

ANGIODYNAMICS INC  
Form 10-K  
August 14, 2009  
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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 May 31, 2009

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)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)  
**603 Queensbury Ave., Queensbury, New York**  
(Address of principal executive offices)  
**Registrant's telephone number, including area code (518) 798-1215**

**11-3146460**  
(I.R.S. Employer  
Identification No.)  
**12804**  
(Zip Code)

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

<b>Title of each class</b>	<b>Name of each exchange on which registered</b>
<b>Common stock, par value \$.01</b>	<b>NASDAQ Global Select Market</b>
<b>Preferred Stock Purchase Rights</b>	<b>NASDAQ Global Select Market</b>

**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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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

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As of November 30, 2008, 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 approximately \$290,652,045, computed by reference to the last sale price of the common stock on that date as reported by The Nasdaq Global Select Market.

As of July 31, 2009, there were 24,433,049 shares of the registrant's common stock outstanding.

### **DOCUMENTS INCORPORATED BY REFERENCE**

The information required for Part III of this annual report on Form 10-K is incorporated by reference from the registrant's Proxy Statement for its 2009 Annual Meeting of Stockholders to be filed within 120 days of registrant's fiscal year ended May 31, 2009.

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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, systems, irreversible electroporation, or IRE, surgical resection systems and embolization products for treating benign and malignant 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 PVD, tumors and other non-coronary 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.

###### **Available Information**

Our internet website is [www.angiodynamics.com](http://www.angiodynamics.com). We make available free-of-charge through our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file or furnish such materials to the Securities and Exchange Commission ( SEC ). In addition, our internet website includes, among other things, charters of various committees of the Board of Directors and our code of business conduct and ethics applicable to all employees, officers and directors. Copies of these documents may be obtained free of charge from our internet website. Any stockholder also may obtain copies of these documents, free of charge, by sending a request in writing to our investor relations firm: EVC Group, 60 East 42<sup>nd</sup> Street, Suite 936, New York, NY 10165. Information on our website or connected to our website is not incorporated by reference into this Annual Report on Form 10-K.

###### **History**

AngioDynamics was founded in 1988 as a division and incorporated in 1992 in Delaware as a wholly owned subsidiary of E-Z-EM. We completed our initial public offering in 2004 by raising net proceeds of approximately \$21.7 million at an offering price of \$11.00 per share. In 2006 we completed a follow-on offering, raising net proceeds of approximately \$61.9 million at a public offering price of \$24.07 per share.

###### **Recent Developments**

###### *CEO Transition*

On January 20, 2009, we entered into an Employment Agreement and Non-Statutory Stock Option Agreement with our then chief executive officer that provided, among other things, for a transition to a new chief executive officer. The transition to the new chief executive was completed in the third quarter of fiscal 2009. The former chief executive officer did not have an operating role after February 28, 2009. Accordingly, we recorded a provision in fiscal 2009 of approximately \$2.9 million in general and administrative expenses for all current and future costs associated with the aforementioned Employment Agreement and Non-Statutory Stock Option Agreement and certain costs associated with the recruitment of a new chief executive officer. The new CEO commenced employment with us in March 2009.

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### *Acquisition of FlowMedica, Inc.*

On January 12, 2009, we completed the acquisition of certain assets of FlowMedica, Inc. for approximately \$1.75 million in cash and a contingent payment based on fiscal 2011 sales of FlowMedica products. With this acquisition, we purchased the Benephit product line, a therapeutic approach to deliver drugs directly to the kidneys in order to prevent and treat acute kidney injury, in the emerging field of Targeted Renal Therapy. Intangible assets acquired totaled approximately \$1.3 million which have been identified as product technologies (10-year weighted average useful life). Inventory acquired totaled approximately \$400,000. The acquisition is being accounted for as a purchase and, accordingly, we have included the results of operations in the financial statements effective January 12, 2009, the date of acquisition. The pro-forma effects of the acquisition were not material to our income statement and balance sheet. Ten employees of FlowMedica, Inc. became employees upon completion of the acquisition.

### *Acquisition of Certain Assets of Diomed*

On June 17, 2008, we completed the acquisition of certain U.S. assets of Diomed, Inc. and UK assets of Diomed UK Limited., in separate transactions, for an aggregate purchase price of approximately \$11.1 million in cash including capitalized acquisition costs. With this acquisition, we substantially strengthened our position in the market for the treatment of varicose veins. The combination of Diomed endovenous laser products with our existing venous product line provides us with a comprehensive venous product offering. The total of the net tangible assets acquired was \$5.5 million. Goodwill recorded as a result of these acquisitions was approximately \$1.9 million. Intangible assets acquired, other than goodwill, totaled approximately \$3.7 million of which \$3.6 million has been identified as customer relationships (8 -year estimated weighted average useful life) and \$100,000 has been identified as product technologies (10 -year estimated weighted average useful life).

The acquisition is being accounted for as a purchase and, accordingly, we have included the results of operations in the financial statements effective June 17, 2008, the date of acquisition. The pro-forma effects of the Diomed acquisition on our income statement and balance sheet were not material. Thirty five employees of Diomed became employees of ours upon completion of the acquisition.

### *Acquisition of Oncobionic*

On May 9, 2008, we completed the acquisition of all the issued and outstanding shares of capital stock of Oncobionic, Inc. pursuant to the terms of the Stock Purchase Agreement entered into on October 12, 2006. The closing of the acquisition came as a result of the successful use of irreversible electroporation (IRE) technology in the first human clinical trial for the treatment of soft tissue, conducted during the first week of April 2008.

Under the October 2006 Stock Purchase Agreement, we agreed to pay a total purchase price of \$25.4 million, including \$400,000 of assumed liabilities. We made payments of \$5.0 million upon the execution of the stock purchase agreement in October 2006, \$10.0 million on May 9, 2008 upon the closing of the acquisition, and \$5.0 million in November 2008. The remaining \$5.0 million is payable in November 2009.

The Stock Purchase Agreement also provides for future royalty payments due on net sales of any catheter-based products sold by us that incorporate irreversible electroporation technology ( IRE ). We hold a license to such technology under a license agreement with the Regents of the University of California (the UC License ).

We have accounted for the acquisition of Oncobionic as a purchase under accounting principles generally accepted in the United States of America. Under the purchase method of accounting, the assets and liabilities of Oncobionic were recorded as of the acquisition date, at their respective fair values, and consolidated with those of AngioDynamics. \$25.2 million of the purchase price was recorded as product technology and is being amortized over a 15 year useful life. We recorded goodwill and a deferred tax liability of \$9.3 million. In future periods the deferred tax liability will be reduced to offset the tax impact of non-deductible amortization expense

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on the intangible assets acquired. The pro-forma impact on prior year results of operations would be approximately \$1,680,000 of additional amortization expense or \$1,040,000, net of tax.

**(b) Narrative Description of Business**

**General**

Historically, we reported our results of operations as a single segment. Beginning June 1, 2008, we organized our business into three reportable segments: Peripheral Vascular, Access and Oncology/Surgery. The Peripheral Vascular segment is comprised of the venous, angiographic, PTA, drainage and thrombolytic product lines. The Access segment is comprised of the dialysis, ports and PICC product lines. The Oncology/Surgery segment is comprised of the RFA, embolization, Habib and NanoKnife product lines. Prior periods have been recast for net sales and gross profit for this new reporting structure.

Our principal competitive advantages are our dedicated market focus, established brands and innovative products. We believe our dedicated focus enhances patient care and engenders loyalty among our customers. As a provider of interventional devices for over 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.

In January 2007, we completed the acquisition of RITA Medical Systems, Inc., ( RITA ), which clarified our position, we believe, as the only company focused on minimally-invasive treatments for cancer patients with an emphasis on the growing segment of interventional oncology. This acquisition created a diversified medical technology company with a broad line of access, diagnostic and therapeutic products that enable interventional physicians and surgeons to treat peripheral vascular disease and cancerous tumors. Interventional oncology is a large and growing area for our existing customer base and RITA's leadership position, premium products and excellent reputation fit our strategy. RITA had a very strong position in vascular access ports, which are an ideal sales fit with our Morpheus<sup>®</sup> CT PICC. In addition, in May 2008 we acquired irreversible electroporation (IRE) technology which will be complementary to RITA's diverse offering of local oncology therapies, including its market-leading RFA systems, Habib Sealer<sup>™</sup> resection devices and LC Beads<sup>™</sup> for tumor embolization. We are in the process of commercializing the IRE technology. In June 2008, we completed the acquisition of certain U.S. and U.K. assets of Diomed, Inc. With this acquisition, we substantially strengthened our position in the market for the treatment of varicose veins. The combination of Diomed endovenous laser products with our existing venous product line provides us with a comprehensive venous product offering. In January 2009, we completed the acquisition of certain assets of FlowMedica, Inc. providing us with the Benephit product line, a therapeutic approach to deliver drugs directly to the kidneys in order to prevent and treat acute kidney injury, in the emerging field of Targeted Renal Therapy.

We sell our broad line of quality devices in the United States through a direct sales force and outside the U.S. through a combination of direct sales and distributor relationships. At May 31, 2009, our sales organization numbered 139 in the U.S. and 15 outside the U.S. including direct sales representatives, clinical specialists, and management personnel. For fiscal years 2009, 2008 and 2007, net sales outside the U.S. as a percentage of total net sales were 11.1%, 9.5%, and 6.3% respectively. Sales to any one country outside the U.S. 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, customer service representatives and other marketing specialists. Our dedicated sales force, growing portfolio of products and acquisitions have contributed to our strong sales growth.

**Peripheral Vascular Disease**

Peripheral vascular disease encompasses several 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

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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 older than 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.

### **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 more than 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 fall under three product groupings, which are paralleled by our organizational structure of three Strategic Business Units – Peripheral Vascular, Access and Oncology/Surgery.

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

We have registered a number of marks with the U.S. Patent and Trademark Office, including Pulse\*Spray; MORPHEUS CT; EVENMORE; ABSCSSION; TOTAL ABSCSSION; SPEEDLYSER; ANGIOFLOW; HYDROTIP; MEMORY TIP; SOS OMNI; StarBurst LifeJet; Circle C; Vortex; LifeGuard; NeoStar; LifeValve;



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Centros; DuraMax; SmartPort; Profiler; VenaCure EVLT; NanoKnife; Benephit; and SOFT-VU. This annual report on Form 10-K also contains trademarks of companies other than AngioDynamics.

## **PERIPHERAL VASCULAR**

The Peripheral Vascular Strategic Business Unit manages our Venous, Angiographic, PTA, Drainage, Thrombolytic Targeted Renal Therapy, Micro Access and Transjugular Access product lines.

### **Venous Products**

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

Our VenaCure EVLT 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 lengthy, painful and traumatic surgical procedure that involves significant patient recovery time. In contrast, venous 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 EVLT 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 family of disposable laser fiber components, training and marketing materials. The diode laser is a self-contained reusable instrument. The disposable components in the system include a 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 materials.

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 older than age 60 suffering from varicose veins, the market for this treatment is large and growing. We believe that Sotradecol®, a sclerosing drug approved by the FDA 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 than our laser-based VenaCure products and, most importantly, can be incorporated with some of our existing patented products. Bioniche Pharma Group Limited has appointed us the exclusive distributor to all persons in the United States of Sotradecol, 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. Sotradecol is the only FDA-approved sodium tetradecyl sulfate injection currently available in the United States.

### **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.

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

*SOFT-VU*<sup>®</sup>. Our proprietary SOFT-VU technology incorporates a soft, atraumatic tip that is easily visualized under fluoroscopy.

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

*Accu-Vu*<sup>™</sup>. 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*<sup>™</sup>. 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*<sup>®</sup>. 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.

## **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*<sup>®</sup>. The WORKHORSE product is a high-pressure, low-profile, non-compliant 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, low-profile, 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*<sup>®</sup>. The PROFILER is a low-profile, high-pressure, non-compliant, 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.

## **Drainage Products**

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

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Our line of drainage products consists of our TOTAL ABSCSSION® general drainage catheters, which we introduced in December 2005, and ABSCSSION® 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 ABSCSSION 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 ABSCSSION catheter permits aspiration while locked or unlocked thus allowing more accurate placement and greater versatility for draining complex situations.

## **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.

## **Targeted Renal Therapy**

With the acquisition of certain assets of FlowMedica on January 12, 2009, AngioDynamics purchased the Benephit product line – a therapeutic approach to deliver drugs directly to the kidneys in order to prevent and treat acute kidney injury. Benephit is representative of the emerging field of Targeted Renal Therapy, which is the delivery of therapeutic agents directly to the kidneys via the renal arteries as an alternative to the standard delivery method of systemic intravenous (IV) infusion to address kidney dysfunction related to a number of conditions, including cardiovascular, endovascular, surgical procedures and diseases. Systemic infusion often is associated with serious side effects such as hypotension. Clinicians have postulated that the amount of medication that reaches the kidneys via systemic infusion often does not attain therapeutic levels and therefore lead to treatment failure. As a result, physicians are now assessing the premise that Targeted Renal Therapy may maximize the benefit of medications because drugs can be delivered in therapeutic doses directly to the kidneys through the renal arteries. Targeted Renal Therapy can be used in numerous hospital settings including the Coronary Catheterization Laboratory, the Radiology Laboratory, the Surgical Suite, the Intensive Care Unit (ICU) and the Coronary Care Unit (CCU). Clinical use of FlowMedica's Benephit® CV Infusion System and Benephit XT Infusion System may prove beneficial to interventional cardiologists, interventional radiologists, nephrologists, and interventionally-skilled cardiothoracic and vascular surgeons.

## **Micro Access**

Our micro access sets provide interventional physicians a smaller introducer system for minimally-invasive procedures. AngioDynamics' Micro Access product line provides physicians with the means to build a custom set from the wide selection of configurations available, including four wires in two different lengths, seven needle options and three sheath dilator options.

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### **Transjugular Access**

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.

### **ACCESS**

The Access Strategic Business Unit manages our Dialysis, Port and PICC product lines.

### **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. Waste substances cannot be excreted when the kidneys malfunction, 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:

*DuraMax<sup>TM</sup>*. The DuraMax catheter is AngioDynamics' latest evolution of our market-leading, stepped-tip catheter design. It incorporates numerous design enhancements that improve ease of use, dialysis efficiency and overall patient outcomes. DuraMax is the initial dialysis catheter that is fully manufactured by AngioDynamics.

*SCHON<sup>TM</sup>*. 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.

*EVENMORE<sup>®</sup>*. The EVENMORE is a low-profile, end-hole design catheter that provides very efficient dialysis. It was designed for long-term use with our proprietary Durathane<sup>®</sup> shaft, which offers high resistance to chemicals used to clean the insertion site.

*DURA-FLOW<sup>TM</sup>*. 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<sup>®</sup>*. 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.

*LIFEJET<sup>®</sup> F-16*. The LIFEJET F-16 chronic dialysis catheter features a unique Circle C lumen design and the largest internal diameter available. This facilitates high flow rates while keeping arterial and venous pressures low.

We purchase some products from Medical Components, Inc., or Medcomp, and resell under our name, including 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.

### **Image-Guided Vascular Access**

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

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include the placement of peripherally inserted central catheter, or PICC, lines, implantable ports and central venous catheters, or CVCs.

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Our PICC products include:

*MORPHEUS® CT PICC. 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. 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.

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 harsh side effects of certain treatment protocols and eliminating the need for repeated access to peripheral veins. Depending upon needle gauge size and the port size, a port can be utilized for up to approximately 2,000 accesses once implanted in the body. Our 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.

Our port products and accessories include:

Our Vortex® line of ports is a clear-flow port technology that, we believe, 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 a 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. This product line consists of the following titanium, plastic and dual-lumen offerings within its family of products: (i) Vortex VX; (ii) Vortex TR; (iii) Vortex LP; and (iv) Vortex MP.

The Smart Port power-injectable port with Vortex technology is a new type of port that offers the ability for a clinician to access a vein for both the delivery of medications or fluids and for administering power-injected contrast to perform a Computed Tomography (CT) scan. The ability to access a port for power-injected contrast studies eliminates the need for additional needle sticks in the patient's arm and wrist veins. Once implanted, repeated access to the bloodstream can be accomplished with greater ease and less discomfort.

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.

Our central venous catheter products include:

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 patients.

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### **ONCOLOGY/SURGERY**

Oncology/Surgery includes our RFA, Embolization and IRE product lines.

#### **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 45-50°C, 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 5cm 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.

*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.





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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. In many cases where tumors recur, however, 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 that 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- 50°C, or 113-122°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<sup>®</sup> resection device under a distribution agreement with EMcision Limited. In addition to the intra-operative (open surgery) device HABIB 4X, AngioDynamics markets a minimally-invasive version of the HABIB 4X device, a Laparoscopic 4X unit, specifically indicated for clinical use in minimally invasive laparoscopic surgery (MILS) procedures in surgical specialties such as: Hepato-Biliary, GI, Surgical Oncology, Transplant Surgery and Urology (Partial Nephrectomy Resections).

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	<b>Product Name</b>	<b>Description</b>
<b>Disposable Electrodes:</b>	StarBurst	Creates a scalable 2-3cm ablation.
	StarBurst XL	Creates a scalable 3-5cm ablation.
	StarBurst SDE	Creates a 2cm ablation, via a side-deployed array.
	StarBurst Semi-Flex	Creates a scalable 3-5cm ablation and has a partially flexible shaft.
	StarBurst XLie	Creates a scalable 4-7cm ablation. Requires an accessory infusion pump for irrigation of saline. Attached tubing standard.
	StarBurst XLie	Creates a scalable 4-7cm ablation. Requires an accessory infusion pump for irrigation of saline. Attached tubing standard.
	Semi-Flex	Creates a scalable 2-4cm ablation. Requires an accessory infusion pump for irrigation of saline.
	StarBurst Talon:	Creates a scalable 2-4cm ablation. Requires an accessory infusion pump for irrigation of saline.
	Straight	Creates a scalable 2-4cm ablation. Requires an accessory infusion pump for irrigation of saline.
	StarBurst Talon:	Creates a scalable 2-4cm ablation. Requires an accessory infusion pump for irrigation of saline.
<b>Resection Device:</b>	Semi-Flex	Creates a scalable 2-4cm ablation. Requires an accessory infusion pump for irrigation of saline.
	HABIB® 4X	Surgical resection device.
<b>Generators:</b>	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 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. In addition, depending on product line, the devices are available in 10, 12, 15 or 25cm 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 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, 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.

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### **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 users the option of choosing an exact desired quantity.

### **NanoKnife Products**

Our recently introduced NanoKnife System is the first commercially available technology platform based on the principles of Irreversible Electroporation (IRE). IRE is for the surgical ablation of soft tissue. IRE utilizes high voltage electrical pulses to permanently open pores in target cell membranes. These permanent pores or nano-scale defects in the cell membranes result in cell death. The treated tissue is then removed by the body's natural processes in a matter of weeks mimicking natural cell death. Unlike other ablation technologies, IRE is non-thermal allowing targeted tissue elimination while sparing critical structures, such as ducts, blood vessels and nerves.

The Nanoknife IRE System consists of two major components: a Low Energy Direct Current (LEDC) Generator and needle-like electrode Probes. Up to six (6) electrode Probes can be placed into or around the targeted soft tissue. Once the Probes are in place, the user enters the appropriate parameters for voltage, number of pulses, interval between pulses, and the pulse length into the generator user interface. The generator then delivers a series of short electric pulses between each electrode Probe. The energy delivery is hyperechoic and can be monitored under real-time ultrasound.

Data gathered through bench, preclinical studies, and early human experience, suggest that the Nanoknife IRE System has the following characteristics:

Spares vital structures. Because IRE is non-thermal, vasculature, nerves and ducts remain intact. IRE enables ablation treatment at or near critical structures, resulting in selective tissue damage.

Eliminates heat sink issues seen with other ablation modalities. Since IRE is non-thermal, it is not susceptible to non-uniform ablation zones due to heat sinks (in the case of RFA) or heat sources (in the case of cryoablation).

Real-time imaging during IRE. An IRE ablation can be detected real-time with ultrasound and CT imaging. Moreover, these imaging modalities are not rendered useless during the procedure as is the case with ultrasound with RFA and cryoablation.

Tissue treated in organs that regenerate may be replaced by normal tissue.

Minimal to no pain reported by patients following treatment.



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### **Research & Development**

Our growth depends in large part on the continuous introduction of new and innovative products, together with ongoing enhancements to our existing products, through internal product development, technology licensing and strategic alliances. We recognize the importance of, and intend to continue to make investments in, research and development. For fiscal 2009, 2008 and 2007, our research and development ( R&D ) expenditures were \$17.9 million, \$14.4 million, and \$20.6 million, respectively, and constituted 9.2%, 8.7%, and 18.3%, respectively, of net sales. A significant portion of our R&D expenses in 2007 related to a 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 in 2007. R&D activities include research, product development, intellectual property and regulatory affairs. We expect that our R&D expenditures will be approximately 10% of net sales in fiscal 2010 primarily due to investment in IRE technology and remain in the range of 8 to 10% of net sales 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 currently, or in the future, may be treated using our products. Our primary device competitors include: Biosphere Medical (Direct LC Bead competitor); Boston Scientific Corporation; Cook Medical; Navilyst Medical; Cordis Corporation, a subsidiary of Johnson & Johnson, Inc.; C.R. Bard; Radionics, a division of Integra LifeSciences Corporation; Medical Components, Inc. or Medcomp; Arrow International, a subsidiary of TeleFlex Medical; Smith's Medical, a subsidiary of Smiths Group plc; EV3, Inc.; Kendall Healthcare, a subsidiary of Covidien; Vascular Solutions; and VNUS Medical, a company recently acquired by Covidien.

Medcomp supplies us with most of our dialysis catheters, but also competes with us by selling other catheters.

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. Additionally, competitors may 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 health care 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

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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 more than 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 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 an important method of communicating with our customers. We receive direct feedback from customers and present new ideas and products at these meetings. As these societies rely on industry participation and support in order to effectively hold these meetings, attendance also reflects our support and commitment to the medical societies.

### **Backlog**

Historically, we ship 95% of products sold in the United States within 48 hours of receipt of the orders, and accordingly our backlog is not significant.

### **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 and a 7,000 square foot manufacturing facility in Fremont, CA. We lease a manufacturing facility of approximately 20,000 square feet in the United Kingdom that we acquired in June 2008 in connection with our acquisition of certain assets of Diomed, Ltd. 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 are able to 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.

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 10% of our net sales for fiscal 2009. To date, we have been able to obtain adequate supplies of all product and components in a timely manner from existing sources.

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In fiscal 2009, 65% of our product sales were derived from products we manufactured or assembled ourselves, with the balance being derived from products man