael Nagel* has served as our Vice President of Sales & Marketing since June 1997. Prior to joining us, Mr. Nagel was the Director of Sales & Marketing at Quantech, Ltd., a developer of point of care medical diagnostic testing products, where he worked since July 1996. From 1992 through July 1996, Mr. Nagel was the mid-west division sales manager of B. Braun Cardiovascular, a manufacturer of cardiovascular devices and catheters. From 1991 through 1992, Mr. Nagel was the Director of Worldwide Sales for the Medical Products Division of Angeion Corporation, a manufacturer of angioplasty accessories and pediatric catheters. Prior to 1991, Mr. Nagel performed a variety of sales and marketing functions with Abbott Labs Diagnostic Division for over five years. Mr. Nagel received his B.A. and M.B.A. degrees from the University of St. Thomas.

*Deborah Jensen* has served as our Vice President of Regulatory Affairs, Clinical Affairs and Quality Systems since October 2000. Ms. Jensen 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, Ms. Jensen was employed as a Regulatory Affairs Manager for Boston Scientific's Scimed division. Prior to May 1993, Ms. Jensen 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.

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.vascularsolutions.com our annual report on Form 10-K, quarterly reports on Form 10Q, current reports on Form 8-K, and amendments to these reports filed or furnished pursuant to Section 13 (a) or 15 (d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

## ITEM 2. PROPERTIES

Our offices are in approximately 29,000 square feet of leased space in a suburb of Minneapolis, Minnesota. These facilities include approximately 12,800 square feet used for manufacturing activities, approximately 3,400 square feet used for research and laboratory activities, with the remainder used for administrative offices. Our lease for these facilities expires March 31, 2003. We entered into a new lease effective April 1, 2003 for a 33,000-square-foot office and manufacturing facility under an operating lease agreement that expires in September 2008. Our new lease provides a lower effective net lease payment per square foot than our existing lease, with reimbursement of our expected moving expenses. Our new office also is located in a suburb of Minneapolis, Minnesota. We believe that our new facility will be adequate to meet our needs through at least the end of the lease period.

## ITEM 3. LEGAL PROCEEDINGS

On July 23, 1999, we were named as the defendant in a patent infringement lawsuit brought by Datascope Corp. in the United States District Court for the District of Minnesota. The complaint requested a judgment that our Duett sealing device infringes and, following FDA approval will infringe, a United States patent held by Datascope and asks for relief in the form of an injunction that would prevent us from selling our product in the United States as well as an award of attorneys' fees, costs and disbursements. On August 12, 1999, we filed our answer to this lawsuit and brought a counterclaim alleging unfair competition and tortious interference. On August 20, 1999, we moved for summary judgement to dismiss Datascope's claims. On March 15, 2000, the court granted summary judgment dismissing all of Datascope's claims, subject to the right of Datascope to recommence the litigation after our receipt of FDA approval of our Duett sealing device. On July 12, 2000, after our receipt of FDA approval, Datascope recommenced this litigation, alleging that the Duett sealing device infringes a United States patent held by Datascope and requesting relief in the form of an injunction that would prevent us from selling our product in the United States, damages caused by our alleged infringement, and other costs, disbursements and attorneys' fees. On November 26, 2002, we entered into an agreement that settled all existing intellectual property litigation with Datascope Corporation. Under the terms of the Settlement Agreement, Datascope granted us a non-exclusive license to its Janzen patents as they apply to all current versions of the Duett sealing sevice, and to certain permitted future product improvements. Datascope also has released us from any claim of patent infringement based on past or future sales of the Duett sealing device. In exchange, we paid Datascope a single lump sum of $3,750,000 in the fourth quarter of 2002.

On July 3, 2000, we were named as the defendant in a patent infringement lawsuit brought by the Daig division of St. Jude Medical in the United States District Court for the District of Minnesota. The complaint requested a judgment that our Duett sealing device infringes a series of four patents known as the Fowler patents held by St. Jude Medical and asks for relief in the form of an injunction that would prevent us from selling our Duett sealing device in the United States, damages caused by the manufacture and sale of our product, and other costs, disbursements and attorneys' fees. On July 12, 2001, we entered into an agreement that settled all existing intellectual property litigation with St. Jude Medical. Under the terms of the settlement agreement, we agreed to pay a royalty of 2.5% of net sales of our Duett sealing device to St. Jude Medical, up to a maximum amount over the remaining life of the St. Jude Fowler patents. In exchange, St. Jude Medical granted to us a non-exclusive license to its Fowler patents and has released us from any claim of patent infringement based on sales of our Duett sealing device. We granted a non-exclusive cross-license to our Gershony patents to St. Jude Medical, subject to a similar royalty payment if St. Jude Medical utilizes our Gershony patents in any future device. Beginning on July 1, 2001, a royalty expense of 2.5% of net sales is included in our cost of goods sold until the maximum royalty is attained.

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 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 fourth quarter ended December 31, 2002.

# PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

On July 25, 2000, we sold 3,500,000 shares of our common stock, at an initial public offering price of $12.00 per share, pursuant to a Registration Statement on Form S-1 (Registration No. 333-84089), which was declared effective by the Securities and Exchange Commission on July 19, 2000. Our net proceeds from the offering were approximately $44.0 million. To date, we have spent approximately $20.0 million of the net proceeds to hire, train and deploy a direct sales force in the United States, $4.1 million to settle the St. Jude and Datascope litigation, $1.6 million to purchase the Acolysis System and $4.5 million for general corporate purposes.

The Company's 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.

| | High | Low |
|---|---|---|
| 2001 | | |
| First Quarter | 10.000 | 5.750 |
| Second Quarter | 9.000 | 5.125 |
| Third Quarter | 9.640 | 1.770 |
| Fourth Quarter | 2.920 | 1.750 |
| 2002 | | |
| First Quarter | 3.700 | 2.480 |
| Second Quarter | 2.700 | 1.680 |
| Third Quarter | 1.780 | .880 |
| Fourth Quarter | 1.200 | .650 |

### Holders

As of December 31, 2002, the Company had 177 shareholders of record. Such number of record holders does not reflect shareholders who beneficially own common stock in nominee or street name.

### Dividends

The Company has paid no cash dividends on its common stock, and it does not intend to pay cash dividends on its common stock in the future.

## ITEM 6. SELECTED FINANCIAL DATA

The selected consolidated financial data below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 below and the Consolidated Financial Statements and the Notes thereto included in Item 8 below.

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2002 | 2001 | 2000 | 1999 | 1998 |
| | (in thousands, except per share amounts) | | | | |
| Statements of Operations Data: | | | | | |
| Net sales | $ 12,101 | $ 12,082 | $ 6,193 | $ 1,429 | $ 494 |
| Cost of sales | 4,986 | 4,961 | 2,701 | 1,065 | 442 |
| Gross profit | 7,115 | 7,121 | 3,492 | 364 | 52 |
| Operating expenses: | | | | | |
| Research and development | 3,227 | 4,124 | 3,117 | 3,068 | 2,348 |
| Clinical and regulatory | 1,348 | 1,288 | 1,082 | 1,324 | 1,376 |
| Sales and marketing | 11,964 | 12,772 | 6,700 | 2,301 | 1,075 |
| General and administrative | 2,167 | 2,498 | 2,255 | 1,904 | 668 |
| Legal settlement | 3,750 | 350 | - | - | - |
| Amortization of purchased technology | 145 | - | - | - | - |
| Total operating expenses | 22,601 | 21,032 | 13,154 | 8,597 | 5,467 |
| Operating loss | (15,486) | (13,911) | (9,662) | (8,233) | (5,415) |
| Interest income | 507 | 1,661 | 1,453 | 371 | 274 |
| Net loss | $ (14,979) | $ (12,250) | $ (8,209) | $ (7,862) | $ (5,141) |
| Net loss per common share – Basic and diluted | $ (1.13) | $ (.93) | $ (.95) | $ (1.95) | $ (1.40) |
| Weighted average number of common shares outstanding | 13,276 | 13,217 | 8,645 | 4,033 | 3,660 |

| | As of December 31, | | | | |
|---|---|---|---|---|---|
| | 2002 | 2001 | 2000 | 1999 | 1998 |
| | (in thousands) | | | | |
| Balance Sheet Data: | | | | | |
| Cash, cash equivalents and available-for-sale securities | $ 16,750 | $ 33,318 | $ 44,098 | $ 10,529 | $ 9,897 |
| Working capital | 18,656 | 34,712 | 46,300 | 10,487 | 9,933 |
| Total assets | 22,280 | 37,593 | 49,661 | 12,295 | 11,007 |
| Long-term debt | - | - | - | - | - |
| Total shareholders' equity | 20,369 | 35,630 | 47,194 | 11,172 | 10,546 |

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

The following discussion of the financial condition and results of operations of the Company should be read in conjunction with the Company's 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 the Company's expectations regarding future trends affecting its 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. The following discussion sets forth certain factors the Company believes 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. Our product line includes the Duett™ sealing device, the D-Stat™ flowable hemostat and the Acolysis® therapeutic ultrasound system. 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 commenced operations in February 1997, and during 1998 and 1999 we received regulatory approvals to market our first product, the Duett sealing device, in several international markets, principally in Europe. On June 22, 2000, we received approval from the FDA of our PMA application for the sale of our Duett sealing device in the United States. As a result, during the third quarter of 2000 we commenced sales of the Duett in the United States through our direct sales force. We commenced sales of the Diagnostic Duett in the United States in December 2001, and commenced sales of the D-Stat in the United States in February 2002. In April 2002, we acquired the assets of the Acolysis system from the secured creditors of Angiosonics, Inc. The Acolysis controller and probes have been sold in international markets, principally in Europe and China, for over two years. During the last quarter of 2002, we commenced active international sales of the Acolysis product.

We have a limited history of operations and have experienced significant operating losses since inception. As of December 31, 2002, we had an accumulated deficit of $50.1 million.

Although we have experienced revenue growth in recent periods, this growth may not be sustainable and, therefore, these recent periods should not be considered indicative of future performance. We may never achieve profitability, or if we achieve profitability it may not be sustained in future periods.

### Critical Accounting Policies:

The critical accounting policies of the Company are described in Note 1 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 or market. We record reserves for inventory shrinkage and for potentially excess, obsolete and slow moving inventory based upon historical experience and forecasted demand. Our reserve requirements 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 upon shipment of products to customers, net of estimated returns. 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. If the historical data the Company uses 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. 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.

**Valuation of Long-Lived Assets and Goodwill**

In fiscal 2002, we adopted Statement of Financial Accounting Standards (SFAS) 142, "Goodwill and Other Intangible Assets." Goodwill is tested for impairment annually or more frequently if changes in circumstance or the occurrence of events suggests an impairment exists. The test for impairment requires us to make several estimates about fair value, most of which are based on projected future cash flows.

We regularly review the carrying value of certain long-lived assets and identifiable intangible assets with respect to any events or circumstances that indicate an impairment or an adjustment to the amortization period is necessary. If circumstances suggest the recorded amounts cannot be recovered, calculated based upon estimated future undiscounted cash flows, the carrying values of these assets are reduced to fair value.

**Results of Operations**

***Year ended December 31, 2002 compared to year ended December 31, 2001***

Net sales increased modestly to $12,100,526 for the year ended December 31, 2002 from $12,082,379 for the year ended December 31, 2001. Approximately 89% of our net sales for the year ended December 31, 2002 were to customers in the United States and 11% of the net sales were to customers in international markets. Net sales in 2002 were negatively affected by the intense competitive environment for our Duett sealing device in the United States market. Net sales during 2002 benefited from the early sales of our D-Stat flowable hemostat, which we launched in February 2002.

Gross profit as a percentage of net sales was unchanged at 59% for the year ended December 31, 2002 and 2001. We added the Diagnostic Duett, D-Stat and Acolysis products to our selling mix during 2002, which all have gross margins greater than 60%. The introduction of the higher margin products in 2002 was offset by a growth in the lower margin international sales. We expect gross margins to slightly increase in 2003 as we again introduce new higher margin products in 2003 and make slight gains in manufacturing efficiencies.

Research and development expenses decreased 22% to $3,227,538 for the year ended December 31, 2002 from $4,123,883 for the year ended December 31, 2001. The decrease was attributable to more focused

development work on the product line extensions and new products during 2002. Research and development expenses can fluctuate due to outside project spending. We expect our research and development expenses to increase modestly during 2003 as we continue to pursue additional new products.

Clinical and regulatory expenses increased 5% to $1,347,694 for the year ended December 31, 2002 from $1,288,301 for the year ended December 31, 2001. Clinical and regulatory expenses fluctuate due to the timing of clinical and marketing studies. We are expecting clinical expenses to increase in 2003 as we move forward with additional indications for our existing D-Stat flowable hemostat and international studies of our new products.

Sales and marketing expenses decreased 6% to $11,963,907 for the year ended December 31, 2002 from $12,771,901 for the year ended December 31, 2001. The reason for the decrease is better cost utilization. We have reviewed our sales and marketing expenditures and focused our spending in the areas that drive sales and provide an adequate financial return. As of December 31, 2002, our direct sales force consisted of approximately 50 employees compared to approximately 65 as of December 31, 2001. As a result, we expect our sales and marketing expenses to again slightly decrease during 2003 as we continue to review our sales and marketing expenditures.

General and administrative expenses decreased 13% to $2,166,883 for the year ended December 31, 2002 from $2,498,435 for the year ended December 31, 2001. The decrease was the result of lower headcount in 2002 compared to 2001. We currently anticipate that general and administrative expenses will decrease in 2003 as we continue to benefit from lower headcount and the settlement of all of our outstanding intellectual property litigation.

Legal settlement expenses were $3,750,000 for the year ended December 31, 2002 and $350,000 for the year ended December 31, 2001. We entered into an agreement that settled all existing intellectual property litigation with Datascope Corporation in 2002 (see "Legal Proceedings" in Item 3 of Part I of this Form 10-K). As part of the settlement, Datascope released us from any claim of patent infringement based on past or future sales of the Duett sealing device. In exchange, we paid Datascope a single lump sum of $3,750,000 in the fourth quarter of 2002. We entered into an agreement that settled all existing intellectual property litigation with St. Jude Medical in 2001 (see "Legal Proceedings" in Item 3 of Part I of this Form 10-K). As a result of the settlement, we agree to pay St. Jude Medical a royalty of 2.5% of our Duett sales up to a maximum amount over the remaining life of the St. Jude Medical patents. We paid $350,000 to St. Jude Medical in 2001 representing the past royalty on net sales of our Duett device since 1998 under the settlement agreement.

Amortization of purchased technology was $145,000 for the year ended December 31, 2002 and $0 for the year ended December 31, 2001. The amortization was the result of 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 decreased to $507,169 for the year ended December 31, 2002 from $1,660,757 for the year ended December 31, 2001 primarily as a result of a reduced cash balance and lower interest rates.

***Year ended December 31, 2001 compared to year ended December 31, 2000***

Net sales increased 95% to $12,082,379 for the year ended December 31, 2001 from $6,193,234 for the year ended December 31, 2000. The increase in net sales was principally the result of a full year of United States sales of our Duett sealing device in 2001, compared to six months of sales in 2000. As a result, 90% of our net sales for the year ended December 31, 2001 were to customers in the United States, while 10% of the net sales were to our customers in international markets.

Gross profit as a percentage of net sales increased to 59% for the year ended December 31, 2001 from 56% for the year ended December 31, 2000. This increase as a percentage of net sales resulted principally from the full year of United States sales in 2001. In the third quarter of 2001 we settled our intellectual property litigation with St. Jude Medical. As part of the settlement agreement, we agreed to pay a royalty of 2.5% of our net sales of the Duett sealing device to St. Jude Medical up to a maximum amount for the remaining life of the patents. This 2.5% royalty was included in our costs of goods sold beginning in the third quarter of 2001. During the fourth quarter of 2001 we commenced initial sales of our Diagnostic Duett version of the Duett sealing device in the United States. The Diagnostic Duett has a substantially lower costs of goods sold than the original Duett, which is offset by a lower average selling price.

Research and development expenses increased 32% to $4,123,883 for the year ended December 31, 2001 from $3,117,339 for the year ended December 31, 2000. This increase was attributable to increased development work on the product line extensions and new products during 2001.

Clinical and regulatory expenses increased 19% to $1,288,301 for the year ended December 31, 2001 from $1,082,029 for the year ended December 31, 2000. The increase was primarily the result of additional personnel and the commencement of clinical studies for new products and new claims for our Duett sealing device during 2001.

Sales and marketing expenses increased 91% to $12,771,901 for the year ended December 31, 2001 from $6,699,722 for the year ended December 31, 2000. This increase was due primarily to the full year of operations of our United States direct sales force during 2001.

General and administrative expenses increased 11% to $2,498,435 for the year ended December 31, 2001 from $2,255,160 for the year ended December 31, 2000. The primary reason for the increase was legal fees associated with the St. Jude Medical and Datscope litigation increased during 2001 as compared with 2000.

Interest income increased to $1,660,757 for the year ended December 31, 2001 from $1,453,491 for the year ended December 31, 2000 primarily as a result of a full year of interest on the cash proceeds received upon the closing of our initial public offering in July 2000.

**Income Taxes**

We have not generated any pre-tax income to date and therefore have not paid any federal income taxes since 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, 2002, we had $46,100,000 of federal net operating loss carryforwards available to offset future taxable income which begin to expire in the year 2013. As of December 31, 2002, we also had federal and state research and development tax credit carryforwards of approximately $1,206,000 which begin to expire in the year 2013. Under the 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 have established a valuation allowance against the entire amount of our deferred tax asset because we have not been able to conclude that it is more likely than not that we will be able to realize the deferred tax asset, due primarily to our history of operating losses.

## 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, 2002, we have sold common stock and preferred stock generating aggregate net proceeds of $70.2 million. At December 31, 2002, we had $16.7 million in cash, cash equivalents and available-for-sale securties on-hand.

During the year ended December 31, 2002, we used $14.3 million in operating activities. The cash used in operating activities was primarily used to fund our net loss for the period of $15.0 million, which was offset by depreciation and amortization of $647,390. Included in the net loss of $15.0 million was the legal settlement of $3,750,000 to Datascope (see "Legal Proceedings" in Item 3 of Part I of this Form 10-K). We generated proceeds of $7,405,132 in investing activities, primarily from the net sales of investment securities of $9,312,031, offset by the $1,550,203 in cash used in the acquisition of Angiosonics' Acolysis System and net equipment purchases of $356,696. We used $363,151 in financing activities during fiscal 2002, primarily from the repurchase of our common stock for $547,722, offset by $184,571 we received through the issuance of common stock.

In April 2002, we paid $1,550,203 in cash to the secured creditors of Angiosonics, Inc. in connection with the acquisition of the Acolysis system, related patents and technologies. This acquisition was funded through existing cash balances.

In August 2002, the Board of Directors adopted a stock repurchase program to acquire up to 1 million shares of our common stock in open market transactions. The program does not obligate the company to acquire any specific number of shares and may be discontinued at any time. Through December 31, 2002, we have repurchased 608,900 shares under our stock repurchase program for $547,722.

We do not have any 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 a negative cash flow for the foreseeable future and our expenses will be a material use of our cash resources. We anticipate that our operating losses will continue through at least mid-2004. We believe that current cash balances along with cash generated from the future sales of products will be sufficient to meet our operating and capital requirements for at least the next 24 months. Our liquidity and capital requirements beyond the next 24 months will depend on numerous factors, including the extent to which our current and future products gain market acceptance and competitive developments.

If cash generated from operations is insufficient to satisfy our cash needs, we may be required to raise additional funds. We currently 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 take advantage of business opportunities or respond to competitive pressures.

## 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 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 the initial sales of our Duett sealing device, and we are in the process of introducing additional interventional medical devices to grow our sales. Our success will depend on the medical community's acceptance of our 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;
- 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.

If we encounter difficulties in growing our sales of our new medical devices in the United States, our business will be seriously harmed.

**We currently rely on the Duett sealing device as our primary source of revenue**

Although we have sold the D-Stat flowable hemostat for approximately one year and we recently commenced marketing of the Acoylsis System, we continue to rely on sales of our principal product, the Duett sealing device, which is being sold in a limited number of international markets and in the United States. Even though we are in the process of developing additional products, preparation of regulatory approval, implementation timing and market uncertainties will exist with each new product. As a result, our success to a large degree is dependent on the maintenance and growth of our Duett sealing device business. To date we have not been able to grow our share of the vascular sealing device market over 5% with our Duett sealing device. If we are unable to maintain and modestly grow our Duett sealing device market share, our business will be seriously harmed.

**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. At December 31, 2002, we had an accumulated deficit of $50.1 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, hire additional employees and expand our commercialization, we expect to incur significant net losses through at least mid-2004. Our business strategies may not be successful and we may not be profitable in any future period. 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 cardiology industry is characterized by numerous patent filings and frequent and substantial intellectual property litigation. Companies in the interventional cardiology industry in general, and in vascular sealing in particular, have employed intellectual property litigation in an attempt to gain a competitive advantage. We are aware of many United States patents issued to other companies in the vascular sealing field which describe vascular sealing devices. Each of the currently marketed vascular sealing products has been subject to infringement litigation. Although we have settled all of our previous intellectual property litigation with respect to our Duett sealing device, it is possible that additional claims relating to the Duett could be brought in the future. In addition, it is possible that we could be subject to intellectual property claims with respect to any of our new products. 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 our products, 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 our 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.

**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 Duett sealing device and new 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;
- 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.

**Our direct sales efforts may not be successful because we have a limited operating history with a direct sales force**

Because we received regulatory approval to sell our Duett sealing device in the United States during 2000, we have only a limited operating history with a direct sales force. We believe that there is significant competition for direct sales personnel and clinical specialists with the advanced sales skills and technical knowledge we require. We may not be able to obtain, train and retain sufficient numbers of direct sales personnel and the future sales efforts of our direct sales force may not be successful.

**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 vascular sealing 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 Duett sealing device obsolete**

The existing market for vascular sealing devices is intensely competitive. We expect competition to increase further as additional companies begin to enter this market and/or modify their existing products to compete directly with ours. Our primary competitors are Abbott Laboratories (through its subsidiary Perclose, Inc.), Datascope Corp. and St. Jude Medical, Inc., which sells a product developed by Kensey Nash Corporation. These companies have:

- 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 Duett sealing device 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 device;
- the impact of recessions in economies outside the United States;
- greater difficulty in collecting accounts receivable and longer collection periods;
- 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. We are currently in the process of moving our facilities to a new location. We believe our new facilities will be 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 moving our production in the near future, 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 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 Duett sealing device or D-Stat hemostat is 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 Duett sealing device or D-Stat hemostat, 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. We believe that in a prospective payment system, such as the system currently used by Medicare, and in many managed care systems used by private healthcare payors, the cost of our product will be incorporated into the overall cost of the procedure and that there will be no separate, additional reimbursement for our product.

In international markets, acceptance of our products is dependent in part upon the availability of reimbursement within prevailing healthcare payment systems. However, we are unaware of any hospitals that receive specific, cost-based, direct reimbursement for the use of our Duett sealing device or our D-Stat hemostat. 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 approval of the FDA and international agencies before we can market and sell our products;
- 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.

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

We purchase components used in our Duett sealing device and D-Stat flowable hemostat from various suppliers and rely on single sources for the collagen and thrombin components of our Duett sealing device

procoagulant and our D-Stat flowable hemostat. There are currently no FDA-approved alternative suppliers of thrombin and very few FDA-approved alternative suppliers of collagen. Our current supply agreement with our thrombin vendor extends through 2004, but there are no assurances that any future agreement would be on similar terms. Because it requires FDA approval, establishing additional or replacement suppliers for thrombin would require a lead-time of at least two years and would involve significant additional costs. Any supply interruption from key vendors or failure by us to engage alternative vendors may limit our ability to manufacture our Duett sealing device and our D-Stat flowable hemostat and could therefore seriously harm our business.

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

Not applicable.

## ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The Consolidated Financial Statements and Notes thereto required pursuant to this Item begin on page 35 of this Annual Report on Form 10-K.

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

None.

## PART III

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

Incorporated herein by reference to the Sections under the headings "Election 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, 2002.

See Item 1 of Part I hereof for information regarding our Executive Officers.

### ITEM 11. EXECUTIVE COMPENSATION

Incorporated herein by reference to the Sections under the headings "Director Compensation" 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, 2002.

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

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, 2002.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

None.

### ITEM 14. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Acting Chief Financial Officer, we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-14(c) under the Exchange Act) as of a date (the "Evaluation Date") within 90 days prior to the filing date of this report. Based upon that evaluation, the Chief Executive Officer and Acting Chief Financial Officer concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective in timely alerting them to the material information relating to us (or our consolidated subsidiaries) required to be included in our periodic SEC filings.

(b) Changes in internal controls.

There were no significant changes made in our internal controls during the period covered by this report or, to our knowledge, in other factors that could significantly affect these controls subsequent to the date of their evaluation.

## PART IV

## ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) Documents filed as part of this Report.

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

(i) Consolidated Balance Sheets

(ii) Consolidated Statements of Operations

(iii) Consolidated Statement of Changes in Shareholders' Equity

(iv) Consolidated Statements of Cash Flows

(v) 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

| Exhibit Number | Description |
|---|---|
| 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)). |
| 4.5 | Stock Purchase Warrant dated June 10, 1999 by and between Vascular Solutions, Inc. and Jones Pharma, Incorporated (incorporated by reference to Exhibit 4.7 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)). |
| 10.1 | Lease Agreement dated February 11, 1998 by and between Massachusetts Mutual Life |

| | |
|---|---|
| | Insurance Company as Landlord and Vascular Solutions, Inc. as Tenant (incorporated by reference to Exhibit 10.2 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)). |
| 10.2 | First Lease Amendment dated June 9, 1999 by and between Duke Realty Limited Partnership as Landlord and Vascular Solutions, Inc. as Tenant (incorporated by reference to Exhibit 10.3 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)). |
| 10.3 | Second Lease Amendment dated October 24, 1999 by and between Duke Realty Limited Partnership as Landlord and Vascular Solutions, Inc. as Tenant (incorporated by reference to Exhibit 10.3 to Vascular Solutions' Form 10-K for the year ended December 31, 2000). |
| 10.4 | Third Lease Amendment dated August 23, 2000 by and between Duke Realty Limited Partnership as Landlord and Vascular Solutions, Inc. as Tenant (incorporated by reference to Exhibit 10.4 to Vascular Solutions' Form 10-K for the year ended December 31, 2000). |
| 10.5 | Bill of Sale and Assignment dated January 31, 1997 by and between Vascular Solutions, Inc. and Dr. Gary Gershony (incorporated by reference to Exhibit 10.4 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)). |
| 10.6 | 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)). |
| 10.7 | 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)). |
| 10.8 | 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)). |
| 10.9* | Form of Employment Agreement by and between Vascular Solutions, Inc. and each of its executive officers (incorporated by reference to Exhibit 10.11 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)). |
| 10.10 | Form of Distribution Agreement (incorporated by reference to Exhibit 10.12 of Vascular Solutions' Registration Statement on Form S-1 (File No. 333-84089)). |
| 10.11* | 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). |
| 10.12 | Settlement Agreement dated July 12, 2001 by and between Vascular Solutions and St. Jude Medical and Daig Corporation (incorporated by reference to Exhibit 99.2 to Vascular Solutions' Form 8-K dated July 12, 2001). |
| 10.13 | Purchase Agreement dated April 30, 2002 by and between Vascular Solutions and Angiosonics (incorporated by reference to Exhibit 99.2 to Vascular Solutions' Form 8-K dated April 30, 2002). |
| 10.14* | Stock Option and Stock Award Plan as Amended July 16, 2002 (incorporated by reference to Exhibit 10.1 of Vascular Solutions' Form 10-Q for the quarter ended June 30, 2002). |
| 10.15 | 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). |
| 10.16 | Settlement Agreement dated November 26, 2002 by and between Vascular Solutions and Datascope (incorporated by reference to Exhibit 99.2 to Vascular Solutions' Form 8-K dated November 26, 2002). |
| 10.17** | License and Supply Agreement dated December 17, 2002 by and between Vascular Solutions and Tepha, Inc. |
| 21 | List of Subsidiaries |

| | |
|---|---|
| 23.1 | Consent of Ernst & Young LLP. |
| 24.1 | Power of Attorney (included on signature page). |
| 99.1 | Certification of Chief Executive Officer and Acting Chief Financial Officer pursuant to Section 906 of Sarbanes-Oxley Act of 2002. |

* Management contract or compensatory plan or arrangement required to be filed as an Exhibit to this Form 10-K.
** Certain portions of this exhibit have been omitted pending a request for confidential treatment from the SEC.

(b) Reports on Form 8-K:

We filed a Form 8-K on November 26, 2002 to report the settlement of patent litigation with Datascope. There were no financial statements required to be filed with the Form 8-K.

(c) See Item 14(a)(3) above.

(d) See Item 14(a)(2) above.

## 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 28th day of February, 2003.

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 or her true and lawful attorneys-in-fact and agents, with full powers of substitution and resubstitution, for him or her and in his or her 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 or she 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 28th day of February 2003, by the following persons in the capacities indicated.

| Signature | Title |
|---|---|
| /s/ Howard Root<br>Howard Root | Chief Executive Officer, Acting Chief Financial Officer and Director<br>(*principal executive officer & principal financial officer*) |
| /s/ James Hennen<br>James Hennen | Controller/Director of Finance<br>(*principal accounting officer*) |
| /s/ James Jacoby, Jr.<br>James Jacoby, Jr. | Director |
| /s/ Richard Nigon<br>Richard Nigon | Director |
| /s/ Michael Kopp<br>Michael Kopp | Director |
| /s/ Paul O'Connell<br>Paul O'Connell | Director |
| /s/ John Erb<br>John Erb | Director |
| /s/ Dr. Gary Dorfman<br>Dr. Gary Dorfman | Director |

## CERTIFICATIONS

I, Howard Root, certify that:

1. I have reviewed this annual report on Form 10-K of Vascular Solutions, Inc.;

2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;

3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

   (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;

   (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and

   (b) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

   (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: February 28, 2003

By: /s/ Howard Root
Howard Root
*Chief Executive Officer and Acting Chief Financial Officer*
(Principal executive officer and principal financial officer)

## SCHEDULE II
## VALUATION AND QUALIFYING ACCOUNTS
## YEARS ENDED DECEMBER 31, 2002, 2001, AND 2000

| Description | Balance at Beginning of Year | Additions Charged to Costs and Expenses | Less Deductions | Balance at End of Year |
|---|---|---|---|---|
| YEAR ENDED DECEMBER 31, 2002: | | | | |
| Sales return allowance | $ 64,526 | $ 174,642 | $ 199,168 | $ 40,000 |
| Allowance for doubtful accounts | 110,000 | 23,592 | 43,592 | 90,000 |
| Total | $ 174,526 | $ 198,234 | $ 242,760 | $ 130,000 |
| YEAR ENDED DECEMBER 31, 2001: | | | | |
| Sales return allowance | -- | 401,733 | 337,207 | 64,526 |
| Allowance for doubtful accounts | 80,000 | 35,304 | 5,304 | 110,000 |
| Total | $ 80,000 | $ 437,037 | 342,511 | $ 174,526 |
| YEAR ENDED DECEMBER 31, 2000: | | | | |
| Sales return allowance | -- | -- | -- | -- |
| Allowance for doubtful accounts | -- | 80,000 | -- | 80,000 |
| Total | $ -- | $ 80,000 | $ -- | $ 80,000 |

Report of Independent Auditors

The Board of Directors and Shareholders
Vascular Solutions, Inc.

We have audited the consolidated balance sheets of Vascular Solutions, Inc. as of December 31, 2002 and 2001, and the related statements of operations, changes in shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. 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 audits.

We conducted our audits in accordance with auditing standards generally accepted in the 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. 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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Vascular Solutions, Inc. at December 31, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States.

Ernst + Young LLP

Minneapolis, Minnesota
January 17, 2003

Vascular Solutions, Inc.

Consolidated Balance Sheets

| | December 31 2002 | 2001 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 1,835,059 | $ 9,091,640 |
| Available-for-sale securities | 14,914,444 | 24,226,475 |
| Accounts receivable, net of reserves of $130,000 and $174,526 in 2002 and 2001, respectively | 1,357,946 | 1,285,011 |
| Inventories | 2,132,516 | 1,782,363 |
| Prepaid expenses | 326,773 | 289,888 |
| Total current assets | 20,566,738 | 36,675,377 |
| Property and equipment, net | 795,885 | 917,579 |
| Intangible assets, net | 917,595 | – |
| Total assets | $22,280,218 | $37,592,956 |
| **Liabilities and shareholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 771,078 | $ 744,856 |
| Accrued compensation | 886,130 | 923,705 |
| Accrued expenses | 253,777 | 294,511 |
| Total current liabilities | 1,910,985 | 1,963,072 |
| Shareholders' equity: | | |
| Common stock, $0.01 par value: | | |
| Authorized shares – 40,000,000 | | |
| Issued and outstanding shares – 12,880,839 – 2002; 13,327,002 – 2001 | 128,808 | 133,270 |
| Additional paid-in capital | 70,355,343 | 70,712,174 |
| Other | (21,278) | (100,834) |
| Accumulated deficit | (50,093,640) | (35,114,726) |
| Total shareholders' equity | 20,369,233 | 35,629,884 |
| Total liabilities and shareholders' equity | $22,280,218 | $37,592,956 |

*See accompanying notes.*

Vascular Solutions, Inc.

Consolidated Statements of Operations

| | Year Ended December 31 | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| Net sales | $ 12,100,526 | $ 12,082,379 | $ 6,193,234 |
| Cost of goods sold | 4,985,587 | 4,961,014 | 2,701,342 |
| Gross profit | 7,114,939 | 7,121,365 | 3,491,892 |
| Operating expenses: | | | |
| Research and development | 3,227,538 | 4,123,883 | 3,117,339 |
| Clinical and regulatory | 1,347,694 | 1,288,301 | 1,082,029 |
| Sales and marketing | 11,963,907 | 12,771,901 | 6,699,722 |
| General and administrative | 2,166,883 | 2,498,435 | 2,255,160 |
| Legal settlement | 3,750,000 | 350,000 | – |
| Amortization of purchased technology | 145,000 | – | – |
| Total operating expenses | 22,601,022 | 21,032,520 | 13,154,250 |
| Operating loss | (15,486,083) | (13,911,155) | (9,662,358) |
| Interest income | 507,169 | 1,660,757 | 1,453,491 |
| Net loss | $(14,978,914) | $(12,250,398) | $ (8,208,867) |
| Basic and diluted net loss per share | $(1.13) | $(0.93) | $(0.95) |
| Shares used in computing basic and diluted net loss per share | 13,276,147 | 13,216,773 | 8,645,152 |

*See accompanying notes.*

Vascular Solutions, Inc.

## Consolidated Statement of Changes in Shareholders' Equity

| | Series A Preferred Stock | | Series B Preferred Stock | | Common Stock | | Additional Paid-In | | Accumulated | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Amount | Shares | Amount | Shares | Amount | Capital | Other | Deficit | Total |
| Balance at December 31, 1999 | 2,000,000 | $20,000 | 1,777,777 | $17,778 | 5,250,291 | $ 52,503 | $25,828,309 | $ (90,931) | $(14,655,461) | $11,172,198 |
| Exercise of stock options | – | – | – | – | 62,940 | 629 | 169,765 | – | – | 170,394 |
| Sale of common stock with the initial public offering at $12.00 per share in July 2000, net of offering costs | – | – | – | – | 4,025,000 | 40,250 | 43,932,416 | – | – | 43,972,666 |
| Conversion of preferred stock in connection with initial public offering | (2,000,000) | (20,000) | (1,777,777) | (17,778) | 3,777,777 | 37,778 | – | – | – | – |
| Amortization of deferred compensation | – | – | – | – | – | – | – | 72,561 | – | 72,561 |
| Deferred compensation related to option grants | – | – | – | – | – | – | 34,750 | (34,750) | – | – |
| Comprehensive loss: | | | | | | | | | | |
| Net loss | – | – | – | – | – | – | – | – | (8,208,867) | (8,208,867) |
| Translation adjustment | – | – | – | – | – | – | – | 14,938 | – | 14,938 |
| Total comprehensive loss | | | | | | | | | | (8,193,929) |
| Balance at December 31, 2000 | – | – | – | – | 13,116,008 | 131,160 | 69,965,240 | (38,182) | (22,864,328) | 47,193,890 |
| Exercise of stock options | – | – | – | – | 120,800 | 1,208 | 304,096 | – | – | 305,304 |
| Issuance of common stock under the Employee Stock Purchase Plan | – | – | – | – | 90,194 | 902 | 308,660 | – | – | 309,562 |
| Value of stock options granted for services | – | – | – | – | – | – | 10,398 | – | – | 10,398 |
| Deferred compensation related to option grants | – | – | – | – | – | – | 123,780 | (123,780) | – | – |
| Amortization of deferred compensation | – | – | – | – | – | – | – | 62,850 | – | 62,850 |
| Comprehensive loss: | | | | | | | | | | |
| Net loss | – | – | – | – | – | – | – | – | (12,250,398) | (12,250,398) |
| Translation adjustment | – | – | – | – | – | – | – | (1,722) | – | (1,722) |
| Total comprehensive loss | | | | | | | | | | (12,252,120) |
| Balance at December 31, 2001 | – | – | – | – | 13,327,002 | 133,270 | 70,712,174 | (100,834) | (35,114,726) | 35,629,884 |
| Exercise of stock options | – | – | – | – | **10,000** | **100** | **19,900** | – | – | **20,000** |
| Issuance of common stock under the Employee Stock Purchase Plan | – | – | – | – | **152,737** | **1,528** | **163,043** | – | – | **164,571** |
| Stock repurchase program | – | – | – | – | **(608,900)** | **(6,090)** | **(541,632)** | – | – | **(547,722)** |
| Deferred compensation related to option grants | – | – | – | – | – | – | **1,858** | **(1,858)** | – | – |
| Amortization of deferred compensation | – | – | – | – | – | – | – | **74,668** | – | **74,668** |
| Comprehensive loss: | | | | | | | | | | |
| Net loss | – | – | – | – | – | – | – | – | **(14,978,914)** | **(14,978,914)** |
| Translation adjustment | – | – | – | – | – | – | – | **6,746** | – | **6,746** |
| Total comprehensive loss | | | | | | | | | | **(14,972,168)** |
| Balance at December 31, 2002 | – | $ – | – | $ – | **12,880,839** | **$128,808** | **$70,355,343** | **$ (21,278)** | **$(50,093,640)** | **$20,369,233** |

*See accompanying notes.*

Vascular Solutions, Inc.

Consolidated Statements of Cash Flows

| | Year Ended December 31 | | |
|---|---|---|---|
| | **2002** | **2001** | **2000** |
| Operating activities | | | |
| Net loss | **$(14,978,914)** | $(12,250,398) | $ (8,208,867) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | **502,390** | 432,721 | 366,745 |
| Amortization | **145,000** | – | – |
| Value of options granted for services | **–** | 10,398 | – |
| Deferred compensation expense | **74,668** | 62,850 | 72,561 |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | **(72,935)** | 686,372 | (1,592,304) |
| Inventories | **113,455** | 684,082 | (1,851,228) |
| Prepaid expenses | **(36,885)** | (58,637) | (138,074) |
| Accounts payable | **26,222** | (22,191) | 240,774 |
| Accrued compensation and expenses | **(78,309)** | (481,583) | 1,106,005 |
| Net cash used in operating activities | **(14,305,308)** | (10,936,386) | (10,004,388) |
| **Investing activities** | | | |
| Purchase of Acolysis assets | **(1,550,203)** | – | – |
| Purchase of property and equipment | **(356,696)** | (456,206) | (575,887) |
| Purchase of securities | **(33,173,021)** | (25,300,530) | (23,349,715) |
| Proceeds from sales of securities | **42,485,052** | 24,423,770 | – |
| Net cash provided by (used in) investing activities | **7,405,132** | (1,332,966) | (23,925,602) |
| **Financing activities** | | | |
| Proceeds from exercise of stock options | **20,000** | 305,304 | 170,394 |
| Net proceeds from sale of common stock | **164,571** | 309,562 | 43,972,666 |
| Repurchase of common stock | **(547,722)** | – | – |
| Net cash (used in) provided by financing activities | **(363,151)** | 614,866 | 44,143,060 |
| Effect of exchange rate changes on cash and cash equivalents | **6,746** | (1,722) | 5,587 |
| (Decrease) increase in cash and cash equivalents | **(7,256,581)** | (11,656,208) | 10,218,657 |
| Cash and cash equivalents at beginning of year | **9,091,640** | 20,747,848 | 10,529,191 |
| Cash and cash equivalents at end of year | **$ 1,835,059** | $ 9,091,640 | $20,747,848 |

*See accompanying notes.*

Vascular Solutions, Inc.

Notes to Consolidated Financial Statements

December 31, 2002

## 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 product line includes the Duett™ sealing device, the D-Stat™ flowable hemostat and the Acolysis® therapeutic ultrasound system. As a vertically-intergrated medical device company, the Company generates ideas and creates new interventional medical devices, and then delivers those products directly to the physician through its direct domestic sales force and international distribution network. The Duett sealing device is designed to provide a complete seal of the puncture site following catheterization procedures such as angiography, angioplasty and stenting. The Diagnostic Duett is a version of the Duett sealing device that is tailored specifically for treating diagnostic patients. The D-Stat flowable hemostat is a thick, yet flowable blood clotting material that is used in a wide variety of interventional medical procedures for the local control of bleeding. The Acolysis intravascular therapeutic ultrasound system delivers ultrasound waves to lyse blood clots and plaque in arteries. The Acolysis system is not available for sale in the United States. The Company was incorporated 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.

*Foreign Currency Translation and Transactions*

Foreign assets and liabilities are translated using the year-end 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.

*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.

2. Summary of Significant Accounting Policies (continued)

*Cash and Cash Equivalents*

The Company classifies all highly liquid investments as cash equivalents. Cash equivalents consist of cash and money market funds and are stated at cost, which approximates market value.

*Available-for-Sale Securities*

The Company classifies investments as available-for-sale securities. Available-for-sale securities consist of bank certificates of deposit, U.S. Government obligations, commercial paper, and investment-grade corporate debt with maturities of up to one year. These investments are stated at amortized cost, which approximates market value.

*Inventories*

Inventories are stated at the lower of cost (first-in, first-out method) or market and are comprised of the following at December 31:

| | 2002 | 2001 |
|---|---|---|
| Raw materials | $1,561,943 | $1,294,507 |
| Work-in-process | 138,134 | 305,527 |
| Finished goods | 432,439 | 182,329 |
| | $2,132,516 | $1,782,363 |

*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 | 3 to 5 years |
| Office and computer equipment | 3 years |
| Furniture and fixtures | 2 to 5 years |
| Leasehold improvements | Remaining term of the lease |
| Research and development equipment | 3 to 5 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.

**2. Summary of Significant Accounting Policies (continued)**

*Revenue Recognition*

In the United States and Germany, the Company sells its products directly to hospitals and clinics. Revenue is recognized upon shipment of products to customers, net of estimated returns.

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. To date, warranty costs have been insignificant.

*Research and Development Costs*

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

*Stock-Based Compensation*

At December 31, 2002, the Company had a stock-based employee compensation plan, which is described more fully in Note 9. The Company accounts for those plans 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 those plans had an exercise price 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 loss per share if the Company had applied the fair value recognition provisions of Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, to stock-based employer compensation.

| | Year Ended December 31 | | |
|---|---|---|---|
| | 2002 | 2001 | 2000 |
| Net loss, as reported | $(14,978,914) | $(12,250,398) | $ (8,208,867) |
| Deduct: Total stock-based employee compensation expense determined under fair-value-based method for all awards | (2,340,094) | (2,631,693) | (2,152,860) |
| Pro forma net loss | $(17,319,008) | $(14,882,091) | $(10,361,727) |
| Net loss per share: | | | |
| Basic and diluted – as reported | $(1.13) | $(0.93) | $(0.95) |
| Basic and diluted – pro forma | $(1.30) | $(1.13) | $(1.20) |

**2. Summary of Significant Accounting Policies (continued)**

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:

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Expected life (years) | 6.50 | 7.00 | 7.50 |
| Expected volatility | 1.01 | 1.21 | 0.93 |
| Risk-free interest rate | 4.30% | 4.88% | 5.96% |

The weighted average fair value of options granted with an exercise price equal to the deemed stock price on the date of grant during 2002, 2001, and 2000 was $1.58, $5.31, and $9.79, 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.

*Concentrations of Credit Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents, investments, and accounts receivable. The Company maintains its accounts for cash and cash equivalents and investments principally at one major bank and two investment firms in the United States. The Company has a formal written investment policy that restricts the placement of investments to issuers evaluated as creditworthy. The Company has not experienced any losses on its deposits of its cash and cash equivalents.

**2. Summary of Significant Accounting Policies (continued)**

With respect to accounts receivable, the Company performs credit evaluations of its customers and does not require collateral. One customer accounted for 5% of gross accounts receivable as of December 31, 2002 and two customers accounted for 11% of gross accounts receivable as of December 31, 2001. There have been no material losses on customer receivables.

*Net Loss Per Share*

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

*Reclassifications*

Certain prior year balances were reclassified to conform to the current year presentation.

*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 or more frequently if changes in circumstances or the occurrence of events suggest an impairment exists. The test for impairment requires the Company to make several estimates about fair value, most of which are based on projected future cash flows. The Company has concluded that no impairment of goodwill exists as of December 31, 2002.

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 annually or as changes in circumstances or the occurrence of events suggests the remaining value is not recoverable.

**3. Acquisition of Certain Assets of Angiosonics, Inc.**

On April 29, 2002, the Company purchased the Acolysis® intravascular ultrasound assets and related patents and technologies from the secured creditors of Angiosonics, Inc. in exchange for $1,500,000 in cash. The Company allocated the purchase price of $1,500,000 and the related transaction fees using the fair market value of the assets. The Company allocated $487,608 to inventory and fixed assets, $870,000 to purchased technology, and $192,595 to goodwill.

**4. Goodwill and Other Intangible Assets**

As discussed in Note 2, the Company adopted SFAS No. 142 in fiscal 2002, 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 Company also acquired goodwill determined to be an indefinite-lived intangible asset. The Company expects the future annual amortization expense for its acquired purchased development to be approximately $217,500 for each of the next three fiscal years and approximately $72,500 in the fourth fiscal year.

Balances of acquired intangible assets as of December 31, 2002 were as follows:

| | Carrying Amount | Accumulated Amortization | Net |
|---|---|---|---|
| Amortizing intangibles: | | | |
| Purchased technology | $ 870,000 | $145,000 | $725,000 |
| Non-amortizing intangibles: | | | |
| Goodwill | 192,595 | – | 192,595 |
| | $1,062,595 | $145,000 | $917,595 |

**5. Property and Equipment**

Property and equipment consists of the following at December 31:

| | 2002 | 2001 |
|---|---|---|
| Property and equipment: | | |
| Manufacturing equipment | $1,017,283 | $ 773,989 |
| Office and computer equipment | 817,143 | 734,146 |
| Furniture and fixtures | 242,694 | 221,347 |
| Leasehold improvements | 143,079 | 143,079 |
| Research and development equipment | 287,964 | 254,906 |
| | 2,508,163 | 2,127,467 |
| Less accumulated depreciation | (1,712,278) | (1,209,888) |
| Net property and equipment | $ 795,885 | $ 917,579 |

## 6. Leases

The Company leases a 29,000 square-foot office and manufacturing facility under an operating lease agreement, which expires in March 2003. The Company gave written notice to the lessor in September 2002 of its intentions to terminate the lease effective March 31, 2003. The Company signed a new lease in September 2002 to lease a 33,000 square-foot office and manufacturing facility under an operating lease agreement, which expires in September 2008. Rent expense related to the operating leases was approximately $303,100, $306,600, and $242,100 for the years ended December 31, 2002, 2001, and 2000, respectively.

Future minimum lease commitments under these operating leases as of December 31, 2002 are as follows:

| | |
|---|---|
| 2003 | $ 256,359 |
| 2004 | 342,225 |
| 2005 | 342,225 |
| 2006 | 356,497 |
| 2007 | 363,634 |
| 2008 | 272,725 |
| | $1,933,665 |

## 7. Income Taxes

At December 31, 2002, the Company had net operating loss carryforwards of approximately $46,100,000 for federal income tax purposes that are available to offset future taxable income and begin to expire in the year 2013. At December 31, 2002, the Company also had federal and Minnesota research and development tax credit carryforwards of approximately $1,206,000 which begin to expire in the year 2013. No benefit has been recorded for such 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.

The components of the Company's deferred tax assets and liabilities as of December 31, 2002 and 2001 are as follows:

| | 2002 | 2001 |
|---|---|---|
| Deferred tax assets: | | |
| Net operating loss carryforwards | $18,452,000 | $12,852,000 |
| Tax credit carryforwards | 1,206,000 | 1,317,000 |
| Depreciation and amortization | 129,000 | 156,000 |
| Accrued compensation | 88,000 | 245,000 |
| Other allowances | 94,000 | 44,000 |
| Inventory reserve | 104,000 | 34,000 |
| | 20,073,000 | 14,648,000 |
| Less valuation allowances | (20,073,000) | (14,648,000) |
| Net deferred taxes | $ – | $ – |

**7. Income Taxes (continued)**

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

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Tax at statutory rate | 34.0% | 34.0% | 34.0% |
| State income taxes | 6.0 | 6.0 | 6.0 |
| Impact of net operating loss carryforward | (40.0) | (40.0) | (40.0) |
| Effective income tax rate | –% | –% | –% |

**8. Initial Public Offering**

On July 25, 2000, the Company completed the initial public offering of its common stock. Upon the closing of the initial public offering, the Company issued 3,500,000 shares of its common stock at an offering price of $12.00 per share, and all of the Company's Series A and Series B preferred stock automatically converted into 3,777,777 shares of common stock. On August 15, 2000, the underwriters exercised in full their overallotment option to purchase an additional 525,000 shares of common stock at $12.00 per share. Cash proceeds from the sale of the 4,025,000 shares of common stock, net of underwriters' discount and offering expenses, totaled approximately $44 million. Upon closing of the Company's initial public offering, the authorized capital stock of the Company consisted of 40,000,000 shares of common stock, par value $0.01 per share, with no shares of preferred stock outstanding or designated.

**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, 2002, the Company reserved 2,400,000 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

9. Stock Options and Warrants (continued)

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.

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 will grant under the plan. The new options will be granted on or about February 18, 2003, which is six months and two business days after the date the options were exchanged. New options granted under the Stock Option Plan will have an exercise price determined by the market price of the Company's stock on the date the new options are granted. The number of shares to be granted to each participating option holder will be equal to the number of shares subject to the eligible options tendered by such option holder. A stock option holder must continue 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 shares, 467,070 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, 1999 | 374,729 | 933,611 | $1.50–$ 6.00 | $ 4.00 |
| Granted | (290,250) | 290,250 | 6.00– 16.50 | 11.12 |
| Exercised | – | (62,940) | 1.50– 5.00 | 2.71 |
| Canceled | 90,150 | (90,150) | 1.50– 16.50 | 4.89 |
| Balance at December 31, 2000 | 174,629 | 1,070,771 | 1.50– 16.50 | 5.85 |
| Shares reserved | 500,000 | – | – | – |
| Granted | (972,000) | 972,000 | 2.51– 7.48 | 5.35 |
| Exercised | – | (120,800) | 1.50– 7.00 | 2.53 |
| Canceled | 347,160 | (347,160) | 1.50– 16.50 | 7.41 |
| Balance at December 31, 2001 | 49,789 | 1,574,811 | 1.50– 16.50 | 5.45 |
| Shares reserved | 500,000 | – | – | – |
| Granted | (186,000) | 186,000 | 0.81– 2.70 | 1.83 |
| Exercised | – | (10,000) | 2.00 | 2.00 |
| Canceled | 849,890 | (849,890) | 1.45– 16.50 | 6.25 |
| Balance at December 31, 2002 | 1,213,679 | 900,921 | | |

**9. Stock Options and Warrants (continued)**

The following table summarizes information about stock options outstanding at December 31, 2002:

| | Options Outstanding | | | Options Exercisable | |
|---|---|---|---|---|---|
| Range of Exercise Prices | Outstanding as of December 31, 2002 | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Exercisable as of December 31, 2002 | Weighted Average Exercise Price |
| $ 0.81–$ 1.50 | 187,711 | 6.8 | $ 1.31 | 121,811 | $ 1.38 |
| 1.51– 3.25 | 340,070 | 8.1 | 2.55 | 163,955 | 2.58 |
| 3.26– 6.00 | 229,000 | 6.9 | 6.00 | 174,320 | 6.00 |
| 6.01– 7.00 | 51,440 | 4.6 | 6.69 | 48,030 | 6.71 |
| 7.01– 10.00 | 90,620 | 8.0 | 7.61 | 54,300 | 7.72 |
| 10.01– 12.00 | 1,000 | 7.3 | 12.00 | 640 | 12.00 |
| 12.01– 16.50 | 1,080 | 0.2 | 16.50 | 1,080 | 16.50 |
| | 900,921 | 7.3 | 3.94 | 564,136 | 4.26 |

For the year ended December 31, 2001, the Company recorded compensation expense of $10,398 in connection with nonqualified stock options granted to outside consultants.

*Deferred Compensation*

In 2002, 2001, and 2000, the Company recorded a total of $160,388 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 $3.21. 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 $74,668, $62,850, and $72,561 for the years ended December 31, 2002, 2001, and 2000, respectively.

*Warrants*

As of December 31, 2002, the Company had 268,000 warrants outstanding and exercisable at a weighted average exercise price of $3.19 per share.

## 10. Employee Stock Purchase Plan

The Company has an Employee Stock Purchase Plan (the Purchase Plan) under which 700,000 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 2002, 2001, and 2000, 152,737 shares, 90,194 shares, and zero shares, respectively, were issued under the Purchase Plan. At December 31, 2002, 457,069 shares were available for issuance under the Purchase Plan.

## 11. Stock Repurchase Program

In August 2002, the Board of Directors authorized a stock repurchase program to acquire up to 1,000,000 shares of outstanding common stock in the open market, block purchases, or private transactions. During fiscal 2002, the Company repurchased and retired 608,900 shares of the Company's common stock for an aggregate purchase price of $547,722. The remaining authorized amount for stock repurchase is 391,100 shares.

## 12. 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 $91,170, $112,084, and $52,357 for contributions to the Plan for the years ended December 31, 2002, 2001, and 2000, respectively.

## 13. 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, 2002 and 2001. Three customers made up 22.4% of net sales for the year ended December 31, 2000.

The Company performs ongoing credit evaluations of its customers but does not require collateral. 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:

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Domestic | 89% | 90% | 67% |
| Foreign | 11 | 10 | 33 |

## 14. Dependence on Key Suppliers

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.

## 15. Commitments and Contingencies

Datascope

In July 1999, the Company was named as a defendant in a patent infringement lawsuit brought by Datascope Corporation (Datascope), a competitor, in the United States District Court of the District of Minnesota. The complaint requested a judgment that the Company's device infringes and, following FDA approval, will infringe, a United States patent held by Datascope and asks for relief in the form of an injunction that would prevent the Company from selling its product in the United States as well as an award of attorney's fees, costs, and disbursements. On August 12, 1999, the Company filed its answer to this lawsuit and brought a counterclaim alleging unfair competition and tortious interference against Datascope. On August 20, 1999, the Company moved for summary judgment to dismiss Datascope's claims. On March 15, 2000, the court granted summary judgment dismissing all of Datascope's claims, subject to the right of Datascope to recommence the litigation after the Company's receipt of FDA approval of the Duett sealing device. On July 12, 2000, after the Company received FDA approval, Datascope recommenced this litigation, alleging that the Duett sealing device infringes a

15. Commitments and Contingencies (continued)

United States patent held by Datascope and requesting relief in the form of an injunction that would prevent the Company from selling its product in the United States, damages caused by the alleged infringement, and other costs, disbursements, and attorneys' fees.

On November 26, 2002, the Company entered into an agreement that settled all existing intellectual property litigation with Datascope Corporation. Under the terms of the settlement agreement, Datascope has granted the Company a nonexclusive license to its Janzen patents as they apply to all current versions of the Duett sealing device, and to certain permitted future product improvements. Datascope also has released the Company from any claim of patent infringement based on past or future sales of the Duett sealing device. In exchange, the Company paid Datascope a single lump sum of $3,750,000 in the fourth quarter.

St. Jude

On July 3, 2000, the Company was named as the defendant in a patent infringement lawsuit brought by the Daig division of St. Jude Medical, Inc. (St. Jude Medical), a competitor, in the United States District Court of the District of Minnesota. The complaint requests a judgment that the Company's Duett sealing device infringes a series of four patents held by St. Jude Medical and asks for relief in the form of an injunction that would prevent the Company from selling its product in the United States, damages caused by the manufacture and sale of the Company's product, and other costs, disbursements, and attorneys' fees.

On July 12, 2001, the Company entered into an agreement that settled all existing intellectual property litigation with St. Jude Medical, Inc. Under the terms of the settlement agreement, the Company agreed to pay a royalty of 2.5% of net sales of the Company's Duett sealing device to St. Jude Medical, up to a maximum amount over the remaining life of the St. Jude Medical Fowler patents. In exchange, St. Jude Medical granted to the Company a nonexclusive license to its Fowler patents and has released it from any claim of patent infringement based on sales of the Duett sealing device. The Company granted a nonexclusive cross-license to its Gershony patents to St. Jude Medical, subject to a similar royalty payment if St. Jude Medical utilizes the Gershony patents in any future device. Beginning on July 1, 2001, a royalty expense of 2.5% of net sales is included in the Company's cost of goods sold until the maximum royalty is attained.

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

| 2002 | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
|---|---|---|---|---|
| Net sales | $2,803 | $3,329 | $3,041 | $2,928 |
| Gross profit | 1,597 | 2,002 | 1,817 | 1,699 |
| Operating loss | (3,689) | (2,871) | (2,777) | (6,149) |
| Net loss | (3,551) | (2,743) | (2,634) | (6,051) |
| Basic and diluted net loss per share | $(0.27) | $(0.20) | $(0.20) | $(0.46) |
| **2001** | | | | |
| Net sales | $3,123 | $3,540 | $2,529 | $2,890 |
| Gross profit | 1,906 | 2,154 | 1,444 | 1,617 |
| Operating loss | (2,988) | (3,263) | (3,891) | (3,769) |
| Net loss | (2,345) | (2,824) | (3,521) | (3,560) |
| Basic and diluted net loss per share | $(0.18) | $(0.21) | $(0.27) | $(0.27) |

The results of the fourth quarter of 2002 include a $3,750,000 settlement of litigation which the Company expensed in that period. (See Note 15.)

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# CORPORATE INFORMATION

## Directors

**James Jacoby, Jr.**
Managing Director, Stephens Inc.

**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 and Chief Medical Officer,
Health Care Value Systems, Inc.

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

## Officers

**Howard Root**
Chief Executive Officer

**Michael Nagel**
Vice President, Sales & Marketing and Secretary

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

**James Quackenbush**
Vice President, Manufacturing

**James Hennen**
Director of Finance and Treasurer

## Investor Relations

James Hennen
Director of Finance
Telephone: 763-656-4300
E-mail: jhennen@vascularsolutions.com

## Transfer Agent and Registrar

Wells Fargo Bank, N.A.
Shareowner Services
161 North Concord Exchange Street
South Saint Paul, Minnesota 55075
Telephone: 651-450-4064

## Independent Auditors

Ernst & Young 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 15, 2003, 3:30 p.m. at:

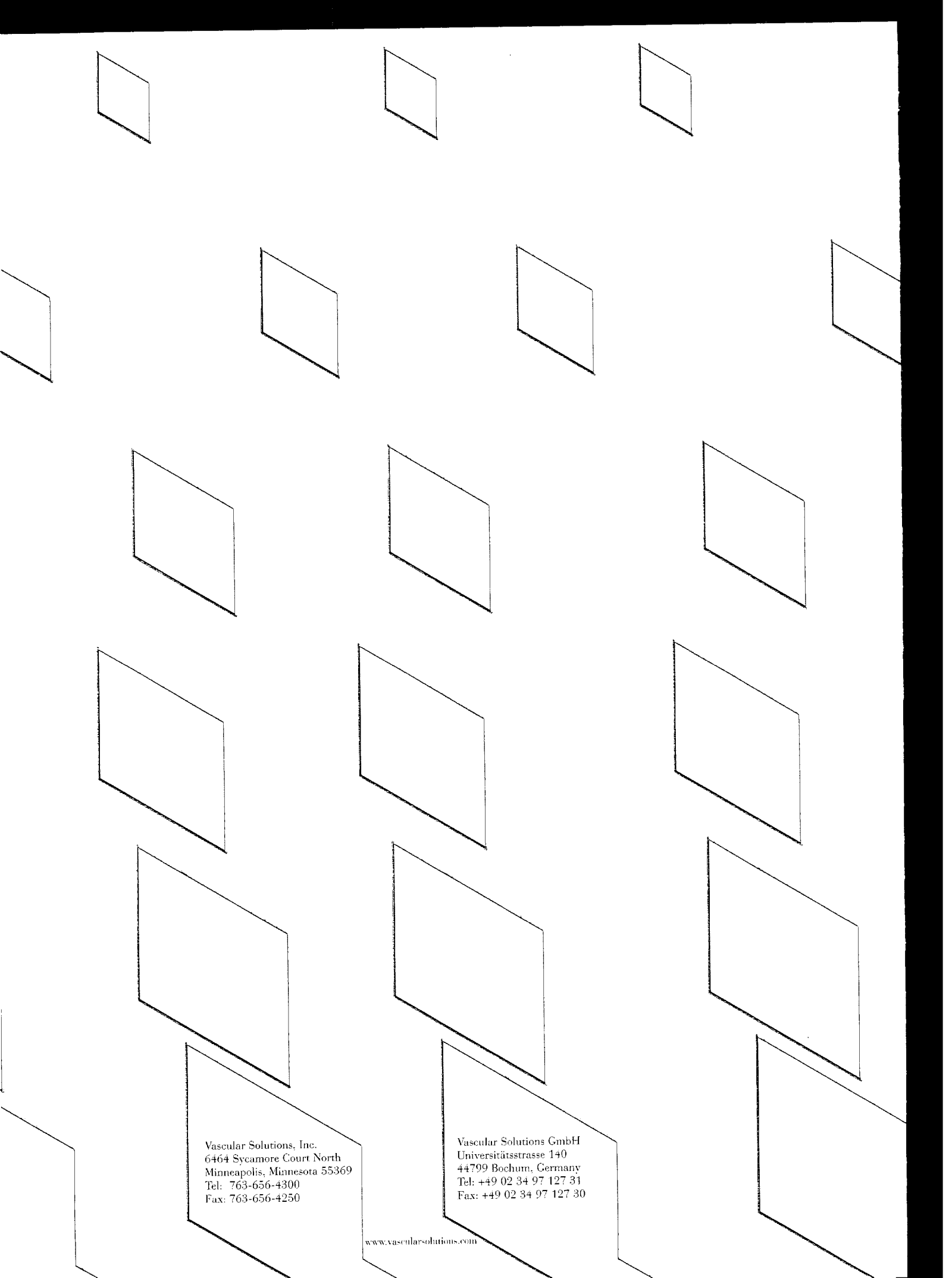
Minneapolis Club
729 Second Avenue South
Minneapolis, Minnesota 55402

## Additional Information

A copy of Vascular Solution's 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.

## Stock Exchange Listing

NASDAQ National Market System
Symbol: VASC



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