

ANGIODYNAMICS INC  
Form 10-K  
August 01, 2016

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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended May 31, 2016

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 (I.R.S. Employer  
incorporation or organization) Identification No.)

14 Plaza Drive Latham, New York 12110  
(Address of principal executive offices) (Zip Code)  
Registrant's telephone number, including area code (518) 795-1400

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 per share NASDAQ Global Select Market

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

As of November 30, 2015, 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 \$431,798,128 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 22, 2016, there were 36,422,398 shares of the registrant's common stock outstanding.

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DOCUMENTS INCORPORATED BY REFERENCE

The information required for Part III of this annual report on Form 10-K is incorporated by reference to the registrant's Proxy Statement for its 2016 Annual Meeting of Stockholders to be filed within 120 days of the registrant's fiscal year ended May 31, 2016.

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## Part I

### Item 1. Business.

#### Overview

AngioDynamics, Inc. (together with its subsidiaries, "AngioDynamics," the "Company," "we," "our" or "us") designs, manufactures and sells a wide range of medical, surgical and diagnostic devices used by professional healthcare providers for vascular access, for the treatment of peripheral vascular disease and for use in oncology and surgical settings. Our devices are generally used in minimally invasive, image-guided procedures.

#### History

AngioDynamics was founded in 1988 and we completed our initial public offering in 2004, 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.

#### Products

Our product offerings fall within three product groupings: Peripheral Vascular, Vascular Access and Oncology/Surgery. All products discussed below have been cleared for sale in the United States by the FDA. International regulatory clearances vary by product and jurisdiction.

#### Peripheral Vascular Products

Our Peripheral Vascular products include Fluid Management, Venous, Thrombus Management, as well as other core products.

#### Fluid Management Products

Our Fluid Management product offering includes the NAMIC<sup>®</sup> Fluid Management portfolio. Since 1969, the NAMIC product line has been a leader in providing clinicians high quality, dependable devices that help in the diagnosis and treatment of cardiovascular and peripheral vascular disease. The NAMIC product line includes an extensive offering of manifolds, contrast management systems, closed fluid systems, guidewires, disposable transducers and interventional accessories. These devices are utilized together and allow clinicians to aspirate or inject contrast, saline, remove waste and monitor invasive blood pressures throughout the procedure.

#### Venous Products

Our venous products focus on the treatment of varicose veins and consist of our VenaCure EVLT<sup>®</sup> laser system, Asclera<sup>®</sup> (polidocanol) injection and Sotradecol<sup>®</sup>.

Our VenaCure EVLT laser system 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 whereby blood refluxes or does not return to the heart. Venous laser treatment is an outpatient procedure that generally allows the patient to quickly return to normal activities with minimal post-operative pain.

With our VenaCure EVLT laser system, laser energy is used to stop the reflux by ablating, or collapsing and destroying, the affected vein. The body subsequently re-routes the blood to other healthy veins. Our products are sold as a system that includes diode laser hardware with our family of disposable laser fiber components, training and

marketing materials. The disposable components in the system include a laser fiber system featuring our NeverTouch® gold-tip technology, an access sheath, access wires and needles. The procedure kits come in a variety of lengths and configurations to accommodate varied patient anatomies. Our VenaCure EVLT 1470 nanometer wavelength laser allows physicians to more efficiently heat the vein wall using lower power settings thereby reducing the risk of collateral damage.

Asclera® (polidocanol) injection is an FDA approved sclerosing drug that we distribute through a global agreement with the manufacturer and their distributor. Asclera is used for sclerotherapy to treat uncomplicated spider veins and uncomplicated reticular veins in the lower extremity. In a clinical study, it was proven to be 95% successful and patients were more satisfied with Asclera than alternative sclerosants.

Sotradecol® (sodium tetradecyl sulfate injection) is an FDA approved sclerosing drug that we distribute through a global agreement with the manufacturer. Sotradecol® has been shown to be an effective non-surgical treatment of small, uncomplicated varicose veins of the lower extremities that show simple dilation with competent valves.

#### Thrombus Management

Our Thrombus Management product offerings include our AngioVac and thrombolytic products.

#### AngioVac

In fiscal 2013, we released our AngioVac venous drainage system which includes a Venous Drainage Cannula and Cardiopulmonary Bypass Circuit. The AngioVac devices are for use with other manufacturer's off-the-shelf pump, filter, and reinfusion cannula, to facilitate venous drainage as part of an extracorporeal bypass procedure. The cannula is indicated for use as a venous drainage cannula and for removal of fresh, soft thrombi or emboli during extracorporeal bypass. The cardiopulmonary bypass circuit is indicated for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

The AngioVac venous drainage cannula is a 22F coil-reinforced cannula designed with a balloon actuated, expandable funnel shaped distal tip. The proprietary funnel shaped tip enhances venous drainage flow when the balloon is inflated, prevents clogging of the cannula with commonly encountered undesirable intravascular material, and facilitates en bloc removal of such extraneous material.

#### 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.

#### Core Products

Our other core peripheral vascular products include Angiographic products and accessories, drainage, micro access and other products.

#### Angiographic Products and Accessories

Angiographic products and accessories are used during peripheral vascular interventional procedures. 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 percutaneous transluminal angioplasty (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 and guidewires that are available in more than 500 tip configurations and lengths.

#### 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, The Total Abscession® Family of Drainage Catheters, consists of our Total Abscession General, Biliary, and Nephrostomy drainage catheters. These products feature our proprietary soft shaft with Blue Silk™

finish for a more comfortable patient fit. The kink-resistant shaft recovers rapidly, even if severely bent, knotted, or twisted. This is particularly beneficial when patients roll over and risk a potential kinking of the catheter during sleep. The thermal molded tip allows for less buckling and kinking upon insertion. Also important is that the shaft diameter equals the inner diameter of the catheter hub to maximize flow. Our Total Abscession drainage catheters feature a tamper-resistant locking mechanism called the Vault® which securely fixes the pigtail and prevents tampering or accidental removal. This locking mechanism helps to prevent the drain from becoming unlocked during routine use, thus reducing a physician's time by avoiding a possible "redo" case, and increasing patient satisfaction by not having to repeat the procedure. The Total Abscession catheter permits aspiration in the locked or unlocked position thus allowing more accurate placement and greater versatility for draining complex situations.



### Micro Access Kits

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

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

### BioFlo®

Our BioFlo products incorporate Endexo Technology into the manufacturing and design of our Vascular Access products. Endexo is a fluorine based additive that creates a non-eluting (permanent), non-heparin based catheter material that is designed to reduce thrombus accumulation and platelet adhesion to all surfaces of the catheter. BioFlo's long-term durability and efficacy is intended to provide clinicians a high degree of safety and confidence in providing better patient care and improved patient outcomes.

### PICC Products

A peripherally inserted central catheter, or PICC, is a long thin catheter that is inserted into a peripheral vein, typically in the upper arm, and advanced until the catheter tip terminates in a large vein in the chest near the heart to obtain intravenous access. PICCs can typically be used for prolonged periods of time and provide an alternative to central venous catheters. Our PICC product offerings include:

**BioFlo® PICC:** Our BioFlo line is the only power injectable PICC available that incorporates Endexo Technology into the manufacturing and design of the catheter. Advanced features such as large lumen diameters allow the BioFlo® PICC to deliver the power injection flow rates required for contrast-enhanced computed tomography (CT) scans compatible with up to 325 psi CT injections.

**Xcela PICC:** The Xcela® PICC line is designed to provide a high degree of safety, ease and confidence in patient care. Advanced features such as large lumen diameters allow the Xcela® PICC to deliver the power injection flow rates required for contrast-enhanced CTs compatible with up to 325 psi CT injections.

**PASV® Valve Technology:** The PASV® Valve Technology is available in both BioFlo and Xcela lines and is designed to automatically resist backflow and reduce blood reflux that could lead to catheter-related complications.

### Port Products

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:

**BioFlo® Port:** Our BioFlo line is the only port available that incorporates Endexo Technology into the manufacturing and design of the catheter. Advanced features include multiple profile and catheter options, a large septum area for ease of access and the ability to administer contrast through a CT (Computed Tomography) injection for purposes of imaging.

**SmartPort®:** The Smart Port power-injectable port with Vortex technology 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

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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. Our Smart Port is available in mini and low-profiles to accommodate more patient anatomies.

Vortex®: Our Vortex port technology line of ports is a clear-flow port technology that, we believe, revolutionized port design. With its rounded chamber, the Vortex port is designed to have no sludge-harboring corners or dead spaces. This product line consists of titanium, plastic and dual-lumen offerings.

PASV® Valve Technology: The PASV® Valve Technology is designed to automatically resist backflow and reduce blood reflux that could lead to catheter-related complications.

LifeGuard®: The LifeGuard Safety Infusion Set and The LifeGuard Vision are used to infuse our ports and complement our port and vascular access catheters. The needles' low profile design is intended to allow clinicians to easily dress the site.

### 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 (ESRD).

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

BioFlo®: Our BioFlo line is the only dialysis catheter available that incorporates Endexo Technology into the manufacturing and design of the catheter. Advanced features include large inner diameter lumens designed for long term patency, a proprietary guidewire lumen to facilitate catheter exchanges and Curved Tip Technology that allows the catheter to self-center in the SVC (Superior Vena Cava).

DuraMax®. The DuraMax catheter is a stepped-tip catheter designed to improve ease of use, dialysis efficiency and overall patient outcomes.

### Oncology / Surgery Products

Our Oncology/Surgery product offerings include our Microwave Ablation products, our Radiofrequency Ablation (RFA) and our NanoKnife product lines.

#### Microwave Ablation Products

The Acculis Microwave Tissue Ablation (MTA) System complements the full range of ablative technologies we offer. When configured for use with the Accu2i pMTA Applicators, it includes the Sulis VpMTA Generator, optional MTA Temperature Probes, Acculis Local Control Station (LCS) and Accu2i pMTA Applicators. Designed for physicians trained in image-guided ablation procedures, intraoperative ultrasound and/or CT guided needle placement, the system is used for thermal coagulation of soft tissue. By utilizing 2.45 GHz of microwave energy, the Acculis MTA System can complete ablations up to 5 cm in six minutes with a single applicator. Applicators are available in 14 cm, 19 cm and 29 cm lengths, offering flexibility in selecting the appropriate length for the procedure. Additionally, an antenna transmits energy directly to the targeted tissue, eliminating the need for electrosurgical grounding pads, while the single, simple to place insertion applicator eliminates the need to deploy an active array.

#### 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 targeted 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<sup>®</sup> Xli-enhanced disposable

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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.

The RFA system consists of a radiofrequency generator and a family of disposable devices. We also market the Habib<sup>®</sup> 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, which is used in minimally invasive laparoscopic surgery (MILS) procedures in surgical specialties such as: Hepato-Biliary, GI, Surgical Oncology, Transplant Surgery and Urology (Partial Nephrectomy Resections). It is clinically indicated to assist in coagulation of tissue during intraoperative and laparoscopic procedures.

#### NanoKnife<sup>®</sup> Ablation System Products

The NanoKnife<sup>®</sup> Ablation System is for the surgical ablation of soft tissue. The NanoKnife Ablation System utilizes low energy direct current 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, NanoKnife Ablation System does not achieve tissue ablation using thermal energy.

The NanoKnife Ablation System consists of two major components: a Low Energy Direct Current, or 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.

#### 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.

Our R&D 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 strong 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.

Our primary device competitors include: Boston Scientific Corporation; Cook Medical; C.R. Bard; Medical Components, Inc. (Medcomp); TeleFlex Medical; Smiths Medical, a subsidiary of Smiths Group plc; Vascular Solutions; Medtronic; Merit Medical; Terumo Medical Corporation; Johnson and Johnson and Total Vein Systems.

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, clinical outcomes, ease of use, reliability, physician familiarity and cost-effectiveness. 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 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 sell our broad line of quality devices in the United States primarily through a direct sales force and internationally through a combination of direct sales and distributor relationships. We support our customers and sales organization with a marketing staff that includes product managers, customer service representatives and other marketing specialists.

We focus our sales and marketing efforts on interventional radiologists, interventional cardiologists, vascular surgeons, urologists and interventional and surgical oncologists.

### Backlog

Historically, we ship the majority of products within 24-48 hours of receipt of the orders, and accordingly our backlog is not significant.

### Manufacturing

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.

We own or lease four primary manufacturing properties providing capabilities which include manufacturing, service, engineering and research, distribution warehouses and offices. These 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. 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" section of this report for additional information. See Item 2 "Properties" for details on each manufacturing location.

### Intellectual Property

Patents, trademarks and other proprietary rights are very important to our business. We also rely upon trade secrets, manufacturing know-how, technological innovations and licensing opportunities to maintain and improve our competitive position. We regularly monitor and review third-party proprietary rights, including patents and patent applications, as available, to aid in the development of our intellectual property strategy, avoid infringement of third-party proprietary rights, and identify licensing opportunities.

The company owns an extensive portfolio of patents and patent applications in the United States and in certain foreign countries. The portfolio also includes exclusive licenses to third party patents and applications.

Most of our products are sold under the AngioDynamics trade name or trademark. Additionally, many are also sold under product trademarks and/or registered product trademarks owned by AngioDynamics, Inc., or an affiliate or

subsidiary. Some products contain trademarks of companies other than AngioDynamics.

See Part I. Item 3 of this report for additional details on litigation regarding proprietary technology.

#### Litigation

We operate in an industry characterized by extensive patent litigation. Patent litigation can result in significant damage awards and injunctions that could prevent the manufacture and sale of affected products or result in significant royalty payments in order to continue selling the products. While it is not possible to predict the outcome of patent litigation incidents to our business, we believe the costs associated with this type of litigation could have a material adverse impact on our consolidated results of operations, financial position, or cash flows. The medical device industry is also susceptible to significant product liability claims. These claims may be brought by individuals seeking relief on their own behalf or



purporting to represent a class. In addition, product liability claims may be asserted against us in the future based on events we are not aware of at the present time. At any given time, we are involved in a number of product liability actions. For additional information, see both Part I. Item 3 of this report and Note O to the consolidated financial statements in this annual report on Form 10-K.

#### 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 international regulations to our specific target markets.

**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 (PMA).

The 510(k) procedure 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 preamendment status based upon products commercially distributed 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. The 510(k) clearance procedure including questions and responses, may take up to 12 months. 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 device cannot demonstrate substantial equivalence it may be subject to either a de novo submission or a PMA.

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 PMA procedure.

The process of FDA submissions requires extensive and expensive validations and testing. The financial outlay for this is large and requires a significant time period. Recent changes in both regulations and FDA perspectives have increased both time and testing requirements, this has caused significant delays and increased costs for approvals. The parameters for increased testing have and will continue to cause severe delays. The increased focus by the FDA on such issues as chemical identification of all colorants, non-acceptance of certain colorants (certain forms of carbon black) continue to cause problems and delays. In addition changes to existing products call into question previously approved devices and result in additional costs for testing and material analysis.

After a product is placed on the market, the product and its manufacturer 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, this has resulted in several suppliers altering price structures for medical device companies. The additional costs due to testing and potential for lawsuits due to material contamination or unforeseen chemical/allergenic reactions has led to some manufacturers actively refusing to supply to medical device companies. The financial expenditure needed to maintain compliance to the requirements of the FDA are extensive and ever increasing. Specific systems are needed to maintain compliance to baseline requirements. In addition complex systems are needed to ensure that specific violations such as 'off label promotion' are avoided. The FDA has specific requirements for labeling and marketing materials. These need extensive policing and evaluation in order to avoid falling foul of the vague FDA constraints. Penalties for breach of off label promotion can result in fines of several million dollars.

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 subassembly, 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. Penalties for failure to maintain compliance to the QSR include warning letters and potentially consent decrees. AngioDynamics has recently removed three warning letters, and the failure to maintain the QSR appropriately could result in the development of further warning letters. In addition 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. In addition, we are 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.

International 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 a dedicated set of regulations regarding medical devices, specifically regulating their design, manufacturing, 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 to the essential requirements of the applicable directives and can be commercially distributed in countries that are members of the European Union. Similar regulations are in place for Canada, Japan, China and most other countries.

In some cases, we rely on our international 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.

International 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.

The process of obtaining approval to distribute medical products is costly and time-consuming in virtually all of the major markets where we sell medical devices. We cannot assure that any new medical devices we develop will be approved in a timely or cost-effective manner or approved at all. 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 and Anti-Fraud and Corrupt Practices Regulation

United States - The delivery of our devices is subject to regulation by the Department of Health and Human Services (HHS) and comparable state and non-U.S. agencies responsible for reimbursement and regulation of health care items and services. U.S. laws and regulations are imposed primarily in connection with the Medicare and Medicaid programs, as well as the government's interest in regulating the quality and cost of health care. Foreign governments also impose regulations in connection with their health care reimbursement programs and the delivery of health care items and services.

U.S. federal health care laws apply when we or customers submit claims for items or services that are reimbursed under Medicare, Medicaid, or other federally-funded health care programs. The principal U.S. federal laws include: (1) the Anti-kickback Statute which prohibits offers to pay or receive remuneration of any kind for the purpose of including or rewarding referrals of items or services reimbursable by a federal health care program; (2) the False Claims Act which prohibits the submission of false or otherwise improper claims for payment to a federally-funded health care program, including claims resulting from a violation

of the Anti-kickback Statute; (3) the Stark law which prohibits physicians from referring Medicare or Medicaid patients to a provider that bills these programs for the provision of certain designated health services if the physician (or a member of the physician's immediate family) has a financial relationship with that provider; and (4) health care fraud statutes that prohibit false statements and improper claims to any third-party payer. There are often similar state false claims, anti-kickback, and anti-self-referral and insurance laws that apply to state-funded Medicaid and other health care programs and private third-party payers. In addition, the U.S. Foreign Corrupt Practices Act (FCPA) can be used to prosecute companies in the U.S. for arrangements with physicians or other parties outside the U.S. if the physician or party is a government official of another country and the arrangement violates the law of that country.

**International** - Our success in international 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 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 annual aggregate policy limit of \$10,000,000, subject to a self-insured retention of \$500,000 per occurrence and \$2,000,000 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.

There is no assurance 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 continue to 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