ANGIODYNAMICS INC
Form 10-K
August 14, 2007
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended June 2, 2007

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 0-50761

AngioDynamics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**11-3146460**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
603 Queensbury Ave., Queensbury, New York	**12804**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code (518) 798-1215

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

Title of each class	**Name of each exchange on which registered**
Common stock, par value $.01	**The NASDAQ Stock Market LLC**
Preferred Stock Purchase Rights	**The NASDAQ Stock Market LLC**

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

None

(Title of Class)

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

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

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. ¨

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

Large accelerated filer ¨ Accelerated filer x Non-accelerated filer ¨
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

As of December 2, 2006, the last business day of the registrant s most recently completed second fiscal quarter, the aggregate market value of the registrant s common stock held by non-affiliates was $285,492,000, computed by reference to the last sale price of the common stock on that date as reported by The Nasdaq National Market.

As of July 31, 2007, there were 23,963,866 shares of the registrant s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant s 2007 Annual Meeting of Stockholders to be held October 22, 2007 are incorporated by reference in Part III of this Form 10-K Report.

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AngioDynamics, Inc. and Subsidiaries

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Part I

Item 1. ***Business***

(a) ***General Development of Business***

Overview

We are a provider of innovative medical devices used in minimally invasive, image-guided procedures to treat peripheral vascular disease, or PVD, and local oncology therapy options for treating cancer, including radiofrequency ablation, or RFA, and systems and embolization products for treating cancerous tumors. We design, develop, manufacture and market a broad line of therapeutic and diagnostic devices that enable interventional physicians (interventional radiologists, vascular surgeons, surgical oncologists and others) to treat PVD, tumors, and other non-coronary diseases. Unlike several of our competitors that focus on the treatment of coronary diseases, we believe that we are the only company whose primary focus is to offer a comprehensive product line for the interventional treatment of these diseases.

We have been in business since 1988. Our corporate headquarters is located at 603 Queensbury Avenue, Queensbury, New York 12804. Our phone number is (518) 798-1215 and our website address is www.angiodynamics.com. (1)

Available Information

We file annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, amendments to those reports and other information with the Securities and Exchange Commission (the SEC). The public can obtain copies of these materials by visiting the SEC s Public Reference Room at 100 F Street, NE, Washington, DC 20549, by calling the SEC at 1-800-SEC-0330 or by accessing the SEC s website at www.sec.gov. In addition, as soon as reasonably practicable after such materials are filed with or furnished to the SEC, we make copies available to the public free of charge on or through our website.

History

AngioDynamics was founded in 1988 as a division of E-Z-EM, Inc., a leading developer and manufacturer of gastrointestinal contrast agents and related imaging accessories. In 1992, AngioDynamics was organized in the State of Delaware as a wholly owned subsidiary of E-Z-EM under the name A.D., Inc. In 1996, E-Z-EM transferred the business of its A.D. division to this subsidiary and we changed our name to AngioDynamics, Inc. In June 2004, we completed the initial public offering of our shares of common stock. The offering consisted of 2,242,500 shares (including 292,500 shares issued pursuant to the underwriters over-allotment option) at an initial public offering price of $11.00 per share. As a result of the offering, E-Z-EM, Inc. held 80.4% of our shares. On October 30, 2004, E-Z-EM distributed all of its shares of AngioDynamics common stock to its stockholders. In May 2006, we completed a follow-on public offering of our shares of common stock. The offering consisted of 2,760,000 shares (including 360,000 shares issued pursuant to the underwriters over-allotment option) at a public offering price of $24.07 per share.

Recent Developments

On January 29, 2007, we completed the acquisition of RITA Medical Systems, Inc. (RITA) for a total purchase price of approximately $244 million, comprised of approximately 7.9 million shares of our common stock, the assumption of outstanding RITA options and other convertible securities, which are exercisable for an

(1) This website address is not intended to function as a hyperlink, and information on our website is not part of this Annual Report on Form 10-K.

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additional 1.9 million shares of our common stock, and approximately $24 million in cash. We acquired RITA for its market position, premium product offerings, developed and emerging technologies in the fields of interventional oncology and vascular access, its intellectual property and its highly skilled workforce.

On October 12, 2006, we entered into a Stock Purchase Agreement (the Purchase Agreement) with Oncobionic, Inc. (Oncobionic) and the shareholders of Oncobionic to acquire all of the issued and outstanding shares of the capital stock of Oncobionic for $25 million, subject to Oncobionic s successful performance and completion of human use tests confirming the acute efficacy of irreversible electroporation in ablating prostate cancer.

(b) ***Narrative Description of Business***

General

We classify our products into two product groups Interventional Products, which consist primarily of angiographic products and accessories, dialysis products, vascular access products, venous products, thrombolytic products, PTA products, and drainage products and Oncology Products, which consist primarily of radio-frequency ablation products, tumor embolization products, and laparoscopic resection products.

Our principal competitive advantages are our dedicated market focus, established brands and innovative products. We believe we are the only company whose primary focus is to offer a comprehensive product line for the treatment of PVD and other non-coronary diseases. Our acquisition of RITA clarifies our position as the only company focused on minimally-invasive treatments for cancer patients. We believe our dedicated focus enhances patient care and engenders loyalty among our customers. As a provider of interventional devices for almost two decades, we believe we have established AngioDynamics brands as premium performance products. We collaborate frequently with leading interventional physicians in developing our products and rely on these relationships to further support our brands. Our chief executive officer is the only business executive from the medical device industry to serve on the Strategic Planning Committee of the Society of Interventional Radiology. This appointment provides us with awareness of emerging clinical trends, high visibility among interventional physicians and opportunities to understand and influence the evolution of interventional therapies.

We sell our broad line of quality devices for minimally invasive therapies in the United States through a direct sales force and outside the U.S. through a combination of direct sales and distributor relationships. As of July 31, 2007, our sales organization numbered 102 in the U.S. and 15 outside the U.S. The 117 employees in the sales organization include direct sales representatives, clinical specialists, and management personnel. For fiscal years 2007, 2006, and 2005, 6.3%, 4.2%, and 5.0%, of our net sales were in non-U.S. markets. Sales to any one country outside the United States did not comprise a material portion of our net sales in any of the last three fiscal years. We support our customers and sales organization with a marketing staff that includes product managers and customer service representatives, and other marketing specialists. Our dedicated sales force and growing portfolio of products have contributed to our strong sales growth.

Peripheral Vascular Disease

Peripheral vascular disease encompasses a number of conditions in which the arteries or veins that carry blood to or from the legs, arms or non-cardiac organs become narrowed, obstructed or stretched. Structural deterioration in the blood vessels due to aging and the accumulation of atherosclerotic plaque results in restricted or diminished blood flow. Common symptoms include numbness, tingling, persistent pain or cramps

in the extremities and deterioration of organ function, such as renal failure or intestinal malabsorption. Common PVDs also include venous insufficiency, a malfunction of one or more valves in the leg veins, which often leads to painful varicose veins and/or potentially life-threatening blood clots, and abdominal aortic aneurysms, or AAA, a ballooning, or stretching, of the aorta, which can lead to a potentially fatal rupture. Individuals who are over age 50, smoke, are overweight, have lipid (i.e., cholesterol) disorders, are diabetic or have high blood pressure are at the greatest risk of developing PVD.

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Peripheral Interventional Medicine

Peripheral interventional medicine involves the use of minimally invasive, image-guided procedures to treat peripheral vascular and other non-coronary diseases. In these procedures, x-rays, ultrasound, MRI and other diagnostic imaging equipment are used to guide tiny instruments, such as catheters, through blood vessels or the skin to treat diseases. Increasing use of these techniques has accompanied advances in device designs and imaging technologies that enable physicians to diagnose and treat peripheral disorders in a much less invasive manner than traditional open surgery. Interventional procedures are generally less traumatic and less expensive, as they involve less anesthesia, a smaller incision and a shorter recovery time.

Peripheral interventional procedures are performed primarily by physicians specially trained in minimally invasive, image-guided techniques. This group of interventional physicians includes interventional radiologists, vascular surgeons and others. Interventional radiologists are board certified radiologists who are fellowship trained in image-guided, percutaneous (through the skin) interventions. These physicians historically have developed many interventional procedures, including balloon angioplasty, vascular stenting and embolization, and perform the majority of peripheral interventional procedures. There are currently more than 5,000 interventional radiologists in the United States performing over four million procedures annually. Vascular surgeons have traditionally been trained for open surgical repair of arterial and venous disorders. A large number are now increasingly performing interventional procedures, and accredited vascular surgery training programs now generally require instruction in interventional, image-guided peripheral vascular procedures. Increasingly, interventional radiologists and vascular surgeons are forming joint practices to capture additional patient referrals by providing a broader range of interventional treatments. Other physicians who perform peripheral interventional procedures include interventional cardiologists and interventional nephrologists.

Interventional and Surgical Oncology

Interventional oncology is an emerging specialty in which minimally invasive techniques and technologies are used to diagnose and treat cancers throughout the body. Percutaneous biopsy, chemoembolization, tumor ablation, PICC and port implantation, and radiofrequency ablation are just a few of the numerous procedures performed by interventional oncologists. In collaboration with other medical specialties focused on the cancer patient, the interventional oncologist brings an expertise in advanced imaging, catheter-based techniques, and minimally invasive procedures not found in other medical specialties.

Products

Our current product offerings consist of the following product categories:

	2007	
Products	**Net Sales $ (dollars in thousands)**	**% of Net Sales**
Interventional Products	$ 101,126	90.1%

Oncology Products	11,101	9.9
Total	$ 112,227	100.0%

All products discussed below have been cleared for sale in the United States by the U.S. Food and Drug Administration, or the FDA.

We have registered a number of marks with the U.S. Patent and Trademark Office, including AngioDynamics; Pulse*Spray; MORPHEUS CT; EVENMORE; ABSCESSION; TOTAL ABSCESSION; SPEEDLYSER; ANGIOFLOW; HYDROTIP; MEMORY TIP; SOS OMNI; HABIB 4X; LifeJet; Circle C; Vortex; LifeGuard; NeoStar; LifeValve; and Soft-Vu. This annual report on Form 10-K also contains trademarks of companies other than AngioDynamics.

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INTERVENTIONAL PRODUCTS

Interventional Products consist primarily of angiographic products and accessories, dialysis products, vascular access products, venous products, PTA products, thrombolytic products, and drainage products.

Angiographic Products and Accessories

Angiographic products and accessories are used during virtually every peripheral vascular interventional procedure. These products permit interventional physicians to reach targeted locations within the vascular system to deliver contrast media for visualization purposes and therapeutic agents and devices, such as stents or PTA balloons. Angiographic products consist primarily of angiographic catheters, but also include entry needles and guidewires specifically designed for peripheral interventions, and fluid management products.

We manufacture angiographic catheters that are available in over 500 tip configurations and lengths, either as standard items or made to order, and an advanced guidewire.

Soft-Vu®. Our proprietary Soft-Vu technology incorporates a soft, atraumatic tip, which is easily visualized under fluoroscopy.

ANGIOPTIC™. The *ANGIOPTIC* line is distinguished from other catheters because the entire instrument is highly visible under fluoroscopy.

Accu-Vu™. The Accu-Vu is a highly visible, accurate sizing catheter used to determine the length and diameter of a vessel for endovascular procedures. Accu-Vu provides a soft, highly radiopaque tip with a choice of platinum radiopaque marker patterns along the shaft for enhanced visibility and accuracy. Sizing catheters are used primarily in preparation for aortic aneurysm stent-grafts, percutaneous balloon angioplasty, peripherally placed vascular stents and vena cava filters.

Mariner™. The Mariner is a hydrophilic-coated angiographic catheter. It uses our patented Soft-Vu catheter technology to deliver contrast media to anatomy that is difficult to reach. The advanced hydrophilic coating technology significantly reduces catheter surface friction, providing smoother navigation through challenging vasculature with optimal handling and control.

AQUALiner®. The AQUALiner is a technologically advanced guidewire. This guidewire is used to provide access to difficult to reach locations in interventional procedures requiring a highly lubricious wire. The AQUALiner guidewire incorporates proprietary advanced coating technology that allows smooth frictionless navigation.

We offer uncoated, Teflon-coated and hydrophilic-coated guidewires to support our core angiographic catheter line. Our major competitors in the peripheral angiographic market are Boston Scientific Corporation, Cook Incorporated and Cordis Corporation, a subsidiary of Johnson & Johnson Inc.

Dialysis Products

We market a complete line of dialysis products that provide short- and long-term vascular access for dialysis patients. Dialysis, or cleaning of the blood, is necessary in conditions such as acute renal failure, chronic renal failure and end-stage renal disease, or ESRD. The kidneys remove excess water and chemical wastes from blood, permitting clean blood to return to the circulatory system. When the kidneys malfunction, waste substances cannot be excreted, creating an abnormal buildup of wastes in the bloodstream. Dialysis machines are used to treat this condition. Dialysis catheters, which connect the patient to the dialysis machine, are used at various stages in the treatment of every dialysis patient.

We currently offer a wide variety of dialysis catheters, including:

Schon™. The Schon chronic dialysis catheter is designed to be self-retaining, deliver high flow rates and provide patient comfort. The Schon is for long-term use.

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EvenMore™. The EvenMore is our first internally manufactured catheter. It is a low profile end-hole design catheter that provides very efficient dialysis. It was designed for long-term use with our proprietary Durathane shaft, which offers high resistance to chemicals used to clean the insertion site.

Dura-Flow™. The Dura-Flow chronic dialysis catheter is designed to be durable, maximize flow rates and provide for easier care and site maintenance. The Dura-Flow chronic dialysis catheter is for long-term use.

Schon XL®. The Schon XL acute dialysis catheter is designed to be kink resistant, deliver high flow rates, offer versatile positioning and provide patient comfort. Schon XL is for short-term use.

Dynamic Flow™. Our Dynamic Flow chronic dialysis catheter is designed for long-term use in dialysis patients. It features a Durathane shaft that offers higher chemical resistance than polyurethane, simplifying site care requirements. The Dynamic Flow also features a split tip design and a proximal shaft that reduces the chance of kinking after it reaches placement.

LifeJet™ F-16. The LifeJet F-16 chronic dialysis catheter features the largest lumens available. This facilitates high flow rates while keeping arterial and venous pressures low.

Circle C®. The *Circle C* design provides the industry with smaller diameter catheters engineered to deliver efficient flow rate with minimal invasiveness for dialysis of apheresis.

We purchase from Medcomp and resell under our name our Schon, Schon XL, and Dura-Flow dialysis catheters under an exclusive worldwide license. We also purchase our Dynamic Flow catheters under a non-exclusive license from Medcomp.

Boston Scientific, C.R. Bard, Inc., Kendall Healthcare Products, a subsidiary of Tyco International Ltd., and Medcomp, are our major competitors in the development, production and marketing of dialysis catheters.

Vascular Access Products

Image-guided vascular access, or IGVA, involves the use of advanced imaging equipment to guide the placement of catheters that deliver primarily short-term drug therapies, such as chemotherapeutic agents and antibiotics, into the central venous system. Delivery to the circulatory system allows drugs to mix with a large volume of blood as compared to intravenous drug delivery into a superficial vessel. IGVA procedures include the placement of percutaneously inserted central catheter, or PICC lines, implantable ports and central venous catheters, or CVCs.

Our vascular access products include:

MORPHEUS® CT PICC. These PICC lines provide short- or long- term peripheral access to the central venous system for intravenous therapy and blood sampling. They are constructed of a biocompatible and durable material called Durathane, and have increased stiffness from the proximal end to the distal end, which provides ease of use and enhanced patient safety and comfort. These products are intended for use with CT injectors, allowing physicians to use the existing PICC for both medications and CT imaging, thus avoiding the need for an additional access site.

MORPHEUS® CT PICC Insertion Kit. In May 2006, we introduced our insertion kit, which allows our Morpheus CT PICC to be inserted at a patient s bedside instead of in the hospital radiology suite. The kit was specifically designed for interventional radiologists, nurse practitioners, physician assistants and radiology technicians who perform placement of PICC lines.

Micro Access Sets. Our micro access sets provide interventional physicians a smaller introducer system for minimally invasive procedures.

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Transjugular Access Set. Our transjugular liver access set is used to provide access in a transjugular intrahepatic portosystemic shunt (TIPS) procedure. A TIPS procedure involves placing a shunt in the liver between the hepatic and portal veins. This relieves the pressure on the portal system in an effort to resolve the bleeding complications often encountered in end-stage liver failure.

Specialty Access Ports. Specialty access ports are implantable devices utilized for the central venous administration of a variety of medical therapies and for blood sampling and diagnostic purposes. Central venous access facilitates a more systemic delivery of treatment agents, while mitigating certain of the harsh side effects of certain treatment protocols and eliminating the need for repeated access to peripheral veins. Once implanted in the body, a port can be utilized for up to approximately 2,000 accesses depending upon needle gauge size and the port size. Our specialty access ports are used primarily in systemic or regional short-and long-term cancer treatment protocols that require frequent infusions of highly concentrated or toxic medications (such as chemotherapy agents, antibiotics or analgesics) and frequent blood samplings. This product line consists of the following families of products: (i) the Vortex family of ports including Vortex VTX, LifePort VTX, Triumph™ VTX and Genesis™ VTX; (ii) LifePort; (iii) Triumph-1; (iv) Infuse-a-Port; (v) OmegaPort; (vi) TitanPort; and (vii) the Vortex MP Port system.

Our Vortex® line of ports is a clear-flow port technology that revolutionized port design. With its rounded chamber, the Vortex® is designed to have no sludge-harboring corners or dead spaces. This contrasts to conventional ports where squared reservoir design promotes sludge accumulation setting the stage for occlusions and infections. A tangential stem adds to the flow dynamics, which is designed to result in a hyper-cleaning flow process to remove blood deposits and drug residuals.

The LifeGuard Safety Infusion Set and *The LifeGuard Vision* are used to infuse our ports and complement our port and vascular access catheters. The innovative design of these products was developed with the input of clinicians to provide safer needle placements, and the needles low profile design is intended to allow clinicians to easily dress the site. We believe that the ease of use and visual confirmation of safety is ideal in the clinical setting.

Neostar®. The Neostar® Tunneled Central Venous Catheters are among the most well known and trusted names in catheters. The central venous catheters are intended for long-term vascular access, suitable for chemotherapy, infusion of intravenous fluids or drugs parental nutrition, transfusion or sampling blood products. With single, double and triple lumen configurations, one-piece Y-hubs for mirror smooth transition points and complete tray availability, the Neostar® is an excellent choice for valued patients.

LifeValve® Platinum. The LifeValve® central venous catheter incorporates the only technology that features two separate areas for aspiration and infusion for more reliable operation and fewer interventions. The patented Duckbill infusion valve is designed to reduce incidence of blood back flow resulting in improved performance. A stiffening stylet and a rounded atraumatic tip facilitate passage into the vessel while the over-the-guidewire feature is engineered to reduce procedure time and complexity.

Our competitors in this market include Arrow International, Inc., Boston Scientific, Cook, C.R. Bard, Deltec, Inc., a subsidiary of Smiths Group plc, and Medcomp.

Venous Products

Our venous products consist of our VenaCure® products and Sotradecol.

Our VenaCure products are used in endovascular laser procedures to treat superficial venous disease (varicose veins). Superficial venous disease is a malfunction of one or more valves in the leg veins. These procedures are a less invasive alternative to vein stripping for the treatment of this condition. Vein stripping is a

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lengthy, painful and traumatic surgical procedure that involves significant patient recovery time. In contrast, laser treatment is an outpatient procedure that generally allows the patient to quickly return to normal activities with no scarring and minimal post-operative pain.

With our VenaCure NeverTouch™ products, laser energy is used to stop the source of the pressure by ablating, or collapsing and destroying, the affected vein. The body subsequently routes the blood to other healthy veins. Our products are sold as a system that includes a diode laser with our NeverTouch disposable components, training and marketing materials. The diode laser is a self-contained reusable instrument. The disposable components in the system include a NeverTouch laser fiber system, an access sheath, access wires and needles. The training and marketing materials include a two-day physician training course, a comprehensive business development package and patient marketing kit.

Although our non-exclusive license to sell the biolitec laser and laser fiber components to interventional radiologists and vascular surgeons in the United States and Canada expired in April 2007, we continue to purchase the laser and laser fibers used in our Precision 810 and Precision 980 VenaCure products from biolitec, Inc. We are discussing an amended and extended agreement with biolitec, and we have identified several other vendors for the lasers and laser fibers to replace those we purchase from biolitec. biolitec sells its ELVeS 810 and ELVeS 980, which are substantially identical to the lasers in our Precision 810 and Precision 980, to customers other than interventional radiologists and vascular surgeons in the United States and Canada and distributes those products without restriction in the rest of the world.

An important part of our focus on the peripheral vascular disease market is the treatment of varicose veins. With an estimated one-half of all Americans over the age of 60 suffering from varicose veins, the market for this treatment is large and growing. We believe that Sotradecol, a sclerosing drug that was recently approved by the FDA and that we introduced in November, 2005, combined with our currently available precision drug-delivery catheter technology, such as UNI*FUSE, will become an important method of treating varicose veins. Sotradecol has been shown to be an effective treatment of small, uncomplicated varicose veins of the lower extremities, in addition to ablation of the great saphenous vein. Catheter-directed sclerotherapy has the advantages of requiring no investment in capital equipment and requires no local anesthesia because it is virtually pain free. We believe that laser-based treatment systems will continue to be an important part of the vein treatment market in the United States for some time, but that laser treatments may eventually be eclipsed by catheter-directed sclerotherapy, as has occurred in Europe. This approach to treating varicose veins has the potential for greater intellectual property protection and higher gross margins than our laser-based VenaCure products and, most importantly, can be incorporated with some of our existing patented products. In October 2005, we entered into a supply and distribution rights agreement with Bioniche Pharma Group Limited under which we were appointed the exclusive distributor to interventional radiologists and several other specialists in the United States of Sotradecol™, a sclerosing drug that was recently approved by the FDA, for the treatment of varicose veins and other vascular indications as may be approved by the FDA. In July 2006, the agreement was amended to expand our exclusive distribution rights to cover all persons in the United States, which may include hospital pharmacies, group purchasing organizations and wholesalers, as well as all physicians, for use in treating varicose veins or other approved vascular indications, subject to Bioniche Pharma s termination of any existing relationships with or commitments to all other third parties for the sale and/or distribution of Sotradecol in the United States. Sotradecol is the only FDA-approved sodium tetradecyl sulfate injection currently available in the United States.

Competition for the treatment of venous insufficiency includes surgical vein stripping treatments, radiofrequency (RF) ablation, which we believe is more expensive and time consuming than laser treatment, and other laser treatments of the greater saphenous vein. The leading provider for RF ablation is VNUS Medical Technologies Inc. Companies competing in the laser segment include biolitec, Diomed, Inc., Dornier MedTech GmbH, and Vascular Solutions, Inc.

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PTA Products

PTA (percutaneous transluminal angioplasty) procedures are used to open blocked blood vessels and dialysis access sites using a catheter that has a balloon at its tip. When the balloon is inflated, the pressure flattens the blockage against the vessel wall to improve blood flow. PTA is now the most common method for opening a blocked vessel in the heart, legs, kidneys or arms.

Our PTA dilation balloon catheters include:

WorkHorse™. Our WorkHorse product is a high-pressure balloon catheter offered in 54 configurations. While the WorkHorse can perform other peripheral PTA procedures, we believe the device is used primarily for treating obstructed dialysis access sites.

WorkHorse™ II. The WorkHorse II is a high-pressure, non-compliant PTA balloon catheter. This product is an extension to our WorkHorse PTA catheter, with enhanced WorkHorse features to improve product performance during declotting procedures for dialysis access sites.

Profiler®. The Profiler is a low profile, high-visibility balloon catheter that features a soft, radiopaque, tapered tip and a flexible, non-kinking catheter shaft with exceptional pushability. The low profile of the Profiler opens access to small vessels and tortuous anatomy and is available with multiple balloon sizes and catheter lengths.

AngioFlow® is a catheter-based flow meter that we believe is the only currently available intra-vascular device to measure blood flow in dialysis access sites during an access site clearing procedure. This capability allows interventional physicians to evaluate the efficacy of an access site clearing procedure during the procedure, thus likely improving the outcome and lessening the need for repeat procedures.

Boston Scientific, Cordis, Cook and C.R. Bard are our primary competitors in the PTA dilation market.

Thrombolytic Products

Thrombolytic catheters are used to deliver thrombolytic agents, which are drugs that dissolve blood clots in hemodialysis access grafts, arteries, veins and surgical bypass grafts. Our thrombolytic catheters include:

*Pulse*Spray® and UNI*FUSE catheters.* Our Pulse*Spray and UNI*FUSE catheters improve the delivery of thrombolytic agents by providing a controlled, forceful and uniform dispersion. Patented slits on the infusion catheter operate like tiny valves for an even distribution of thrombolytic agents. We believe that these slits reduce the amount of thrombolytic agents and the time necessary for these procedures, resulting in cost savings and improved patient safety.

SPEEDLYSER®. Our SPEEDLYSER thrombolytic catheter is used to deliver thrombolytic agents into obstructed dialysis grafts. This catheter features *Pulse*Spray* slit technology that simplifies catheter insertion and drug delivery.

Our primary competitors in this market include Cook and EV3, Inc.

Drainage Products

Drainage products percutaneously drain abscesses and other fluid pockets. An abscess is a tender inflamed mass that typically must be drained by a physician.

Our line of drainage products consists of our TOTAL ABSCESSION® general drainage catheters, which we introduced in December 2005, and ABSCESSION® general and biliary drainage catheters. These products feature our proprietary soft catheter material, which is designed for patient comfort. These catheters also recover their shape even if bent or severely deformed when patients roll over and kink the catheters during sleep. Our TOTAL

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ABSCESSION general drainage catheter features a tamper-resistant locking mechanism known as the VAULT . This locking mechanism eliminates the need to replace drainage catheters that become unlocked during routine use, thus reducing physician time and increasing patient comfort. The TOTAL ABSCESSION catheter permits aspiration while locked or unlocked, thus allowing more accurate placement and greater versatility for draining complex situations.

Our primary competitors for drainage products include Boston Scientific, Cook and C.R. Bard.

ONCOLOGY PRODUCTS

Oncology products consist of Radiofrequency Ablation products and Embolization Products.

Radiofrequency Ablation Products

Radiofrequency Ablation (RFA) products use radiofrequency energy to provide a minimally invasive approach to ablating solid cancerous or benign tumors. Our system delivers radiofrequency energy to raise the temperature of cells above 45 to 50 degrees celsius, causing cellular death.

The physician inserts the disposable needle electrode device into the target body tissue, typically under ultrasound, computed tomography or magnetic resonance imaging guidance. Once the device is inserted, pushing on the handle of the device causes a group of curved wires to be deployed from the tip of the electrode. When the power is turned on, these wires deliver radiofrequency energy throughout the tumor. In addition, temperature sensors on the tips of the wires measure tissue temperature throughout the procedure. During the procedure, our system automatically adjusts the amount of energy delivered in order to maintain the temperature necessary to ablate the targeted tissue. For a typical five centimeter ablation using our Starburst XLie disposable device, the ablation process takes approximately ten minutes. When the ablation is complete, pulling back on the handle of the device causes the curved wire array to be retracted into the device so it can be removed from the body. Our disposable device cauterizes the tissue along the needle tract, which we believe kills any residual cancer cells that might be removed from the tumor.

Benefits of the RFA System

The benefits of our system include:

Effective Treatment Option. We believe that our system provides an effective treatment option to liver cancer patients who previously had few options available to effectively address their unresectable liver tumors. Further, our system provides an effective treatment option for patients whose tumors have metastasized to the bone and cause pain that cannot be adequately relieved by other means. In the future, our system may offer patients with other types of tumors a similar treatment option.

Minimally Invasive Procedure. The RFA system offers physicians an effective minimally invasive treatment option with few side effects or complications. Our products can be used in an outpatient procedure that requires only local anesthesia, and patients are typically sent home the same day with a small bandage over the entry site. Alternatively, patients can be treated with just an overnight hospital stay either through a small wound in the skin or laparoscopically through several small incisions. Compared to existing alternatives, we believe our minimally invasive procedure is cost effective and can result in reduced hospital stays.

Proprietary Array Design and Temperature Feedback Provide Procedural Control. Our array design enables the physician to predictably ablate large volumes of targeted tissue. In addition, our temperature feedback feature allows physicians to ensure that the temperature is high enough at the electrode to achieve cell death.

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Repeat Treatments Possible. Cancer is most often a recurrent disease. However, due to the invasive nature of other treatment options, such as surgery, the majority of patients who undergo traditional therapies cannot be retreated in the event that new tumors appear or previously treated tumors reappear. Because of the minimally invasive nature of our procedure, patients treated with our RFA system can often be retreated.

Broadly Applicable Technology. Our significant clinical experience with liver tumors and bone tumors as well as feasibility studies in other organs indicates that our technology may in the future be broadly applied to the ablative treatment of solid tumors in the lung, breast, uterus, prostate and kidney.

While there are numerous benefits of our system, there are some side effects of treatment as well. Published reports on the use of the RFA system indicate low overall complication rates. These include ground-pad burns, which are burns that can occur when there is a concentration of heat at the ground-pad site, bleeding, abscesses and, in cases involving the treatment of bone tumors, fractures and nerve damage. Studies have also shown some recurrence of tumors following treatment with our system. However, in many cases where tumors recur, our procedure can often be repeated. In rare cases, unintentional physician misuse of our system has resulted in patient deaths.

Radiofrequency Ablation Product Technology

Our radiofrequency ablation products are based on proprietary technology used to ablate tissue in a controlled manner. A radiofrequency generator supplies energy through our disposable device placed within the targeted tissue. Our devices contain curved, space-filling arrays of wires which are deployed from the tip to allow the radiofrequency energy to be dispersed throughout the tumor.

Radiofrequency energy supplied by the generator produces ionic agitation, or cellular friction, in the tissue closely surrounding the electrode. This friction produces heat that can be used to predictably ablate volumes of tissue. To effectively ablate tissue, it must be heated to an approximate temperature of 45° to 50°C, or 113° to 122°F.

Our system is designed to permit the physician to set the desired treatment time and temperature at the beginning of the procedure. Once that temperature is reached, our proprietary temperature control technology automatically adjusts the energy supplied from the generator to maintain the optimal temperature within the tissue during the course of the procedure. We believe our system has the potential to provide a more effective ablation than competing technologies by providing critical tissue temperature feedback during the procedure.

Some of our products make use of saline to enhance the ablation process. This saline is used to irrigate the ablation site and is delivered through the curved array of wires in our devices. The use of saline can significantly increase the speed of the ablation treatment and permits ablation of larger tumors.

The RFA system consists of a radiofrequency generator and a family of disposable devices. We also market the HABIB 4X resection device under a distribution agreement with EMcision Limited.

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	Product Name	Description
Disposable Electrodes:	StarBurst	Creates a scalable 2 to 3 centimeter ablation.
	StarBurst XL	Creates a scalable 3 to 5 centimeter ablation.
	StarBurst SDE	Creates a 2 centimeter ablation, via a side-deployed array.
	StarBurst Semi-Flex	Creates a scalable 3 to 5 centimeter ablation and has a partially flexible shaft.
	StarBurst XLie	Creates a scalable 4 to 7 centimeter ablation. Requires an accessory infusion pump for irrigation of saline. Attached tubing standard.
	StarBurst Talon: Straight	Creates a scalable 2 to 4 centimeter ablation. Requires an accessory infusion pump for irrigation of saline.
	StarBurst Talon: Semi-Flex	Creates a scalable 2 to 4 centimeter ablation. Requires an accessory infusion pump for irrigation of saline.
Resection Device:	HABIB 4X	Surgical resection device.
Generators:	Model 1500X	250 Watt Capable Generator with Field-Software Upgradeability.

RFA Disposable Electrodes

Our RFA disposable electrodes all consist of needle shaped electrodes containing curved wire arrays that are deployed into the targeted body tissue. Each device contains several thermocouples, or temperature sensors, which provide feedback to the physician of the tissue temperature during the ablation and which allow the generator to automatically adjust the amount of radiofrequency energy so that the desired tissue temperature can be achieved.

Our RFA disposable electrodes are available in different array sizes to allow the physician to create a spherical ablation volume of anywhere from two to seven centimeters. Three centimeters is slightly smaller than a ping-pong ball. Seven centimeters is approximately the size of a tennis ball. In addition, depending on product line, the devices are available in 10, 12, 15 or 25 centimeter lengths to allow physicians to access tumors that are located more or less deeply within the body. Each RFA disposable device is supplied with one or more ground pads to allow a return path for the flow of radiofrequency energy from the patient back to the generator.

RF Resection Device

We have an exclusive worldwide license with EMcision Limited to sell the HABIB 4X bipolar radiofrequency resection device. This product is designed to coagulate a surgical resection plane to facilitate a fast dissection with limited blood loss. It is compatible with our Model 1500 and Model 1500X radiofrequency generators.

RFA Generators

All of our generators employ an internal computer to assist the physician in safely and effectively controlling the delivery of radiofrequency during ablation or surgical resection procedures. In addition, each

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generator has a display to convey information to the physician while using the system. Our Model 1500X generators have the ability, using a laptop computer, to display real-time, color-coded graphs of items such as power, and temperature and impedance to aid the user in controlling the system and to collect procedural information for the patient s record. These generators are designed to have their software changed in the field through the insertion of a small card containing electronic memory circuits.

Embolization Products

LC Beads are compressible, visibly-tinted N-fil Hydrogel microspheres supplied in convenient pre-prepared single vials. Embolic material is injected into selected vessels to block the blood flow feeding the tumor or malformation, causing it to shrink over time.

Features

PROVEN MATERIAL A sulfonate modified N-fil Hydrogel microsphere.

ENHANCED VISUAL VERIFICATION Tinted beads for immediate enhanced visualization prior to delivery.

OPTIMAL SIZES Industry standard size ranges for ease in selectivity of bead sizes and a wide array of calibrated bead sizes designed to ensure precise match to targeted vessels.

CONVENIENT CONFIGURATION Provided in a pre-prepared vial of embolic/saline solution; designed to minimize preparation time. Sold in single vials to allow user the option of choosing an exact desired quantity.

Research & Development

Our future success will depend in part on our ability to continue to develop new products and enhance existing products. We recognize the importance of, and intend to continue to make investments in, research and development. Approximately 60% of our net sales for fiscal 2007 were from products we introduced in the last five fiscal years. For fiscal 2007, 2006, and 2005, our research and development (R&D) expenditures were $20.6 million, $5.9 million, and $4.6 million, respectively, and constituted 18.3%, 7.5%, and 7.6%, respectively, of net sales. A significant portion of our R&D expenses in 2007 related to a non-cash charge of $12.1 million for in-process R&D required under purchase accounting rules from our acquisition of RITA. Without this charge, our R&D expenses were approximately 7.5% of net sales. R&D activities include research, product development, and regulatory affairs. We expect that our R&D expenditures will reach approximately 8 to 9% of net sales in fiscal 2008 and remain at that level thereafter. However, downturns in our business could cause us to reduce our R&D spending.

Our research and product development teams work closely with our sales force to incorporate customer feedback into our development and design process. We believe that we have a reputation among interventional physicians as a good partner for product development because of our

tradition of close physician collaboration, dedicated market focus, responsiveness and execution capabilities for product development and commercialization.

Competition

We encounter significant competition across our product lines and in each market in which our products are sold. These markets are characterized by rapid change resulting from technological advances and scientific discoveries. We face competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. In addition, we compete with providers of other medical therapies, such as pharmaceutical companies, that may offer non-surgical therapies for conditions that are

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currently or in the future may be treated using our products. Our primary device competitors include: Boston Scientific, Cook, Cordis, C.R. Bard, Diomed, Medcomp, Radionics, a division of Tyco Healthcare, which is a division of Tyco International; and VNUS Medical. Medcomp supplies us with most of our dialysis catheters, but also competes with us by selling Dynamic Flow catheters, which we buy from them on a non-exclusive basis, and other dialysis catheters that we do not license from them. Many of our competitors have substantially greater financial, technological, research and development, regulatory, marketing, sales and personnel resources than we do. Competitors may also have greater experience in developing products, obtaining regulatory approvals, and manufacturing and marketing such products. Competitors may also obtain patent protection or regulatory approval or clearance, or achieve product commercialization, before us, any of which could materially adversely affect us.

We believe that our products compete primarily on the basis of their quality, ease of use, reliability, physician familiarity and cost-effectiveness. Generally, our products are sold at higher prices than those of our competitors. In the current environment of managed care, which is characterized by economically motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we have been increasingly required to compete on the basis of price. We believe that our continued competitive success will depend upon our ability to develop or acquire scientifically advanced technology, apply our technology cost-effectively across product lines and markets, develop or acquire proprietary products, attract and retain skilled development personnel, obtain patent or other protection for our products, obtain required regulatory and reimbursement approvals, manufacture and successfully market our products either directly or through outside parties, and maintain sufficient inventory to meet customer demand.

Sales and Marketing

We focus our sales and marketing efforts on interventional radiologists, vascular surgeons, and interventional and surgical oncologists. There are over 5,000 interventional radiologists, 2,000 vascular surgeons, and 2,000 interventional and surgical oncologists in the United States. We seek to educate these physicians on the clinical efficacy, performance, ease of use, value and other advantages of our products.

We also involve ourselves in assisting interventional physicians with clinical practice building for outpatient interventional procedures. This can include outpatient practices in uterine fibroid embolization (UFE), vein, dialysis access management, tumor ablation, pain management, and broad based interventional procedures.

We promote our products through medical society meetings that are attended by interventional radiologists, vascular surgeons, interventional cardiologists, interventional nephrologists, interventional oncologists, and others. Our attendance at these meetings is one of our most important methods of communicating with our customers. At these meetings, we receive direct feedback from customers and present new ideas and products. Our attendance at these meetings also reflects our support and commitment to the medical societies, as these societies rely on industry participation and support in order to effectively hold these meetings. The support we provide includes sponsorship of medical society research foundations, general financial support for holding these meetings, and special awards to physicians and others.

Backlog

At July 31, 2007, we had a backlog of unfilled customer orders of $275,000, compared to a backlog of $70,000 at July 31, 2006. We expect the entire backlog at July 31, 2007 will be filled during fiscal 2008. Because, historically, we ship 95% of products sold in the United States within 48 hours of receipt of the orders, we do not consider our backlog to be indicative of our future operating results.

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Manufacturing

We own a manufacturing, administrative, engineering and warehouse facility of approximately 104,000 square feet in Queensbury, New York. We also lease a manufacturing facility of approximately 60,000 square feet located in Manchester, Georgia. We believe these facilities have sufficient capacity to meet our anticipated manufacturing needs for the next five years.

We manufacture certain proprietary components and products and assemble, inspect, test and package our finished products. By designing and manufacturing many of our products from raw materials, and assembling and testing our subassemblies and products, we believe that we can maintain better quality control, ensure compliance with applicable regulatory standards and our internal specifications, and limit outside access to our proprietary technology. We have custom-designed proprietary manufacturing and processing equipment and have developed proprietary enhancements for existing production machinery.

Our management information system includes order entry, invoicing, on-line inventory management, lot traceability, purchasing, shop floor control and shipping and distribution analysis, as well as various accounting-oriented functions. This system enables us to track our products from the inception of an order through all parts of the manufacturing process until the product is delivered to the customer. Our management information system enables us to ship 95% of products sold in the United States within 48 hours of when an order is received.

We purchase components from third parties. Most of our components are readily available from several supply sources. We also purchase finished products from third parties. One supplier, Medcomp, currently supplies most of our dialysis catheters. Medcomp products accounted for approximately 17% of our net sales for fiscal 2007. Another supplier, biolitec, Inc., supplies us with the laser and laser fibers which are the principal components of our VenaCure products. Sales of our VenaCure products accounted for approximately 11% of our net sales for fiscal 2007. To date, we have been able to obtain adequate supplies of all product and components in a timely manner from existing sources.

In fiscal 2007, 70% of our net sales were derived from products we manufactured or assembled ourselves, with the balance being derived from products manufactured for us by third parties. Our Queensbury and Manchester facilities are registered with the FDA and have been certified to ISO 13485 standards, as well as the CMD/CAS Canadian Medical Device Regulations. ISO 13485 is a quality system standard that satisfies European Union regulatory requirements, thus allowing us to market and sell our products in European Union countries. If we were to lose this certification, we would no longer be able to sell our products in these countries until we made the necessary corrections to our operations or satisfactorily completed an alternate European Union approval route that did not rely on compliance with quality system standards. Our manufacturing facilities are subject to periodic inspections by regulatory authorities to ensure compliance with domestic and non-U.S. regulatory requirements. See Government Regulation.

Intellectual Property

As of July 31, 2007, we owned 111 U.S. patents and had exclusive licenses to 24 U.S. patents. Additionally, we either owned or had exclusive rights to 55 pending U.S. patent applications. Internationally, we owned 68 patents, had exclusive licenses to 4 patents, and either owned or had exclusive rights to 73 pending patent applications, all of which are foreign counterparts of the U.S. cases.

We believe that our success is dependent, to a large extent, on patent protection and the proprietary nature of our technology. We intend to continue to file and prosecute patent applications for our technology in jurisdictions where we believe that patent protection is effective and

advisable, generally in the United States and other appropriate jurisdictions.

Notwithstanding the foregoing, the patent positions of medical device companies, including our company, are uncertain and involve complex and evolving legal and factual questions. The coverage sought in a patent

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application can be denied or significantly reduced either before or after the patent is issued. Consequently, there can be no assurance that any of our pending patent applications will result in an issued patent. There is also no assurance that any existing or future patent will provide significant protection or commercial advantage, or whether any existing or future patent will be circumvented by a more basic patent, thus requiring us to obtain a license to produce and sell the product. Generally, patent applications can be maintained in secrecy for at least 18 months after their earliest priority date. In addition, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent the subject matter covered by each of our pending U.S. patent applications or that we were the first to file non-U.S. patent applications for such subject matter.

If a third party files a patent application relating to an invention claimed in our patent application, we may be required to participate in an interference proceeding declared by the U.S. Patent and Trademark Office to determine who owns the patent. Such proceeding could involve substantial uncertainties and cost, even if the eventual outcome is favorable to us. There can be no assurance that our patents, if issued, would be upheld as valid in court.

Third parties may claim that our products infringe on their patents and other intellectual property rights. Some companies in the medical device industry have used intellectual property infringement litigation to gain a competitive advantage. If a competitor were to challenge our patents, licenses or other intellectual property rights, or assert that our products infringe its patent or other intellectual property rights, we could incur substantial litigation costs, be forced to make expensive changes to our product designs, license rights in order to continue manufacturing and selling our products, or pay substantial damages. Third-party infringement claims, regardless of their outcome, would not only consume our financial resources but also divert our management s time and effort. Such claims could also cause our customers or potential customers to defer or limit their purchase or use of the affected products until resolution of the claim.

In January 2004, Diomed filed an action against us alleging that our VenaCure products for the treatment of varicose veins infringe on a patent held by Diomed. In March 2007, the jury ruled in Diomed s favor and awarded compensatory damages of $9.71 million. We have disputed the infringement verdict on multiple grounds and on June 20, 2007, filed an appeal in the U.S. Court of Appeals for the Federal Circuit in Washington, D.C. In October 2005, VNUS filed a patent infringement action against us and other companies seeking similar relief. If VNUS is ultimately successful in its action, our results of operations could be negatively affected. See Item 3 of this report for additional details.

We rely on trade secret protection for certain unpatented aspects of our proprietary technology. There can be no assurance that others will not independently develop or otherwise acquire substantially equivalent proprietary information or techniques, that others will not gain access to our proprietary technology or disclose such technology, or that we can meaningfully protect our trade secrets. We have a policy of requiring key employees and consultants to execute confidentiality agreements upon the commencement of an employment or consulting relationship with us. Our confidentiality agreements also require our employees to assign to us all rights to any inventions made or conceived during their employment with us. We also generally require our consultants to assign to us any inventions made during the course of their engagement by us. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for us in the event of unauthorized use, transfer or disclosure of confidential information or inventions.

The laws of foreign countries generally do not protect our proprietary rights to the same extent, as do the laws of the United States. In addition, we may experience more difficulty enforcing our proprietary rights in certain foreign jurisdictions.

Government Regulation

The products we manufacture and market are subject to regulation by the FDA under the Federal Food, Drug, and Cosmetic Act, or FDCA, and, in some instances, state authorities and foreign governments.

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United States FDA Regulation

Before a new medical device can be introduced into the market, a manufacturer generally must obtain marketing clearance or approval from the FDA through either a 510(k) submission (a premarket notification) or a premarket approval application, or PMA.

The 510(k) procedure is less rigorous than the PMA procedure, but is available only in particular circumstances. The 510(k) clearance procedure is available only if a manufacturer can establish that its device is substantially equivalent in intended use and in safety and effectiveness to a predicate device, which is a legally marketed device with 510(k) clearance in class I or II or grandfather status based upon commercial distribution on or before May 28, 1976. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The 510(k) clearance procedure generally takes from four to 12 months from the time of submission, but may take longer. In some cases, supporting clinical data may be required. The FDA may determine that a new or modified device is not substantially equivalent to a predicate device or may require that additional information, including clinical data, be submitted before a determination is made, either of which could significantly delay the introduction of new or modified device products. If a product does not satisfy the criteria of substantial equivalence, it is placed in class III and premarket approval is required prior to the introduction of that product into the market.

The PMA application procedure is more comprehensive than the 510(k) procedure and typically takes several years to complete. The PMA application must be supported by scientific evidence providing pre-clinical and clinical data relating to the safety and efficacy of the device and must include other information about the device and its components, design, manufacturing and labeling. The FDA will approve a PMA application only if a reasonable assurance that the device is safe and effective for its intended use can be provided. As part of the PMA application review, the FDA will inspect the manufacturer s facilities for compliance with its Quality System Regulation, or QSR. As part of the PMA approval the FDA may place restrictions on the device, such as requiring additional patient follow-up for an indefinite period of time. If the FDA s evaluation of the PMA application or the manufacturing facility is not favorable, the FDA may deny approval of the PMA application or issue a not approvable letter. The FDA may also require additional clinical trials, which can delay the PMA approval process by several years. After the PMA is approved, if significant changes are made to a device, its manufacturing or labeling, a PMA supplement containing additional information must be filed for prior FDA approval.

Historically, our products have been introduced into the market using the 510(k) procedure and we have never had to use the more rigorous PMA procedure. We are currently conducting clinical trials for products related to our IRE technology. We expect the results of these trials to be available within the next 9-12 months.

The FDA clearance and approval processes for a medical device are expensive, uncertain and lengthy. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals for any product on a timely basis or at all. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or the failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

After a product is placed on the market, the product and its manufacture are subject to pervasive and continuing regulation by the FDA. The FDA enforces these requirements by inspection and market surveillance. Our suppliers also may be subject to FDA inspection. We must therefore continue to spend time, money and effort to maintain compliance. Among other things, we must comply with the Medical Device Reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur. We must also comply with the FDA s corrections and removal reporting regulation, which requires that manufacturers report to the FDA field corrections and product recalls or removals if

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undertaken to reduce a risk to health posed by a device or to remedy a violation of the FDCA that may present a risk to health. The labeling and promotion activities for devices are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The FDA actively enforces regulations prohibiting the marketing of devices for unapproved new uses.

The devices manufactured by us also are subject to the QSR, which imposes elaborate testing, control, documentation and other quality assurance procedures. Every phase of production, including raw materials, components and subassemblies, manufacturing, testing, quality control, labeling, tracing of consignees after distribution, and follow-up and reporting of complaint information is governed by the FDA s QSR. Device manufacturers are required to register their facilities and list their products with the FDA and certain state agencies. The FDA periodically inspects manufacturing facilities and, if there are alleged violations, the operator of a facility must correct them or satisfactorily demonstrate the absence of the violations or face regulatory action.

We are subject to inspection and marketing surveillance by the FDA to determine our compliance with all regulatory requirements. Recently, the FDA has placed an increased emphasis on enforcement of the QSR and other postmarket regulatory requirements. Non-compliance with applicable FDA requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the FDA to grant marketing approvals, withdrawal of marketing approvals, a recommendation by the FDA to disallow us to enter into government contracts, and criminal prosecutions. The FDA also has the authority to request repair, replacement or refund of the cost of any device manufactured or distributed by us.

Other

We and our products are also subject to a variety of state and local laws in those jurisdictions where our products are or will be marketed, and Federal, state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. For example, we are registered with the Office of the Professions of the New York State Department of Education. We are also subject to various Federal and state laws governing our relationships with the physicians and others who purchase or make referrals for our products. For instance, Federal law prohibits payments of any form that are intended to induce a referral for any item payable under Medicare, Medicaid or any other Federal healthcare program. Many states have similar laws. There can be no assurance that we will not be required to incur significant costs to comply with such laws and regulations now or in the future or that such laws or regulations will not have a material adverse effect upon our ability to do business.

Non-U.S. Regulation

Internationally, all of our current products are considered medical devices under applicable regulatory regimes, and we anticipate that this will be true for all of our future products. Sales of medical devices are subject to regulatory requirements in many countries. The regulatory review process may vary greatly from country to country. For example, the European Union has adopted numerous directives and standards relating to medical devices regulating their design, manufacture, clinical trials, labeling and adverse event reporting. Devices that comply with those requirements are entitled to bear a Conformité Européenne, or CE Mark, indicating that the device conforms with the essential requirements of the applicable directives and can be commercially distributed in countries that are members of the European Union.

In some cases, we rely on our non-U.S. distributors to obtain regulatory approvals, complete product registrations, comply with clinical trial requirements and complete those steps that are customarily taken in the applicable jurisdictions.

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Non-U.S. sales of medical devices manufactured in the United States that are not approved or cleared by the FDA for use in the United States, or are banned or deviate from lawful performance standards, are subject to FDA export requirements. Before exporting such products to a foreign country, we must first comply with the FDA s regulatory procedures for exporting unapproved devices.

There can be no assurance that new laws or regulations regarding the release or sale of medical devices will not delay or prevent sale of our current or future products.

Third-Party Reimbursement

United States

Our products are used in medical procedures generally covered by government or private health plans. Accordingly, our sales and the prices we charge for our products depend significantly on the extent to which those third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans, cover our products and the procedures performed with them.

In general, a third-party payor only covers a medical product or procedure when the plan administrator is satisfied that the product or procedure improves health outcomes, including quality of life or functional ability, in a safe and cost-effective manner. Even if a device has received clearance or approval for marketing by the FDA, there is no assurance that third-party payors will cover the cost of the device and related procedures.

In many instances, third-party payors use price schedules that do not vary to reflect the cost of the products and equipment used in performing those procedures. In other instances, payment or reimbursement is separately available for the products and equipment used, in addition to payment or reimbursement for the procedure itself. Even if coverage is available, third-party payors may place restrictions on the circumstances where they provide coverage or may offer reimbursement that is not sufficient to cover the cost of our products. Many competing products are less expensive than ours. Therefore, although coverage may be available for our products and the related procedures, the levels of approved coverage may not be sufficient to justify using our products instead of those of competitors.

Third-party payors are increasingly challenging the prices charged for medical products and procedures and, where a reimbursement model is used, introducing maximum reimbursements for the procedures they cover. We believe that the minimally invasive procedures in which our products are used are generally less costly than open surgery. However, there is no guarantee that these procedures will be reimbursed. Third-party payors may not consider these minimally invasive procedures to be cost-effective and may therefore refuse to authorize coverage.

Third-party payors who cover the cost of medical products or equipment, in addition to allowing a general charge for the procedure, often maintain lists of exclusive suppliers or approved lists of products deemed to be cost-effective. Authorization from those third-party payors is required prior to using products that are not on these lists as a condition of reimbursement. If our products are not on the approved lists, healthcare providers must determine if the additional cost and effort required to obtain prior authorization, and the uncertainty of actually obtaining coverage, is justified by any perceived clinical benefits from using our products.

Finally, the advent of contracted fixed rates per procedure has made it difficult to receive reimbursement for disposable products, even if the use of these products improves clinical outcomes. In addition, many third-party payors are moving to managed care systems in which providers contract to provide comprehensive healthcare for a fixed cost per person. Managed care providers often attempt to control the cost of healthcare by authorizing fewer elective surgical procedures. Under current prospective payment systems, such as the diagnosis related group system and the hospital out-patient prospective payment system, both of which are used by Medicare and in many managed care systems used by private third-party payors, the cost of our products will be incorporated into the overall cost of a procedure and not be separately reimbursed. As a result, we cannot be certain that hospital administrators and physicians will purchase our products, despite the clinical benefits and opportunity for cost savings that we believe can be derived from their use.

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If hospitals and physicians cannot obtain adequate reimbursement for our products or the procedures in which they are used, our business, financial condition, results of operations, and cash flows could suffer a material adverse impact.

Non-U.S.

Our success in non-U.S. markets will depend largely upon the availability of reimbursement from the third-party payors through which healthcare providers are paid in those markets. Reimbursement and healthcare payment systems in non-U.S. markets vary significantly by country. The main types of healthcare payment systems are government sponsored healthcare and private insurance. Reimbursement approval must be obtained individually in each country in which our products are marketed. Outside the United States, we generally rely on our distributors to obtain reimbursement approval in the countries in which they will sell our products. There can be no assurance that reimbursement approvals will be received.

Insurance

Our product liability insurance coverage is limited to a maximum of $10,000,000 per product liability claim and an aggregate policy limit of $10,000,000, subject to deductibles of $250,000 per occurrence and $500,000 in the aggregate. The policy covers, subject to policy conditions and exclusions, claims of bodily injury and property damage from any product sold or manufactured by us.

We cannot assure you that this level of coverage is adequate. We may not be able to sustain or maintain this level of coverage and cannot assure you that adequate insurance coverage will be available on commercially reasonable terms or at all. A successful product liability claim or other claim with respect to uninsured or underinsured liabilities could have a material adverse effect on our business.

Environmental

We are subject to Federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain hazardous and potentially hazardous substances used in connection with our operations. Although we believe that we have complied with these laws and regulations in all material respects and, to date, have not been required to take any action to correct any noncompliance, there can be no assurance that we will not be required to incur significant costs to comply with environmental regulations in the future.

Employees

As of July 31, 2007, we had 530 full-time employees, including 293 in manufacturing; 51 in research, product development and regulatory approval/quality assurance; 148 in sales and marketing; and 38 in administration. None of our employees is represented by a labor union, and we have never experienced a work stoppage.

Item 1A. ***Risk Factors***

Our financial and operating results are subject to a number of factors, many of which are not within our control. These factors include the following:

If we fail to develop or market new products and enhance existing products, we could lose market share to our competitors and our results of operations could suffer.

The market for interventional devices is characterized by rapid technological change, new product introductions, technological improvements, changes in physician requirements and evolving industry standards. To be successful, we must continue to develop and commercialize new products and to enhance versions of our

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existing products. Our products are technologically complex and require significant planning, design, development and testing before they may be marketed. This process generally takes at least 12 to 18 months from initial concept and may take up to several years. In addition, product life cycles are relatively short because medical device manufacturers continually develop smaller, more effective and less expensive versions of existing devices in response to physician demand. Our success in developing and commercializing new and enhanced versions of our products is affected by our ability to:

- timely and accurately identify new market trends;
- accurately assess customer needs;
- minimize the time and costs required to obtain regulatory clearance or approval;
- adopt competitive pricing;
- timely manufacture and deliver products;
- accurately predict and control costs associated with the development, manufacturing and support of our products; and
- anticipate and compete effectively with our competitors efforts.

Market acceptance of our products depends in part on our ability to demonstrate that our products are cost-effective and easier to use, as well as offer technological advantages. Additionally, we may experience design, manufacturing, marketing or other difficulties that could delay or prevent our development, introduction or marketing of new versions of our products. As a result of such difficulties and delays, our development expenses may increase and, as a consequence, our results of operations could suffer.

Competition may decrease our market share and cause our revenues to decline.

The markets for interventional devices are highly competitive, and we expect competition to continue to intensify. We may not be able to compete effectively, and we may lose market share to our competitors. The principal competitors in the markets for our products currently include: Boston Scientific Corporation; Cook, Incorporated; Cordis Corporation, a subsidiary of Johnson & Johnson, Inc.; C.R. Bard Inc.; Radionics, a division of Tyco Healthcare, which is a division of Tyco International; Diomed Inc.; Medical Components, Inc., or Medcomp; and VNUS Medical Technologies, Inc. Many of our competitors have substantially greater:

- financial and other resources;
- variety of products;

technical capabilities;

ability to develop and introduce new products;

patent portfolios that may present an obstacle to our conduct of business;

name recognition; and

distribution networks and in-house sales forces.

Our competitors may succeed in developing technologies and products earlier, in obtaining patent protection or regulatory clearance earlier, or in commercializing new products or technologies more rapidly than us. Our competitors may also develop products and technologies that are superior to those we are developing or that otherwise could render our products obsolete or noncompetitive. In addition, we may face competition from providers of other medical therapies, such as pharmaceutical companies, that may offer non-surgical therapies for conditions that are currently or in the future may be treated using our products. Our products are generally sold at higher prices than those of our competitors. However, in the current environment of managed care, which is characterized by economically motivated buyers, consolidation among healthcare providers, increased competition and declining reimbursement rates, we are increasingly being required to compete on the basis of price. If we are not able to compete effectively, our market share and revenues may decline.

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We may be exposed to risks associated with acquisitions, including integration risks and risks associated with methods of financing and the impact of accounting treatment. Accordingly, completed acquisitions may not enhance our business.

Part of our growth strategy is to acquire businesses and technologies that are complementary to ours. Any such acquisitions would be accompanied by the risks commonly encountered in acquisitions, including the:

- potential disruption of our business while we evaluate opportunities, complete acquisitions and develop and implement new business strategies to take advantage of these opportunities;
- inability of our management to maximize our financial and strategic position by incorporating an acquired technology or business into our existing offerings;
- difficulty of maintaining uniform standards, controls, procedures and policies;
- difficulty of assimilating the operations and personnel of acquired businesses;
- potential loss of key employees of acquired businesses, and the impairment of relationships with employees and customers as a result of changes in management; and
- uncertainty as to the long-term success of any acquisitions we may make.

We cannot assure you that any completed acquisition will enhance our business. If we proceed with one or more significant acquisitions in which the consideration consists of cash, a substantial portion of our available cash, could be used to consummate the acquisitions. If we consummate one or more acquisitions in which the consideration consists of capital stock, our stockholders could suffer significant dilution of their interest in us. In addition, we could incur or assume significant amounts of indebtedness in connection with acquisitions. Further, acquisitions could also result in significant goodwill and/or amortization charges for acquired businesses or technologies.

If we fail to adequately protect our intellectual property rights, our business may suffer.

Our success depends in part on obtaining, maintaining and enforcing our patents, trademarks and other proprietary rights, and our ability to avoid infringing the proprietary rights of others. We take precautionary steps to protect our technological advantages and intellectual property. We rely upon patent, trade secret, copyright, know-how and trademark laws, as well as license agreements and contractual provisions, to establish our intellectual property rights and protect our products. However, these measures may not adequately protect our intellectual property rights.

Our patents may not provide commercially meaningful protection, as competitors may be able to design around our patents to produce alternative, non-infringing designs. Additionally, we may not be able to effectively protect our rights in unpatented technology, trade secrets and confidential information. Although we require our new employees, consultants and corporate partners to execute confidentiality agreements, these agreements may not provide effective protection of our information or, in the event of unauthorized use or disclosure, may not provide

adequate remedies.

If third parties claim that our products infringe their intellectual property rights, we may be forced to expend significant financial resources and management time defending against such actions and our results of operations could suffer.

Third parties may claim that our products infringe their patents and other intellectual property rights. Identifying third-party patent rights can be particularly difficult because, in general, patent applications can be maintained in secrecy for at least 18 months after their earliest priority date. Some companies in the medical device industry have used intellectual property infringement litigation to gain a competitive advantage. If a competitor were to challenge our patents, licenses or other intellectual property rights, or assert that our products

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infringe its patent or other intellectual property rights, we could incur substantial litigation costs, be forced to make expensive changes to our product design, license rights in order to continue manufacturing and selling our products, or pay substantial damages. Third-party infringement claims, regardless of their outcome, would not only consume our financial resources but also divert our management s time and effort. Such claims could also cause our customers or potential customers to purchase competitors products or defer or limit their purchase or use of our affected products until resolution of the claim.

In January 2004, Diomed filed an action against us alleging that our VenaCure products for the treatment of varicose veins infringe a patent held by Diomed for a laser system that competes with our VenaCure products. In March 2007, the jury ruled in Diomed s favor and awarded compensatory damages of $9.71 million. On July 2, 2007, the judge for the Federal District in Boston, Massachusetts, issued an injunction that prohibits us from selling our original bare fiber VenaCure product. We have disputed the infringement verdict on multiple grounds and on June 20, 2007, filed an appeal in the U.S. Court of Appeals for the Federal Circuit in Washington, D.C In October 2005, VNUS Medical Technologies filed an action against us, Diomed and another defendant alleging, among other things, that the manufacture, use and sale of our VenaCure products infringe several patents held by VNUS and seeking injunctive relief and compensatory and treble damages. For fiscal 2007, sales of our VenaCure products accounted for approximately 11% of our total sales. If VNUS is ultimately successful in its action against us, our results of operations could suffer. See Item 3 Legal Proceedings.

We are dependent on single and limited source suppliers, which puts us at risk for supplier business interruptions.

We currently purchase significant amounts of several key products and product components from single and limited source suppliers and anticipate that we will do so for future products as well. For fiscal 2007, approximately 30% of our net sales were derived from sales of products manufactured for us by third parties. In addition, approximately 15% of our sales growth over our past two fiscal years was attributable to products that we licensed or obtained from third parties. Our principal single source supplier, Medcomp, supplies us with most of our dialysis catheters, which accounted for about 17% of our net sales (16% of total inventory purchases) in fiscal 2007. Medcomp also competes with us by selling Dynamic-Flow, a dialysis catheter for which it has not granted us exclusive rights, and other catheters that we do not purchase from them. Additionally, we purchase the laser and laser fibers, which are the principal components of our VenaCure products, primarily from biolitec, which also competes with us. Sales of our VenaCure products accounted for about 11% of our net sales in fiscal 2007. Our contract with biolitec expired in April 2007, and we have identified several other vendors for the lasers and laser fibers to replace those we purchase from biolitec. Any delays in delivery of or shortages in those products and components could interrupt and delay manufacturing of our products and result in the cancellation of orders for our products. Any or all of these suppliers could discontinue the manufacture or supply of these products and components at any time. We may not be able to identify and integrate alternative sources of supply in a timely fashion or at all. Any transition to alternate suppliers may result in production delays and increased costs and may limit our ability to deliver products to our customers. Furthermore, if we are unable to identify alternative sources of supply, we would have to modify our products to use substitute components, which may cause delays in shipments, increased design and manufacturing costs and increased prices for our products.

If we do not maintain our relationships with interventional physicians, our growth will be limited and our business could be harmed.

Physicians typically influence the medical device purchasing decisions of the hospitals and other healthcare institutions in which they practice. Consequently, our relationships with interventional physicians are critical to our continued growth. We believe that these relationships are based on the quality of our products, our physician-driven product development efforts, our marketing efforts and our presence at medical society meetings. Any actual or perceived diminution in the quality of our products, or our failure or inability to maintain these other efforts, could damage our current relationships, or prevent us from forming new relationships, with interventional physicians and cause our growth to be limited and our business to be harmed.

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Our business could be harmed if we lose the services of our key personnel.

Our business depends upon our ability to attract and retain highly qualified personnel, including managerial, sales and technical personnel. We are particularly dependant upon the efforts of Eamonn P. Hobbs, our president and chief executive officer, a bio-medical engineer with over 26 years of experience in the interventional radiology, interventional cardiology and gastroenterology medical device industries. Mr. Hobbs is the only business executive from the medical device industry to ever serve on the Strategic Planning Committee of the Society of Interventional Radiology, or SIR, and he received an honorary fellowship from the SIR in 2005. We compete for key personnel with other companies, healthcare institutions, academic institutions, government entities and other organizations. We do not have written employment agreements with our executive officers. Our ability to maintain and expand our business may be impaired if we are unable to retain our current key personnel or hire or retain other qualified personnel in the future.

Undetected defects may increase our costs and impair the market acceptance of our products.

Our products have occasionally contained, and may in the future contain, undetected defects. When these problems occur, we must divert the attention of our engineering personnel to address them. We cannot assure you that we will not incur warranty or repair costs, be subject to liability claims for damages related to product defects, or experience manufacturing, shipping or other delays or interruptions as a result of these defects in the future. Our insurance policies may not provide sufficient protection should a claim be asserted. In addition, the occurrence of defects may result in significant customer relations problems and injury to our reputation, and may impair market acceptance of our products.

If a product liability claim is brought against us or our product liability insurance coverage is inadequate, our business could be harmed.

The design, manufacture and marketing of the types of medical devices we sell entail an inherent risk of product liability. Our products are used by physicians to treat seriously ill patients. We have been subject to product liability claims in the past, and patients may in the future bring claims in a number of circumstances and for a number of reasons, including if our products were misused, if they produced unsatisfactory results or if the instructions for use and operating manuals for our products were found to be inadequate. Claims could also be brought by our customers. We carry a product liability policy with limits of $10 million per occurrence and in the aggregate per year, with a $250,000 deductible per incident and an aggregate deductible limit of $500,000 per year. We believe, based on claims made against us in the past, that our existing product liability insurance coverage is reasonably adequate to protect us from any liabilities we might incur. However, we cannot assure you that this coverage will be sufficient to satisfy any claim made against us. In addition, we may not be able to maintain adequate coverage at a reasonable cost and on reasonable terms, if at all. Any product liability claim brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing any coverage in the future. Additionally, if one or more product liability claims is brought against us for uninsured liabilities or is in excess of our insurance coverage, our business could be harmed. Further, such claims may require us to recall some of our products, which could result in significant costs to us and could divert management s attention from our business.

Healthcare reform could cause a decrease in demand for our interventional products.

There are currently widespread legislative efforts to control healthcare costs in the United States and abroad, which we expect will continue in the future. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 provides that from 2004 through 2008, reimbursement levels for durable medical equipment will no longer be increased on an annual basis and a competitive bidding program will be introduced. At this time, we are unable to determine whether and to what extent these changes will apply to our products and our business. Similar legislative efforts in the future could negatively impact demand for our products.

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Inadequate levels of reimbursement from governmental or other third-party payors for procedures using our products may cause our revenues to decline.

Changes in healthcare systems in the United States or elsewhere could adversely affect the demand for our products, as well as the way we conduct business. Third-party payors have adopted, and are continuing to adopt, a number of healthcare policies intended to curb rising healthcare costs. These policies include:

- controls on government-funded reimbursement for healthcare services and price controls on medical products and services providers;
- challenges to the pricing of medical procedures or limits or prohibitions on reimbursement for specific devices and therapies through other means; and
- the introduction of managed care systems in which healthcare providers contract to provide comprehensive healthcare for a fixed cost per person.

We are unable to predict whether Federal, state or local healthcare reform legislation or regulation affecting our business may be proposed or enacted in the future, or what effect any such legislation or regulation would have on our business. These policies, or any reductions in the number of authorizations granted for procedures performed using our current and proposed products or in the levels of reimbursement for those procedures, could cause our revenues to decline.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for new devices and procedures. These systems are subject to the same pressures to curb rising healthcare costs and control healthcare expenditures as exist in the United States. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, sales of our products outside of the United States may decrease and we may fail to achieve or maintain significant non-U.S. sales.

If we cannot obtain and maintain marketing clearance or approval from governmental agencies, we will not be able to sell our products.

Our products are medical devices that are subject to extensive regulation in the United States and in the foreign countries in which they are sold. Unless an exemption applies, each medical device that we wish to market in the United States must receive either 510(k) clearance or premarket approval from the U.S. Food and Drug Administration, or the FDA, before the product can be sold. Either process can be lengthy and expensive. The FDA s 510(k) clearance procedure, also known as premarket notification, is the process we have used for our current products. This process usually takes from four to 12 months from the date the premarket notification is submitted to the FDA, but may take significantly longer. Although we have obtained 510(k) clearances for our current products, our clearances may be revoked by the FDA if safety or effectiveness problems develop with the devices. The premarket approval process is much more costly, lengthy and uncertain. It generally takes from one to three years from the date the application is submitted to, and filed with, the FDA, and may take even longer. Regulatory regimes in other countries similarly require approval or clearance prior to our marketing or selling products in those countries. We rely on our distributors to obtain regulatory clearances or approvals of our products outside of the United States. If we are unable to obtain additional clearances or approvals needed to market existing or new products in the United States or elsewhere or obtain these clearances or approvals in a timely fashion or at all, or if our existing clearances are revoked, our revenues and profitability may decline.

Modifications to our current products may require new marketing clearances or approvals or require us to cease marketing or recall the modified products until such clearances or approvals are obtained.

Any modification to an FDA-cleared medical device that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, requires a new FDA 510(k) clearance or, possibly, a premarket approval. The FDA requires every manufacturer to make its own

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determination as to whether a modification requires a new 510(k) clearance or premarket approval, but the FDA may review and disagree with any decision reached by the manufacturer. We have modified aspects of some of our devices since receiving regulatory clearance. We believed that some of these modifications did not require new 510(k) clearance or premarket approval and, therefore, we did not seek new 510(k) clearances or premarket approvals. In the future, we may make additional modifications to our products after they have received FDA clearance or approval and, in appropriate circumstances, determine that new clearance or approval is unnecessary. Regulations in other countries in which we market or sell, or propose to market or sell, our products may also require that we make judgments about changes to our products and whether or not those changes are such that regulatory approval or clearance should be obtained. In the United States and elsewhere, regulatory authorities may disagree with our past or future decisions not to seek new clearance or approval and may require us to obtain clearance or approval for modifications to our products. If that were to occur for a previously cleared or approved product, we may be required to cease marketing or recall the modified device until we obtain the necessary clearance or approval. Under these circumstances, we may also be subject to significant regulatory fines or other penalties. If any of the foregoing were to occur, our business could suffer.

If we or some of our suppliers fail to comply with the FDA s Quality System Regulation, or QSR, and other applicable postmarket requirements, our manufacturing operations could be disrupted, our product sales and profitability could suffer, and we may be subject to a wide variety of FDA enforcement actions.

After a device is placed on the market, numerous regulatory requirements apply. We are subject to inspection and marketing surveillance by the FDA to determine our compliance with all regulatory requirements. Our failure to comply with applicable regulatory requirements could result in the FDA or a court instituting a wide variety of enforcement actions against us, including a public warning letter; an order to shut-down some or all manufacturing operations; a recall of products; fines or civil penalties; seizure or detention of our products; refusing our requests for 510(k) clearance or a premarket approval, or PMA, of new or modified products; withdrawing 510(k) clearance or PMA approvals already granted to us; and criminal prosecution.

Our manufacturing processes and those of some of our suppliers must comply with the FDA s Quality System Regulation, or QSR, which governs the methods used in, and the facilities and controls used for, the design, testing, manufacture, control, quality assurance, installation, servicing, labeling, packaging, storage and shipping of medical devices. The FDA enforces the QSR through unannounced inspections. If we or one of our suppliers fails a QSR inspection, or if a corrective action plan adopted by us or one of our suppliers is not sufficient, the FDA may bring an enforcement action, and our operations could be disrupted and our manufacturing delayed. We are also subject to the FDA s general prohibition against promoting our products for unapproved or off-label uses, the FDA s adverse event reporting requirements and the FDA s reporting requirements for field correction or product removals. The FDA has recently placed increased emphasis on its scrutiny of compliance with the QSR and these other postmarket requirements.

If we or one of our suppliers violate the FDA s requirements or fail to take adequate corrective action in response to any significant compliance issue raised by the FDA, the FDA can take various enforcement actions which could cause our product sales and profitability to suffer.

In addition, most other countries require us and our suppliers to comply with manufacturing and quality assurance standards for medical devices that are similar to those in force in the United States before marketing and selling our products in those countries. If we or our suppliers should fail to do so, we would lose our ability to market and sell our products in those countries.

Even after receiving regulatory clearance or approval, our products may be subject to product recalls, which may harm our reputation and divert managerial and financial resources.

The FDA and similar governmental authorities in other countries have the authority to order mandatory recall of our products or order their removal from the market if there are material deficiencies or defects in design, manufacture, installation, servicing or labeling of the device, or if the governmental entity finds that our

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products would cause serious adverse health consequences. A government mandated or voluntary recall or field action by us could occur as a result of component failures, manufacturing errors or design defects, including labeling defects. Any recall of our products may harm our reputation with customers and divert managerial and financial resources.

Failure to attract additional capital which we may require to expand our business could curtail our growth.

We may require additional capital to expand our business. If cash generated internally is insufficient to fund capital requirements, we will require additional debt or equity financing. In addition, we may require financing to fund any significant acquisitions we may seek to make. Needed financing may not be available or, if available, may not be available on terms satisfactory to us and may result in significant stockholder dilution. Covenants in our industrial bond financing may also restrict our ability to obtain additional debt financing. If we fail to obtain sufficient additional capital in the future, we could be forced to curtail our growth strategy by reducing or delaying capital expenditures and acquisitions, selling assets, restructuring our operations or refinancing our indebtedness.

Any disaster at our manufacturing facilities could disrupt our ability to manufacture our products for a substantial amount of time, which could cause our revenues to decrease.

We conduct our manufacturing and assembly at two facilities in Queensbury, New York, and Manchester, Georgia. It would be difficult, expensive and time-consuming to transfer resources from one facility to the other, replace, or repair these facilities and our manufacturing equipment if they were significantly affected by a disaster. Additionally, we might be forced to rely on third-party manufacturers or to delay production of our products. Insurance for damage to our properties and the disruption of our business from disasters may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all. In addition, if one of our principal suppliers were to experience a similar disaster, uninsured loss or under-insured loss, we might not be able to obtain adequate alternative sources of supplies or products or could face significant delays and incur substantial expense in doing so. Any significant uninsured loss, prolonged or repeated disruption, or inability to operate experienced by us or any of our principal suppliers could cause significant harm to our business, financial condition and results of operations.

Item 1B. ***Unresolved Staff Comments***

None

Item 2. ***Properties***

We own a manufacturing, administrative, engineering and warehouse facility of approximately 104,000 square feet situated on 18 acres in Queensbury, New York. In 2003, we financed an expansion of this facility with the proceeds of industrial revenue bonds, and the land and buildings are subject to a first mortgage in favor of a bank. In 2006, we issued taxable adjustable rate notes to finance an expansion of 36,000 square feet to our warehouse and manufacturing facility. See Item 7 of this annual report, Management s Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources, for a discussion of these financings. We anticipate requiring additional administrative and engineering space within the next one to two years.

We also lease two additional properties. We lease a manufacturing facility of approximately 60,000 square feet located in Manchester, Georgia. This facility includes office and research and development space and is leased through 2010. We lease an additional 14,500 square feet of office and research and development space in Fremont, California. The lease is non-cancelable and expires in April 2010.

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Item 3. Legal Proceedings

Diomed v. AngioDynamics

On January 6, 2004, Diomed filed an action against us entitled *Diomed, Inc. v. AngioDynamics, Inc., et al.*, civil action no. 04 10019 RGS in the U.S. District Court for the District of Massachusetts. Diomed s complaint alleges that we have infringed on Diomed s U.S. patent no. 6,398,777 by selling a kit for the treatment of varicose veins (now called the VenaCure Procedure Kit) and two diode laser systems (the Precision 980 Laser and the Precision 810 Laser), and by conducting a training program for physicians in the use of our VenaCure Procedure Kit. The complaint alleges our actions have caused, and continue to cause, Diomed to suffer substantial damages. The complaint seeks to prohibit us from continuing to market and sell these products, as well as conducting our training program, and asks for compensatory and treble money damages, reasonable attorneys fees, costs and pre-judgment interest.

On March 28, 2007, the jury returned a verdict in favor of Diomed and awarded compensatory monetary damages in the amount of $8.36 million. The jury concluded, however, that there was no willful infringement by us. On May 22, 2007, the judge for the Federal District Court in Boston denied our motion to overturn the verdict and increased the judgment for compensatory damages by $1.35 million, to $9.71 million, to cover pretrial interest and post-verdict sales of the infringing products. The judgment also requires the Company to pay interest to Diomed at an annual rate of approximately 5% of the damage award for the period of time between the verdict and actual payment of the award. As such, we have recorded a charge of $9.71 million to general and administrative expenses and $80,000 to interest expense in the consolidated statement of operations for the year ended June 2, 2007 with a corresponding credit under the heading Other long-term liabilities in our consolidated balance sheet as of June 2, 2007.

We have disputed the infringement verdict and on June 20, 2007, filed an appeal in the U.S. Court of Appeals for the Federal Circuit in Washington, D.C.

On July 2, 2007, the judge for the Federal District Court in Boston, Massachusetts, issued an injunction that prohibits us from selling our original bare fiber VenaCure kits and the laser consoles for use with those kits. In anticipation of this injunction, we stopped selling our bare fiber kits in April 2007, and beginning June 2, 2007, began selling our new NeverTouch disposable kits and laser consoles which, we believe, are unaffected by the injunction.

Until April 2007, we purchased the lasers and laser fibers for our laser systems from biolitec under the biolitec Supply Agreement. In 2006, biolitec advised us that, based on the refinement of the claims in the Diomed action, biolitec believed such claims were not within biolitec s indemnification obligations under the biolitec Supply Agreement. We advised biolitec that we disagreed with biolitec s position and that we expected biolitec to continue to honor its indemnification obligations to us under the biolitec Supply Agreement. Pending the outcome of ongoing discussions regarding this issue, biolitec agreed to continue to provide, at its cost and expense, our defense in the Diomed action. In April 2007, biolitec informed us that, as of April 15, 2007, biolitec would terminate any further defense of us in this action. As a result of biolitec s actions, and to protect our own interests, since April 15, 2007, we have paid our own defense costs with regard to this matter.

We will act vigorously to enforce our rights against biolitec to honor its obligations under the biolitec Supply Agreement. However, in the event it is ultimately determined that the claims asserted in this action are not within biolitec s indemnification obligations under the biolitec Supply Agreement, we may be required to reimburse biolitec for the costs and expenses of defending the Diomed action and may be responsible for paying any settlements or judgments in this action.

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VNUS Medical Technologies v. Diomed, Vascular Solutions, and AngioDynamics

On October 4, 2005, VNUS Medical Technologies, Inc. (VNUS) filed an action against AngioDynamics and others (collectively, the Defendants) entitled *VNUS Medical Technologies, Inc. v. Diomed Holdings, Inc., Diomed Inc., AngioDynamics, Inc., and Vascular Solutions, Inc.*, case no. C05-2972 MMC, filed in the U.S. District Court for the Northern District of California. The complaint alleges that the Defendants infringed on VNUS s U.S. patent nos. 6,258,084, 6,638,273, 6,752,803, and 6,769,433 by making, using, selling, offering to sell and/or instructing users how to use Diomed s EVLT products, AngioDynamics VenaCure products, and Vascular Solutions Vari-Lase products. The complaint alleges the Defendants actions have caused, and continue to cause, VNUS to suffer substantial damage. The complaint seeks to prohibit the Defendants from continuing to market and sell these products and asks for compensatory and treble money damages, reasonable attorneys fees, costs and pre-judgment and post-judgment interest. We believe that our products do not infringe the VNUS patents and that the patents are invalid. We have filed an answer to the complaint, including a counterclaim for relief and a demand for jury trial. In November 2006, the court scheduled the trial in this action for October 2007. There is a reasonable possibility of an outcome unfavorable to us in this action, with a range of potential loss between $0 and $36 million.

Hazel Smart v. St. Mary s Hospital

We were named as a defendant in an action entitled *Karen Incardona, Temporary Administrator of the Estate of Hazel Smart v. St. Mary s Hospital*, et al, filed in the District Court of Waterbury, Connecticut, on January 3, 2007. The complaint alleges that we and our co-defendant, Medical Components, Inc. (Medcomp), manufactured and sold a defective catheter that was used in the treatment of, and caused the death of, a hemodialysis patient, as well as committing other negligent acts. The complaint seeks compensatory and other monetary damages in unspecified amounts. Under our distribution agreement with Medcomp, Medcomp is required to indemnify us against all our costs and expenses, as well as losses, liabilities and expenses (including reasonable attorneys fees) that relate in any way to products covered by the agreement. We tendered the defense of the *Smart* action to Medcomp, and Medcomp accepted defense of this action. Based upon our prior experience with Medcomp, we expect Medcomp to honor its indemnification obligation if it is unsuccessful in defending this action.

Holleran v. RITA Medical Systems, Inc. et al

On December 15, 2006, an alleged holder of RITA common stock filed a purported class action lawsuit captioned *Holleran v. RITA Medical Systems, Inc., et al .*, Case No. RG 06-302394, or the Stockholder Action, in the Superior Court of the State of California for the County of Alameda. The complaint names as defendants RITA and each of RITA s directors.

In the complaint, the plaintiff alleged that, in pursuing the transaction with the Company and approving the merger agreement, the directors of RITA breached their fiduciary duties to RITA s stockholders by, among other things, executing a merger agreement with a termination fee, a no solicitation clause and a restriction on issuing press releases without AngioDynamics consent, engaging in self-dealing and prematurely selling RITA before RITA s share value could reflect projected profitable financial information and the commencement of market release shipments of RITA s Habib 4X laparoscopic tool. The plaintiffs have further alleged that the merger agreement resulted from a process designed to ensure the sale of RITA to AngioDynamics for the benefit of RITA insiders.

The complaint filed by plaintiff sought, among other things, a determination that the litigation is properly maintained as a class action, a declaration that the merger agreement was entered into in breach of the RITA directors fiduciary duties, rescission of the merger or any of the terms thereof to the extent implemented, imposition of a constructive trust with respect to any payments or awards to be issued to defendants, an injunction enjoining RITA, the RITA directors and others from consummating the merger unless and until the

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joint proxy statement/prospectus is revised, a direction requiring that the RITA directors exercise their fiduciary duties to obtain a transaction which is in the best interests of RITA stockholders, an award of costs, including attorneys and experts fees, and other unspecified relief.

RITA and AngioDynamics agreed to settle the Stockholder Action and, in connection therewith, made certain modifications to the disclosures accompanying the amended joint proxy statement which was filed with the SEC on December 22, 2006, and to provisions in the Merger Agreement. Additionally, RITA and AngioDynamics agreed to reimburse the plaintiff s attorneys in the amount of $300,000 as awarded by the court. The court granted final approval of the parties settlement on August 1, 2007.

S.D. v. RITA Medical Systems Health Benefits Plan

On October 31, 2006, S.D. filed an action entitled *S.D., on her own behalf and as guardian of T.D., and Island View Residential Treatment Center, Inc. v. RITA Medical Systems Health Benefits Plan and Blue Cross of California*, case number 1:06-cv-135 DB, in the U.S. District Court for the District of Utah. The claim asserts a cause of action for recovery of benefits under 29 U.S.C. section 1132(a)(1)(B). The complaint alleges that the action of defendants in failing to make payment for the treatment provided by Island View Residential Treatment Center is a violation of the RITA Benefits Plan, the Blue Cross insurance policy, and California state law. RITA Benefits Plan denies all wrongdoing and intends to vigorously defend this action. On June 11, 2007, the court stayed the action pending resolution of an independent lawsuit involving Island View and Blue Cross of California and having similar issues. Progress in this action has not reached a point to assess with any reasonable degree of certainty the likelihood of an unfavorable outcome or an estimate of any potential loss.

Donald Neal Wilkerson v. Tasha Christian and RITA Medical Systems, Inc.

We have been named as a defendant in a wrongful death action entitled *Donald Neal Wilkerson, individually and as the Administrator of the Estate of Sandra Hatcher Wilkerson, deceased v. Tasha Christian and RITA Medical Systems, Inc.*, civil action number 06-871, and related arbitration proceedings, filed in the U.S. District Court for the Middle District of North Carolina on October 4, 2006. The plaintiff seeks unspecified damages, including both compensatory and punitive damages, costs, and such other relief as the court may deem appropriate in allegedly causing the death of Sandra Wilkerson.

On November 20, 2006, RITA filed a motion to dismiss the complaint on the ground that plaintiff s claims are time barred by the applicable statute of limitations. On November 29, 2006, plaintiff filed an Amended Complaint. RITA moved to dismiss the Amended Complaint on December 13, 2006, on statute of limitations grounds. Progress in this action has not reached a point to assess with any reasonable degree of certainty the likelihood of an unfavorable outcome or an estimate of any potential loss.

We are party to other legal actions that arise in the ordinary course of our business. We believe that any liability resulting from any currently pending litigation will not, individually or in the aggregate, have a material adverse effect on our business, financial condition, results of operations, or cash flows.

Item 4. ***Submission of Matters to a Vote of Security Holders***

None.

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Part II

Item 5. ***Market for Registrant s Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities.***

Our common stock is traded on The Global Market tier of The NASDAQ Stock Market LLC (formerly the Nasdaq National Market), under the symbol ANGO.

The following table sets forth, for the periods indicated, the high and low sale prices for our common stock as reported by The Nasdaq National Market.

	Sale Price	
	High	**Low**
Fifty-two weeks ended June 2, 2007		
Fourth Quarter	$ 23.87	$ 15.68
Third Quarter	$ 26.93	$ 20.13
Second Quarter	$ 24.84	$ 15.20
First Quarter	$ 30.00	$ 16.04

	Sale Price	
	High	**Low**
Fifty-three weeks ended June 3, 2006		
Fourth Quarter	$ 31.29	$ 21.68
Third Quarter	$ 29.54	$ 19.84
Second Quarter	$ 23.46	$ 18.44
First Quarter	$ 26.00	$ 19.00

As of July 31, 2007, there were 361 record holders of our common stock.

Dividends

We did not declare any cash dividends on our common stock during our last two fiscal years. We do not anticipate paying any cash dividends on our common stock for the foreseeable future.

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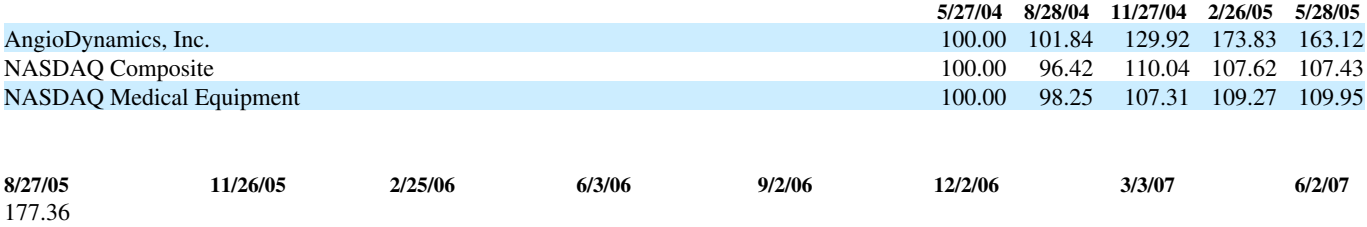
Performance Graph

The following graph compares the cumulative 3-year total return to shareholders on AngioDynamics, Inc. s common stock relative to the cumulative total returns of the NASDAQ Composite index and the NASDAQ Medical Equipment index. An investment of $100 (with reinvestment of all dividends) is assumed to have been made in our common stock and in each of the indexes on 5/27/2004 and its relative performance is tracked through 6/2/2007.



* $ 100 invested on 5/27/04 in stock or on 4/30/04 in index-including reinvestment of dividends.
Indexes calculated on month-end basis.

	5/27/04	8/28/04	11/27/04	2/26/05	5/28/05
AngioDynamics, Inc.	100.00	101.84	129.92	173.83	163.12
NASDAQ Composite	100.00	96.42	110.04	107.62	107.43
NASDAQ Medical Equipment	100.00	98.25	107.31	109.27	109.95

8/27/05	11/26/05	2/25/06	6/3/06	9/2/06	12/2/06	3/3/07	6/2/07
177.36							