TELEFLEX INC
Form 10-K
February 24, 2014

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2013 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 1-5353

TELEFLEX INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	23-1147939
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
155 South Limerick Road, Limerick, Pennsylvania	19468
(Address of principal executive offices)	(Zip Code)

Registrant’s telephone number, including area code: (610) 948-5100

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 $1 per share	New York Stock Exchange

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

NONE

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, 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 x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the 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 the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer x 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 Act). Yes ¨ No x

The aggregate market value of the Common Stock of the registrant held by non-affiliates of the registrant (30,123,650 shares) on June 30, 2013 (the last business day of the registrant's most recently completed fiscal second quarter) was $2,334,281,638 [(1)] . The aggregate market value was computed by reference to the closing price of the Common Stock on such date.

The registrant had 41,216,674 Common Shares outstanding as of February 14, 2014.

DOCUMENT INCORPORATED BY REFERENCE:

Certain provisions of the registrant's definitive proxy statement in connection with its 2013 Annual Meeting of Shareholders, to be filed within 120 days of the close of the registrant's fiscal year, are incorporated by reference in Part III hereof.

(1) For the purposes of this definition only, the registrant has defined “affiliate” as including executive officers and directors of the registrant and owners of more than five percent of the common stock of the registrant, without conceding that all such persons are “affiliates” for purposes of the federal securities laws.

TELEFLEX INCORPORATED

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

TABLE OF CONTENTS

CERTIFICATION OF CHIEF FINANCIAL OFFICER, PURSUANT TO RULE 13a-14(a) UNDER THE EXCHANGE ACT
CERTIFICATION OF CHIEF EXECUTIVE OFFICER, PURSUANT TO RULE 13a-14(b) UNDER THE EXCHANGE ACT
CERTIFICATION OF CHIEF FINANCIAL OFFICER, PURSUANT TO RULE 13a-14(b) UNDER THE EXCHANGE ACT

Information Concerning Forward-Looking Statements

All statements made in this Annual Report on Form 10-K, other than statements of historical fact, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “will,” “would,” “should,” “guida “continue,” “project,” “forecast,” “confident,” “prospects” and similar expressions typically are used to identify forward-lookin statements. Forward-looking statements are based on the then-current expectations, beliefs, assumptions, estimates and forecasts about our business and the industry and markets in which we operate. These statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or implied by these forward-looking statements due to a number of factors, including:

- changes in business relationships with and purchases by or from major customers or suppliers, including delays or cancellations in shipments;
- demand for and market acceptance of new and existing products;
- our ability to integrate acquired businesses into our operations, realize planned synergies and operate such businesses profitably in accordance with expectations;
- our ability to effectively execute our restructuring programs;
- the impact of recently passed healthcare reform legislation and changes in Medicare, Medicaid and third-party coverage and reimbursements;
- competitive market conditions and resulting effects on revenues and pricing;
- increases in raw material costs that cannot be recovered in product pricing;
- global economic factors, including currency exchange rates, interest rates and sovereign debt issues;
- difficulties entering new markets; and
- general economic conditions.

For a further discussion of the risks relating to our business, see Item 1A “Risk Factors” in this Annual Report on Form 10-K. We expressly disclaim any obligation to update these forward-looking statements, except as otherwise specifically stated by us or as required by law or regulation.

PART I

ITEM 1. BUSINESS

Teleflex Incorporated is referred to herein as “we,” “us,” “our,” “Teleflex” and the “Company.”

THE COMPANY

Teleflex is a global provider of medical technology products that enhance clinical benefits, improve patient and provider safety and reduce total procedural costs. We primarily design, develop, manufacture and supply single-use medical devices used by hospitals and healthcare providers for common diagnostic and therapeutic procedures in critical care and surgical applications. We market and sell our products to hospitals and healthcare providers in more than 150 countries through a combination of our direct sales force and distributors. Because our products are used in numerous markets and for a variety of procedures, we are not dependent upon any one end-market or procedure. We manufacture our products at 27 manufacturing sites, with major manufacturing operations located in the Czech Republic, Germany, Malaysia, Mexico and the United States.

We are focused on achieving consistent, sustainable and profitable growth by increasing our market share and improving our operating efficiencies through:

- the development of new products and product line extensions;
- the investment in new technologies and broadening their applications;
- the expansion of the use of our products in existing markets, as well as the introduction of our products into new geographic markets;
- achieving economies of scale as we continue to expand, by leveraging our direct sales force and distribution network with new products, and increasing efficiencies in our manufacturing and distribution facilities; and
- the broadening of our product portfolio through select acquisitions, licensing arrangements and partnerships that enhance, extend or expedite our development initiatives or our ability to increase our market share.

Our research and development capabilities, commitment to engineering excellence and focus on low-cost manufacturing enable us to consistently bring cost effective, innovative products to market that improve the safety, efficacy and quality of healthcare. Our research and development initiatives focus on developing new, innovative products for existing and new therapeutic applications as well as enhancements to, and line extensions of, existing products. We introduced 27 new products and line extensions during 2013. Our portfolio of existing products and pipeline of potential new products consist primarily of Class I and Class II devices, which require 510(k) clearance by the United States Food and Drug Administration, or FDA, for sale in the United States. We believe that 510(k) clearance reduces our research and development costs and risks, and typically results in a shorter timetable for new product introductions as compared to the premarket approval, or PMA, process that would be required for Class III devices.

We also continue to broaden our product portfolio with select acquisitions. During 2013, we acquired:

- Vidacare Corporation, a provider of intraosseous, or inside the bone, access devices, which complements our vascular access and specialty product portfolios in our critical care product group;
- the assets of Ultimate Medical Pty. Ltd. and its affiliates, a supplier of airway management devices with a variety of laryngeal mask airways and other related products, which complement the anesthesia product portfolio in our critical care product group; and
- Eon Surgical, Ltd., a developer of a minimally invasive microlaparoscopy surgical platform technology designed to enhance surgeons’ ability to perform scarless surgery while producing better patient outcomes, which complements the product portfolio in our surgical care product group.

Similarly, in 2012, we broadened our product portfolio through the acquisition of substantially all of the assets of LMA International N.V. (LMA), a global provider of laryngeal masks whose products are used in anesthesia and emergency care. This acquisition enhanced our anesthesia product portfolio. In addition, consistent with our strategy to invest in new technologies and research and development to support our future growth, we completed four late-stage technology acquisitions during 2012.

See Note 3 to the consolidated financial statements included in this Annual Report on Form 10-K for a discussion of the acquisitions.

OUR PRODUCTS

We categorize our broad-based platform of products into four groups: Critical Care, Surgical Care, Cardiac Care and OEM and Development Services ("OEM"). The following charts set forth our net revenues by product group as a percentage of our total consolidated net revenues for the years ended December 31, 2013, 2012 and 2011.

The following table sets forth our net revenues for 2013, 2012 and 2011 by product group.

	2013	2012	2011
	(Dollars in millions)		
Critical Care	$1,182.7	$1,040.3	$1,005.4
Surgical Care	306.5	291.1	276.9
Cardiac Care	75.9	79.4	80.6
OEM and Development Services	131.2	140.2	129.6
Total net revenues	$1,696.3	$1,551.0	$1,492.5

We generally serve three end-markets: hospitals and healthcare providers, medical device manufacturers and home care. These markets are influenced by a number of factors, including demographics, utilization and reimbursement patterns. The following charts set forth the percentage of net revenues for the years ended December 31, 2013, 2012 and 2011 derived from each of our end markets.

The following charts set forth the percentage of our net revenues for the years ended December 31, 2013, 2012 and 2011 by major geographic region, based on the Teleflex facility generating the sale.

Critical Care

We are a leading provider of specialty products for critical care, which is predominantly comprised of single-use products. Our critical care products are used in a wide range of procedures for vascular access, anesthesia and airway management, respiratory therapy, treatment of urologic conditions and other specialty procedures. The large majority of our critical care products are sold to the hospitals and healthcare providers, with a smaller percentage sold to alternate sites, such as home care, emergency medical services (EMS), long term care centers, primary care centers, hospice and animal health facilities. Our critical care product group is our largest product group, representing 70 percent of net revenues in 2013.

Vascular Access

Our vascular access products, which accounted for 33 percent of our Critical Care net revenues in 2013, facilitate a variety of critical care therapies, including the administration of intravenous medications and other therapies and the measurement of blood pressure and taking of blood samples through a single puncture site.

Our vascular access catheters and related devices consist principally of the following:

- ARROW® central venous catheters, or CVCs, are inserted in the neck or shoulder area, come in multiple lengths and up to four channels, or lumens. The ARROW CVC has a pressure injectable option which gives clinicians who perform contrast-enhanced CT scans the ability to use an indwelling pressure injectable ARROW CVC to inject contrast dye for their scan without having to insert a second catheter.
- ARROW arterial catheterization sets facilitate arterial pressure monitoring and blood withdrawal for glucose, blood-gas and electrolyte measurement in a wide variety of critical care and intensive care settings.
- ARROW peripherally inserted central catheters, or PICCs, are soft, flexible catheters that are inserted in the upper arm and advanced into the superior vena cava to administer various types of intravenous medications and therapies. ARROW PICCs have a pressure injectable option that can withstand the higher pressures required by the injection of contrast media for CT scans.
- ARROW percutaneous sheath introducers are used to insert cardiovascular and other catheterization devices into the vascular system during critical care procedures.
- ARROW jugular axillo-subclavian central catheters, or JACC, with Chlorag+ard® technology provide an alternative to traditional acute CVCs and peripheral central venous access. Introduced in 2013, this CVC for acute or long-term use combines antimicrobial and antithrombogenic protection with smaller french sizes to meet the unique challenges posed by patients today. This product is ideal for patients with renal issues, chronic patients with poor peripheral access or those with a history of or risk for venous thrombosis.
- The ARROW VPS, is an advanced vascular positioning system that facilitates precise placement of a PICC or CVC within the heart. The ARROW VPS analyzes multiple metrics, in real time, from its biosensor to help clinicians navigate through the vasculature and precisely identify the correct catheter tip placement in the heart. Approved by the FDA as an alternative to chest x-ray confirmation, the ARROW VPS helps to shorten hospital stays while lowering costs associated with catheter insertion procedures. In 2013, we launched the next generation of our ARROW VPS, the ARROW VPS G4™, which provides further enhancements to our VPS technology, such as statement of final catheter position, improved sterile field capability and integration with hospital data management systems.

- The Vidacare EZ-IO® system, added to our vascular product portfolio through our acquisition of Vidacare Corporation in December 2013, provides immediate vascular access for the delivery of medications and fluids via the intraosseous route, or in the bone, when traditional vascular access is difficult or impossible. In emergency situations, EZ IO enables fast access to deliver lifesaving therapies to help stabilize a patient until a traditional catheter can be inserted.

The large majority of our CVCs are treated with the ARROWg+ard or ARROWg+ard Blue Plus antimicrobial surface treatments to reduce the risk of catheter related bloodstream infection. ARROWg+ard Blue Plus provides antimicrobial treatment of the interior lumens and hubs of each catheter. The Chlorag+ard technology, an option on our PICC catheters, provides both antimicrobial and anti thrombogenic protection for up to 30 days. These surface treatments help reduce healthcare acquired conditions, such as Catheter Related Blood Stream Infection (CRBSI), potentially saving the hospitals significant cost under the new pay for performance standards.

We also offer many of our vascular access catheters in a Maximal Barrier Precautions Tray. The tray is available for CVCs, PICCs and multi access catheters (MAC) and includes a full body drape, coated or non-coated catheter and other accessories. These kits are designed to assist healthcare providers in complying with guidelines for reducing catheter-related bloodstream infections that have been established by a variety of health regulatory agencies, such as the Centers for Disease Control and Prevention and the Joint Commission on the Accreditation of Healthcare Organizations. Our newer ErgoPACK system provides components which are packaged in the tray in the order in which they will be needed during the procedure and incorporates features intended to enhance ease of use and patient and provider safety.

We believe that our vascular product portfolio offers the opportunity to reduce injuries to the healthcare provider, expedite placement of a central venous catheter, reduce patient exposure to x-rays, expedite infusion of medication and reduce the risk of catheter related infection and thrombosis for the patient. Moreover, we believe our products can help hospitals achieve reduced costs, improved quality and patient outcomes and increased patient satisfaction.

Anesthesia

Our anesthesia products, described below, include airway and pain management products and accounted for 31 percent of our Critical Care product net revenues in 2013.

Airway Management

Our airway management products, marketed under the LMA® and Rusch® brands, are designed to help eliminate airway related complications and improve procedural efficiencies for patients in surgical, critical care and emergency settings.

The LMA laryngeal mask products are used in anesthesia and emergency care. The Rusch brand of products includes reusable and disposable laryngoscope blades and handles, endotracheal tubes, endobronchial tubes, oral and nasal airways, endobronchial blockers, and other accessories.

As a result of our acquisition of the Ultimate Medical business in 2013, we now offer Ultimate Medical's broad range of laryngeal mask airways, including the Cuff Pilot™, an integrated cuff pressure indicator for single-use airway management devices. The Cuff Pilot is a single-use device that provides constant inside-the-cuff pressure indication, enabling at-a-glance clinical assessments. The Cuff Pilot technology is currently used with our Ultimate Medical portfolio of laryngeal masks and has potential application for use with LMA™ laryngeal masks and Rusch endotracheal and tracheostomy tubes.

In 2013, we introduced the Rusch TruLite™ Laryngoscope System, a disposable laryngoscope blade and handle system for single-patient use. Rusch single use laryngoscope eliminates the potential risk of patient cross-contamination and the cost of maintaining reusable laryngoscopes.

In 2012, we acquired the EZ-Blocker Endobronchial Blocker, which is designed to provide an improved alternative to double lumen endobronchial tubes and single balloon bronchial blockers to achieve lung isolation. The EZ-Blocker Endobronchial Blocker's Y-shaped distal end enables effective placement of the balloons in the right or left bronchus when performing thoracic surgical procedures, while also enabling secure placement at the carina. This placement minimizes the need to manipulate the catheter after placement, reducing the potential of cuffs becoming dislodged.

Pain Management

Our portfolio of pain management products are marketed under the Arrow brand and are designed to provide pain relief during a broad range of surgical and obstetric procedures, thereby helping clinicians better manage each patient's individual pain while reducing complications and associated costs. Our pain management products include epidural catheters and trays, spinal needles and trays and peripheral nerve block needles, catheters, trays and ambulatory pain pumps.

In 2013, we expanded our pain management portfolio by adding the Arrow AutoFuser® disposable pain pump. The AutoFuser pump is designed to provide an accurate and flexible method to deliver analgesic medication for continuous peripheral nerve block or site-specific applications, helping physicians to take control of patients' post-operative pain to promote faster recovery and reduce overall length of stay. AutoFuser pain pumps are available in three different sizes with a selection of fixed or variable basal infusion rates, allowing physicians to customize their patients' pain protocol. The parallel bolus feature enables patients to administer a controlled amount of additional anesthetic to the target site without interrupting the continuous infusion of medication, providing an effective method to manage pain, which is a common post-operative challenge.

This AutoFuser pain pump can be used in conjunction with the recently introduced Arrow FlexBlock™ continuous peripheral nerve block catheter. The FlexBlock catheter features an echogenic, coil-reinforced design that offers a combination of ultrasound visibility, flexibility and excellent kink resistance.

We offer a variety of single shot nerve block needles, including the ARROW UltraQuik™, StimuQuik® and StimuQuik ECHO, providing solutions to clinicians performing peripheral nerve blocks, whether they use ultrasound only, nerve stimulation only, or a combined approach. We commenced sales of Arrow UltraQuik peripheral nerve block needles in 2013. These echogenic needles are designed to help increase overall block success for clinicians who use ultrasound-guidance when performing single-injection peripheral nerve blocks. UltraQuik needles maintain many of the same features as the Arrow StimuQuik ECHO needles, including five grooved rings at the distal tip of the needle to help clinicians identify the needle tip under ultrasound.

Respiratory Care

Our respiratory care products accounted for 15 percent of our Critical Care product net revenues in 2013. Our Hudson RCI brand has been a leader in respiratory care for more than 65 years, providing innovative products designed to help clinicians improve patient outcomes while reducing costs. Our respiratory products are used in a variety of care settings and include oxygen therapy products, including oxygen masks, cannulas, humidifiers and tubing; aerosol therapy products, including small and large volume nebulizers, peak flow meters and aerosol chambers; spirometry products, including incentive breathing exercisers; and ventilation management products, including ventilator circuits, humidification devices and bacteria/virus filters.

In 2013, for the second consecutive year, we were among the six companies to receive the Zenith Award awarded by the American Association for Respiratory Care (AARC) in recognition of the quality products, programs and support provided to the respiratory community.

In 2013 we received FDA 510(k) clearance for our ISO-Gard® Mask with ClearAir™ Technology, a new product that helps to reduce clinician exposure to hazardous waste anesthetic gases (WAG), which are commonly used in surgical procedures globally. When patients are recovering in the post anesthesia care unit (PACU) of a hospital, they typically exhale these gases into the nurses' breathing zone and work environment. The Occupational Safety and Health Administration (OSHA) has noted of several potential adverse health effects from WAG exposure, including nausea, dizziness, headaches and fatigue.

The ISO-Gard Mask is designed to reduce WAG within a nurse's breathing zone to minimize the cumulative effect of low-level exposure to these hazardous gases in the PACU. The multi-purpose mask collects and removes, or scavenges, WAG while simultaneously delivering oxygen to the patient. The patent-pending ClearAir technology creates a unidirectional flow of oxygen through the nasal/oral area of the patient for inhalation, while negative pressure or suction is applied to the port in the lower portion of the mask to scavenge the patient's exhalation. By providing a means to reduce the amount of WAG within the breathing zone of the caregiver, hospitals can better comply with OSHA and the National Institute for Occupational Safety and Health's recommendations for workplace safety.

Specialty

Our specialty products accounted for 21 percent of our Critical Care product net revenues in 2013. Specialty products include interventional access products as well as products provided to specialty market customers. Interventional access products focus on dialysis, oncology and critical care at hospitals. Products sold to specialty market customers, including home care, pre-hospital and other alternative channels of care, focus on urology, respiratory and anesthesia products.

Our specialty product line of urology products provides bladder management for patients in the hospital and individuals in the home care markets. The product portfolio consists principally of a wide range of catheters (including Foley, intermittent, external and suprapubic), urine collectors, catheterization accessories and products for operative endourology marketed under the Rusch brand name.

The Gibeck® TRACH-VENT® HME family of products are designed to provide humidification for spontaneously breathing tracheostomized patients. In November 2012, we introduced the Gibeck TRACH VENT T with 5mm Collar. This HME (Heat and Moisture Exchanger) provides optimal moisture via Gibeck Microwell paper while accommodating all patient sizes.

Over the past few years, we have continued to expand our specialty product offerings to include a wider range of intermittent catheters, catheter insertion kits and accessories used mainly for people with spinal cord injury, spina bifida, and multiple sclerosis. Many of these products are designed to support user safety and infection prevention efforts. For example, an intermittent catheter with hydrophilic coating, an ergothan tip, protective sleeve and sterile saline solution is marketed in our EMEA region. In the United States, we recently expanded our hydrophilic coated intermittent catheter line to include female lengths, coudés for difficult catheterizations, as well as complete sterile insertion kits for both standard (male) and female lengths. The uncoated intermittent catheter line in the United States was also expanded recently to include a full range of female length catheters and a complete offering of sterile insertion kits for the standard (male), coudé, and female styles.

Sales of our specialty intermittent catheters in the United States have benefited from a change in reimbursement policy. Home care markets are subject to local and regional reimbursement regulations that can impact volumes and pricing. In the United States, reimbursement regulations were implemented in 2008 that permit reimbursement for up to 200 catheters per month, replacing the previous limit of four catheters per month. The change promoted a shift from re-useable catheters, with their inherent risk of infections, to single-use intermittent catheters.

Our interventional access products are used in a wide range of applications, including dialysis, oncology and critical care. Dialysis products include the ARROW branded long term hemodialysis catheters, antimicrobial acute hemodialysis catheters and the ARROW-Trerotola™ Percutaneous Thrombectomy Device. Our long term hemodialysis catheter portfolio offers both antegrade and retrograde insertion options for both split and step tip configurations. The most recent addition of the NextStep® Retrograde Femoral Length catheter completed the product portfolio in June 2013 after FDA 510(k) clearance. The ARROW acute hemodialysis catheters are available with ARROWg+ard antimicrobial technology which reduces the risk catheter related bacteremia.

In addition, our recent acquisition of Vidacare expanded our specialty products portfolio by adding the Vidacare EZ-IO Intraosseous Vascular Access, OnControl® Bone Marrow and OnControl Bone Access systems to the products we offer to our interventional access and specialty markets customers. As previously described, the Vidacare EZ-IO Intraosseous Vascular Access system provides immediate vascular access via the intraosseous route, enabling emergency care providers to quickly administer critical medications and fluids, particularly when traditional vascular access is difficult or impossible. Vidacare's OnControl Bone Marrow System enables rapid and safe access for hematology and oncology diagnostic practices. The Vidacare OnControl Bone Access System provides rapid and safe

access for surgical bone applications, such as vertebroplasty and the biopsy of the vertebral body and bone lesions.

The ARROW Polysite® Low Profile Hybrid Port received FDA 510(k) clearance in December 2013. Available with or without pressure injection capability, the hybrid design combines a lightweight plastic body for patient comfort and a strong titanium reservoir for durability.

Interventional access products also include several ARROW branded products for Critical Care applications, including diagnostic and drainage kits, embolectomy balloons, and reinforced percutaneous sheath introducers.

Surgical Care

Our surgical care products sales represented 18 percent of our net revenues in 2013. Our surgical products, which are predominantly comprised of single-use products, include: ligation and closure products, including appliers, clips and sutures used in a variety of surgical procedures; access ports used in minimally invasive surgical procedures, including robotic surgery; and fluid management products used for chest drainage. Our surgical products also include reusable hand-held instruments for general and specialty surgical procedures. We market our surgical products under the Deknatel, Pilling, Pleur-evac, Taut and Weck brand names.

In 2013 we added a microlaparoscopic product line to the surgical portfolio, designed to enhance surgeons' ability to perform scarless surgery while producing better patient outcomes. Microlaparoscopy, unlike NOTES (Natural Orifice Translumenal Endoscopic Surgery), or single incision surgery, provides surgeons a mechanism for performing minimally invasive procedures without significant changes in technique. The technology may be utilized for an entire procedure or as an adjunct to existing approaches that require additional access without adding to larger incisions and the associated risks. This product line is expected to generate revenues in late 2014.

In 2012 we launched the Weck EFx™ Endo Fascial Closure System, a port site closure device used in laparoscopic surgical procedures. The Weck EFx System encompasses a design for port site closure that enables reproducible fascial closure in varying body types with a controlled suture delivery. This approach to port site closure is designed to minimize complications and costs associated with port-site herniation.

Hem-o-lok, a significant part of the Weck portfolio, is a unique locking polymer ligation clip that combines the security of a suture with the speed of a metal clip for open and laparoscopic surgery. Hem-o-lok clips have special applications in robotic, laparoscopic and cardiovascular surgery.

Cardiac Care

Cardiac Care products accounted for approximately 4 percent of net revenues in 2013. Products in this category include diagnostic catheters and capital equipment. Our diagnostic catheters include thermodilution and wedge pressure catheters; specialized angiographic catheters, such as Berman and Reverse Berman catheters; therapeutic delivery catheters, such as temporary pacing catheters; sheaths for femoral and trans-radial aortic access used in diagnostic and therapeutic procedures; and intra-aortic balloon, or IAB, catheters. Capital equipment includes our intra-aortic balloon pump, or IABP, consoles. IABP products are used to augment oxygen delivery to the cardiac muscle and reduce the oxygen demand after cardiac surgery, serious heart attack or interventional procedures. We market our cardiac care products under the Arrow brand name.

The IAB and IABP product lines feature the AutoCAT 2 WAVE console and the FiberOptix catheter, which together utilize fiber optic technology for arterial pressure signal acquisition and enable the patented WAVE timing algorithm to support the broadest range of patient heart rhythms, including severely arrhythmic patients.

OEM and Development Services

Product development and production services marketed to original equipment manufacturers, or OEMs, represented 8 percent of our net revenues in 2013. Our OEM division, which includes the TFX OEM® and Deknatel® OEM nameplates, provides custom-engineered extrusions, diagnostic and interventional catheters, sheath/dilator sets (introducers) and kits, sutures, performance fibers, and bioresorbable resins and fibers. We offer an extensive portfolio of integrated capabilities, including engineering, material selection, regulatory affairs, prototyping, testing and validation, manufacturing, assembly, and packing.

HISTORY AND RECENT DEVELOPMENTS

Teleflex was founded in 1943 as a manufacturer of precision mechanical push/pull controls for military aircraft. From this original single market, single product orientation, we have grown and evolved through entries into new businesses, development of new products, introduction of products into new geographic or end-markets and through acquisitions of companies. Throughout our history, we have continually focused on providing innovative, technology-driven, specialty-engineered products that help our customers meet their business requirements.

Over the past several years, we have significantly changed the composition of our portfolio of businesses, expanding our presence in the medical device industry, while divesting all of our businesses serving the aerospace, automotive, industrial and marine markets. The most significant of these transactions occurred in 2007 with our acquisition of Arrow

International, a leading global supplier of catheter-based medical technology products used for vascular access and cardiac care, and the divestiture of our automotive and industrial businesses. Our acquisition of Arrow significantly expanded our single-use product offerings for critical care, enhanced our global footprint and added to our research and development capabilities. With the divestitures of our marine business and cargo container and systems businesses in 2011, we became exclusively a medical device company.

We expect to continue to increase the size of our business through a combination of acquisitions and organic growth initiatives. From time to time, we explore and engage in discussions regarding acquisitions that would augment our existing medical device platform.

GOVERNMENT REGULATION

We are subject to comprehensive government regulation both within and outside the United States relating to the development, manufacture, sale and distribution of our products.

Regulation of Medical Devices in the United States

All of our medical devices manufactured or sold in the United States are subject to the Federal Food, Drug, and Cosmetic Act ("FDC Act"), as implemented and enforced by the FDA. The FDA and, in some cases, other government agencies administer requirements for the design, testing, safety, effectiveness, manufacturing, labeling, storage, record keeping, clearance, approval, advertising and promotion, distribution, post-market surveillance, import and export of our medical devices.

Unless an exemption applies, each medical device that we market must first receive either clearance (by submitting a premarket notification ("510(k)")) or approval (by filing a premarket approval application ("PMA")) from the FDA pursuant to the FDC Act. To obtain 510(k) clearance, a manufacturer must demonstrate that the proposed device is substantially equivalent to a legally marketed device, referred to as the predicate device. Substantial equivalence is established by the applicant showing that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics or has been shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device. The FDA's 510(k) clearance process usually takes from four to twelve months, but it can last longer. A device that is not eligible for the 510(k) process because there is no predicate device may be reviewed through the de novo process. A device not eligible for 510(k) clearance must follow the PMA approval pathway, which requires proof of the safety and effectiveness of the device to the FDA's satisfaction. The process of obtaining PMA approval is much more costly, lengthy and uncertain than the 510(k) process. It generally takes from one to three years or even longer. Our portfolio of existing products and pipeline of potential new products consist primarily of Class I and Class II devices that require 510(k) clearance. In addition, modifications made to devices after they receive clearance or approval may require a new 510(k) clearance or approval of a PMA or PMA supplement. We cannot be sure that 510(k) clearance or PMA approval will be obtained for any device that we propose to market.

A clinical trial is almost always required to support a PMA application and is sometimes required for a 510(k). The sponsor of a clinical study must comply with and conduct the study in accordance with the applicable federal regulations, including FDA's investigational device exemption ("IDE") requirements, and good clinical practice ("GCP"). Clinical trials must also be approved by an institutional review board, or IRB, which is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects and which has the authority to approve, require modifications in, or disapprove research to protect the rights, safety, and welfare of the human research subject. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. An IRB

may also require the clinical trial at the site to be halted for failure to comply with the IRB's requirements, or may impose other conditions.

After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include the following:

- device listing and establishment registration;
- adherence to the Quality System Regulation ("QSR") which requires stringent design, testing, control, documentation, complaint handling and other quality assurance procedures;
- labeling requirements;
- FDA prohibitions against the promotion of off-label uses or indications;

- adverse event reporting;
- post-approval restrictions or conditions, including post-approval clinical trials or other required testing;
- post-market surveillance requirements;
- the FDA's recall authority, whereby it can ask for the recall of products from the market; and
- voluntary corrections or removals reporting and documentation.

In September 2013, the FDA issued final regulations and draft guidance documents regarding the Unique Device Identification ("UDI") System, which will require manufacturers to mark certain medical devices with unique identifiers. While the FDA expects that the UDI System will help track products during recalls and improve patient safety, it will require us to make changes to our manufacturing and labeling, which could increase our costs. The UDI System is being implemented in stages based on device risk, with the first requirements taking effect in September 2014 and the last taking effect in September 2020.

Our manufacturing facilities, as well as those of certain of our suppliers, are subject to periodic and for-cause inspections to verify compliance with the QSR as well as other regulatory requirements.

If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, it could institute a wide variety of enforcement actions, ranging from issuance of a warning or untitled letter to more severe sanctions, such as product recalls or seizures, civil penalties, consent decrees, injunctions, criminal prosecution, operating restrictions, partial suspension or total shutdown of production, refusal to permit importation or exportation, refusal to grant, or delays in granting, clearances or approvals or withdrawal or suspension of existing clearances or approvals. The FDA also has the authority to request repair, replacement or refund of the cost of any medical device manufactured or distributed by us. Any of these actions could have an adverse effect on our business.

Regulation of Medical Devices Outside of the United States

Medical device laws also are in effect in many of the markets outside of the United States in which we do business. These laws range from comprehensive device approval requirements for some or all of our products to requests for product data or certifications. Inspection of and controls over manufacturing, as well as monitoring of device-related adverse events, are components of most of these regulatory systems.

Healthcare Laws

We are subject to various federal, state and local laws in the United States targeting fraud and abuse in the healthcare industry. These laws prohibit us from, among other things, soliciting, offering, receiving or paying any remuneration to induce the referral or use of any item or service reimbursable under Medicare, Medicaid or other federally or state financed healthcare programs. Violations of these laws are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. In addition, we are subject to federal and state false claims laws in the United States that prohibit the submission of false payment claims under Medicare, Medicaid or other federally or state funded programs. Certain marketing practices, such as off-label promotion, and violations of federal anti-kickback laws may also constitute violations of these laws.

We are also subject to various federal and state reporting and disclosure requirements related to the healthcare industry. Recent rules issued by the Centers for Medicare & Medicaid Services (CMS) require us to collect and, beginning in March 2014, report information on payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The reported data will be posted in searchable form on a public website beginning September 30, 2014. Failure to submit required information may result in civil monetary penalties. In addition, several states now require medical device companies to report expenses relating to the marketing and promotion of device products and to report gifts and payments to individual

physicians in these states. Other states prohibit various other marketing-related activities. The federal government and still other states require the posting of information relating to clinical studies and their outcomes. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with the different compliance and/or reporting requirements among a number of jurisdictions increases the possibility that a healthcare company may run afoul of one or more of the requirements, resulting in increased compliance costs that could adversely impact our results of operations.

Other Regulatory Requirements

We are also subject to the United States Foreign Corrupt Practices Act and similar anti-bribery laws applicable in jurisdictions outside the United State that generally prohibit companies and their intermediaries from improperly offering or paying anything of value to non-United States government officials for the purpose of obtaining or retaining business. Because of the predominance of government-sponsored healthcare systems around the world, most of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our policies mandate compliance with these anti-bribery laws. We operate in many parts of the world that have experienced governmental corruption to some degree, and in certain circumstances strict compliance with anti-bribery laws may conflict with local customs and practices. In the sale, delivery and servicing of our medical devices and software outside of the United States, we must also comply with various export control and trade embargo laws and regulations, including those administered by the Department of Treasury's Office of Foreign Assets Control ("OFAC") and the Department of Commerce's Bureau of Industry and Security ("BIS") which may require licenses or other authorizations for transactions relating to certain countries and/or with certain individuals identified by the United States government. Despite our global trade and compliance program, our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these requirements are punishable by criminal or civil sanctions, including substantial fines and imprisonment.

COMPETITION

The medical device industry is highly competitive. We compete with many companies, ranging from small start-up enterprises to companies that are larger and more established than us and have access to significantly greater financial resources. Furthermore, extensive product research and development and rapid technological advances characterize the market in which we compete. We must continue to develop and acquire new products and technologies for our businesses to remain competitive. We believe that we compete primarily on the basis of clinical superiority and innovative features that enhance patient benefit, product reliability, performance, customer and sales support, and cost-effectiveness. Our major competitors include C. R. Bard, Inc., Covidien and CareFusion.

SALES AND MARKETING

Our product sales are made directly to hospitals, healthcare providers, distributors and to original equipment manufacturers of medical devices through our own sales forces and through independent representatives and through independent distributor networks.

BACKLOG

Most of our products are sold to hospitals or healthcare providers on orders calling for delivery within a few days or weeks, with longer order times for products sold to medical device manufacturers. Therefore, our backlog of orders is not indicative of probable revenues in any future 12-month period.

PATENTS AND TRADEMARKS

We own a portfolio of patents, patents pending and trademarks. We also license various patents and trademarks. Patents for individual products extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. Trademark rights may potentially extend for longer periods of time and are dependent upon national laws and use of the marks. All capitalized product names throughout this document are trademarks owned by, or licensed to, us or our subsidiaries. Although these have been of value and are expected to continue to be of value in the future, we do not consider any single patent or trademark,

except for the Teleflex and Arrow brands, to be essential to the operation of our business.

SUPPLIERS AND MATERIALS

Materials used in the manufacture of our products are purchased from a large number of suppliers in diverse geographic locations. We are not dependent on any single supplier for a substantial amount of the materials used or components supplied for our overall operations. Most of the materials and components we use are available from multiple sources, and where practical, we attempt to identify alternative suppliers. Volatility in commodity markets, particularly steel and plastic resins, can have a significant impact on the cost of producing certain of our products. We may not be able to successfully pass these cost increases through to all of our customers, particularly original equipment manufacturers.

RESEARCH AND DEVELOPMENT

We are engaged in both internal and external research and development. Our research and development costs principally relate to our efforts to bring innovative new products to the markets we serve, and our efforts to enhance the clinical value, ease of use, safety and reliability of our existing product lines. Our research and development efforts support our strategic objectives to provide safe and effective products that reduce infections, improve patient and clinician safety, enhance patient outcomes and enable less invasive procedures. Our research and development expenditures were $65.0 million, $56.3 million and $48.7 million for the years-ended December 31, 2013, 2012 and 2011, respectively.

We also acquire or license products and technologies that are consistent with our strategic objectives and enhance our ability to provide a full range of product and service options to our customers.

SEASONALITY

Portions of our revenues are subject to seasonal fluctuations. Incidence of flu and other disease patterns as well as the frequency of elective medical procedures affect revenues related to single-use products. Historically, we have experienced higher sales in the fourth quarter as a result of these factors.

EMPLOYEES

We employed approximately 11,400 full-time and temporary employees at December 31, 2013. Of these employees, approximately 3,000 were employed in the United States and 8,400 in countries other than the United States. Approximately 5 percent of our employees in the United States and in other countries were covered by union contracts or collective-bargaining arrangements. We believe we have good relationships with our employees.

ENVIRONMENTAL

We are subject to various environmental laws and regulations both within and outside the United States. Our operations, like those of other medical device companies, involve the use of substances regulated under environmental laws, primarily in manufacturing and sterilization processes. While we continue to make capital and operational expenditures relating to compliance with existing environmental laws and regulations, we cannot ensure that our costs of complying with current or future environmental protection, health and safety laws and regulations will not exceed our estimates or have a material adverse effect on our business, financial condition, results of operations and cash flows. Further, we cannot ensure that we will not be subject to additional environmental claims for personal injury or cleanup in the future based on our past, present or future business activities.

INVESTOR INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Therefore, we file reports, proxy statements and other information with the Securities and Exchange Commission (SEC). Copies of such reports, proxy statements, and other information may be obtained by visiting the Public Reference Room of the SEC at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a website (http://www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

You can access financial and other information about us in the Investors section of our website, which can be accessed at www.teleflex.com. We make available through our website, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed with or

furnished to the SEC under Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after electronically filing or furnishing such material to the SEC. The information on our website is not part of this Annual Report on Form 10-K. The reference to our website address is intended to be an inactive textual reference only.

We are a Delaware corporation incorporated in 1943. Our executive offices are currently located at 155 South Limerick Road, Limerick, PA 19468. Our telephone number is (610) 948-5100. We expect to relocate our corporate offices in the first half of 2014 to 550 East Swedesford Road, Suite 400, Wayne, PA 19087.

EXECUTIVE OFFICERS

The names and ages of our executive officers and the positions and offices held by each such officer are as follows:

Name	Age	Positions and Offices with Company
Benson F. Smith	66	Chairman, President, Chief Executive Officer and Director
Liam Kelly	47	Executive Vice President and President, International
Thomas E. Powell	52	Executive Vice President and Chief Financial Officer

Mr. Smith has been our Chairman, President and Chief Executive Officer since January 2011, and has served as a Director since April 2005. Prior to January 2011, Mr. Smith was the managing partner of Sales Research Group, a research and consulting organization. From 1999 to January 2011, he also served as the Chief Executive Officer of BFS & Associates LLC, which specialized in strategic planning and venture investing. From 2000 until 2005, Mr. Smith also served as a speaker and author at The Gallup Organization, a global research-based consultancy firm. Prior to that, Mr. Smith worked for C.R. Bard, Inc., a company specializing in medical devices, for approximately 25 years, where he held various executive and senior level positions, most recently as President and Chief Operating Officer from 1994 to 1998.

Mr. Kelly has been our Executive Vice President, President, International since June 2012. He previously held several positions with regard to our EMEA segment, including President from June 2011 to June 2012, Executive Vice President from November 2009 to June 2011, and Vice President of Marketing from April 2009 to November 2009. Prior to joining Teleflex, Mr. Kelly held various senior level positions with Hill-Rom Holdings, Inc., a medical device company, from October 2002 to August 2009, serving as its Vice President of International Marketing and R&D from August 2006 to February 2009.

Mr. Powell has been our Executive Vice President and Chief Financial Officer since February 2013. From March 2012 to February 2013, Mr. Powell was Senior Vice President and Chief Financial Officer. He joined Teleflex in August 2011 as Senior Vice President, Global Finance. Prior to joining Teleflex, Mr. Powell served as Chief Financial Officer and Treasurer of Tomotherapy Incorporated, a medical device company, from June 2009 until June 2011. In 2008, he served as Chief Financial Officer of Textura Corporation, a software provider. From April 2001 until January 2008, Mr. Powell was employed by Midway Games, Inc., a software provider, serving as its Executive Vice President, CFO and Treasurer from September 2001 until January 2008. Mr. Powell has also held leadership positions with Dade Behring, Inc. (now Siemens Healthcare Diagnostics), PepsiCo, Bain & Company, Tenneco Inc. and Arthur Andersen & Company.

Our officers are elected annually by our board of directors. Each officer serves at the discretion of the board.

ITEM 1A. RISK FACTORS

We are subject to risks that could adversely affect our business, financial condition and results of operations. These risks include, but are not limited to the following:

We face strong competition. Our failure to successfully develop and market new products could adversely affect our business.

The medical device industry is highly competitive. We compete with many domestic and foreign medical device companies ranging from small start-up enterprises that might sell only a single or limited number of competitive

products or compete only in a specific market segment, to companies that are larger and more established than us, have a broad range of competitive products, participate in numerous markets and have access to significantly greater financial and marketing resources than we do.

In addition, the medical device industry is characterized by extensive product research and development and rapid technological advances. The future success of our business will depend, in part, on our ability to design and manufacture new competitive products and enhance existing products. Our product development efforts may require us to make substantial investments. There can be no assurance that unforeseen problems will not occur with respect to the development, performance or market acceptance of new technologies or products, such as our inability to:

- identify viable new products;
- obtain adequate intellectual property protection;
- gain market acceptance of new products; or

- successfully obtain regulatory approvals.

In addition, our competitors currently may be developing, or may develop in the future, products that provide better features, clinical outcomes or economic value than those that we currently offer or subsequently develop. Our failure to successfully develop and market new products or enhance existing products could have an adverse effect on our business, financial condition and results of operations.

Our customers depend on third party coverage and reimbursements and the failure of healthcare programs to provide coverage and reimbursement, or the reduction in levels of reimbursement, for our medical products could adversely affect us.

The ability of our customers to obtain coverage and reimbursement for our products is important to our business. Demand for many of our existing and new medical products is, and will continue to be, affected by the extent to which government healthcare programs and private health insurers reimburse our customers for patients' medical expenses in the countries where we do business. Even when we develop or acquire a promising new product, demand for the product may be limited unless reimbursement approval is obtained from private and governmental third party payors. Internationally, healthcare reimbursement systems vary significantly, with medical centers in some countries having fixed budgets, regardless of the extent of patient treatment. Other countries require application for, and approval of, government or third party reimbursement. Without both favorable coverage determinations by, and the financial support of, government and third party insurers, the market for many of our medical products would be adversely affected. We cannot be sure that third party payors will maintain the current level of coverage and reimbursement to our customers for use of our existing products. Adverse coverage determinations or any reduction in the amount of reimbursement could harm our business by reducing potential customers' selection of our products and the prices they are willing to pay.

In addition, as a result of their purchasing power, third party payors are implementing cost cutting measures such as seeking discounts, price reductions or other incentives from medical products suppliers and imposing limitations on coverage and reimbursement for medical technologies and procedures. These trends could compel us to reduce prices for our existing products and potential new products and could cause a decrease in the size of the market or a potential increase in competition that could negatively affect our business, financial condition and results of operations.

We may not be successful in achieving expected operating efficiencies and sustaining or improving operating expense reductions, and may experience business disruptions associated with restructuring, facility consolidations, realignment, cost reduction and other strategic initiatives.

Over the past several years we have implemented a number of restructuring, realignment and cost reduction initiatives, including the realignment of our North American organizational structure, facility consolidations and reductions in our workforce. While we have realized some efficiencies from these actions, we may not realize the benefits of these initiatives to the extent we anticipated. Further, such benefits may be realized later than expected, and the ongoing difficulties in implementing these measures may be greater than anticipated, which could cause us to incur additional costs or result in business disruptions. In addition, if these measures are not successful or sustainable, we may undertake additional realignment and cost reduction efforts, which could result in significant additional charges. Moreover, if our restructuring and realignment efforts prove ineffective, our ability to achieve our other strategic goals and business plans may be adversely affected.

In addition, as part of our efforts to increase operating efficiencies, we began, in 2012, and are continuing to transition our businesses to a single enterprise resource planning, or ERP, system. In the third quarter of 2013, we completed the initial phase of this transition without experiencing any significant disruptions to our business or operations. However, in the event we encounter any problems with future phases of this transition, we could experience business disruptions, which could adversely affect customer relationships and divert the attention of

management away from daily operations. In addition, any delays in the implementation of the ERP system could cause us to incur additional unexpected costs. Should we experience such difficulties, our business, cash flows and results of operations could be adversely affected.

We are subject to extensive government regulation, which may require us to incur significant expenses to ensure compliance. Our failure to comply with those regulations could have a material adverse effect on our business, results of operations and financial condition.

Our products are classified as medical devices and are subject to extensive regulation in the United States by the FDA and by comparable government agencies in other countries. The regulations govern the development, design, approval, manufacturing, labeling, importing and exporting and sale and marketing of many of our products. Moreover,

these regulations are subject to future change. Failure to comply with applicable regulations could lead to adverse effects on our business, which could include:

- partial suspension or total shutdown of manufacturing;
- product shortages;
- delays in product manufacturing;
- product seizures;
- recalls;
- criminal prosecution;
- injunctions;
- fines or civil penalties;
- operating restrictions;
- denial of requests for regulatory clearance or approval of new products;
- withdrawal or suspension of required clearances, approvals or licenses; and
- prohibitions against exporting of products to, or importing products from, countries outside the United States.

We could be required to expend significant financial and human resources to remediate failures to comply with applicable regulations and quality assurance guidelines. In addition, civil and criminal penalties, including exclusion under Medicaid or Medicare, could result from regulatory violations. Any one or more of these events could have a material adverse effect on our business, financial condition and results of operations.

In the United States, before we can market a new medical device, or a new use of, or claim for, or significant modification to, an existing product, we generally must first receive either 510(k) clearance or approval of a premarket approval, or PMA, application from the FDA. In order for us to obtain 510(k) clearance, the FDA must determine that our proposed product is “substantially equivalent” to a device legally on the market, known as a “predicate” device. To establish substantial equivalence, the applicant must show that the proposed device has the same intended use as the predicate device, and it either has the same technological characteristics, or it has been shown to be equally safe and effective and does not raise different questions of safety and effectiveness as compared to the predicate device. Obtaining PMA approval is more difficult, requiring us to demonstrate the safety and effectiveness of the device based, in part, on data obtained in human clinical trials. Similarly, most major markets for medical devices outside the United States also require clearance, approval or compliance with certain standards before a product can be commercially marketed. The process of obtaining regulatory clearances and approvals to market a medical device, particularly from the FDA and certain foreign governmental authorities, can be costly and time consuming, and clearances and approvals might not be granted for new products on a timely basis, if at all. In addition, once a device has been cleared or approved, a new clearance or approval may be required before the device may be modified or its labeling changed. Furthermore, the FDA or a foreign governmental authority may make its review and clearance or approval process more rigorous, which could require us to generate additional clinical or other data, and expend more time and effort, in obtaining future product clearances or approvals. The regulatory clearance and approval process may result in, among other things, delayed realization of product revenues, substantial additional costs or limitations on indicated uses of products, any one of which could have a material adverse effect on our financial condition and results of operations.

Even after a product has received marketing approval or clearance, such product approval or clearance can be withdrawn or limited due to unforeseen problems with the device or issues relating to its application. Violations of FDA requirements for medical devices could result in FDA enforcement actions, including:

- warning or untitled letters;
- fines or civil penalties;

- delays in obtaining new regulatory clearances;
- product seizures or recalls;
- injunctions;
- criminal prosecution;
- advisories or other field actions; and

operating restrictions.

Medical devices are cleared or approved for one or more specific intended uses. Promoting a device for an off-label use could result in government enforcement action.

Furthermore, our facilities are subject to periodic inspection by the FDA and other federal, state and foreign government authorities, which require manufacturers of medical devices to adhere to certain regulations, including the FDA's Quality System Regulation, which requires periodic audits, design controls, quality control testing and documentation procedures, as well as complaint evaluations and investigation. The FDA also requires the reporting of certain adverse events and may require the reporting of recalls or other field safety corrective actions. Issues identified through such inspections and reports may result in FDA enforcement action through any of the actions discussed above. Moreover, issues identified through such inspections and reports may require significant resources to resolve.

We may incur material losses and costs as a result of product liability and warranty claims that may be brought against us and recalls, which may adversely affect our results of operations and financial condition. Furthermore, as a medical device company, we face an inherent risk of damage to our reputation if one or more of our products are, or are alleged to be, defective.

Our businesses expose us to potential product liability risks that are inherent in the design, manufacture and marketing of our products. In particular, our medical device products are often used in surgical and intensive care settings with seriously ill patients. In addition, many of our products are designed to be implanted in the human body for varying periods of time. Product defects or inadequate disclosure of product-related risks with respect to products we manufacture or sell could result in patient injury or death. Product liability and warranty claims often involve very large or indeterminate amounts, including punitive damages. The magnitude of potential losses from product liability lawsuits may remain unknown for substantial periods of time, and the cost to defend against these lawsuits may be significant. We could experience material warranty or product liability losses in the future and incur significant costs to defend these claims.

In addition, if any of our products are, or are alleged to be, defective, we may voluntarily participate, or be required by regulatory authorities to participate, in a recall of that product. In the event of a recall, we may experience lost sales and be exposed to individual or class-action litigation claims. Moreover, negative publicity regarding a quality or safety issue, whether accurate or inaccurate, could reduce market acceptance of our products, harm our reputation, decrease demand for our products, result in the loss of customers, lead to product withdrawals or harm our ability to successfully launch and market our products in the future.Product liability, warranty and recall costs may have a material adverse effect on our business, financial condition and results of operations.

The ongoing volatility in the domestic and global financial markets combined with a continuation of constrained global credit markets could adversely impact our operating results, financial condition and liquidity.

We are subject to risks arising from adverse changes in general domestic and global economic conditions, including the economic slowdown and disruption of credit markets in recent years. The credit and capital markets experienced extreme volatility and disruption in recent years, leading to recessionary conditions and depressed levels of consumer and commercial spending. These recessionary conditions have caused customers to reduce, delay or cancel purchases of our products and services. While recent economic indicators suggest improvement in the United States and global economy, we cannot predict the duration or extent of any economic recovery or the extent to which our customers will return to more normalized spending behaviors. If the recessionary conditions worsen, our customers may terminate existing purchase orders or reduce the volume of products or services they purchase from us.

Adverse economic and financial market conditions may also cause our suppliers to be unable to meet their commitments to us or may cause them to make changes in the credit terms they extend to us, such as shortening the

required payment period for our accounts payable or reducing the maximum amount of trade credit available to us. These types of actions could significantly affect our liquidity and could have a material adverse effect on our results of operations.

Additionally, our customers, particularly in the European region, have extended or delayed payments for products and services already provided, which may lead to collectability concerns regarding our accounts receivable from these customers. To date, we have not experienced an inordinate amount of payment defaults by our customers, and we have sufficient lending commitments in place to enable us to fund our foreseeable additional operating needs. However, in light of the ongoing volatility in the domestic and global financial markets, combined with a continuation of constrained global credit markets there is a risk that our customers and suppliers may be unable to access liquidity. As of December 31, 2013 and 2012, our aggregate net receivables in Italy, Spain, Portugal and Greece were $97.9 million and $101.0 million,

respectively. In 2013, 2012 and 2011, net revenues from these countries were approximately 8%, 9% and 9% of total net revenues, respectively, and average days that accounts receivable were outstanding were 260, 288 and 318 days, respectively. Although we maintain allowances for doubtful accounts to cover the estimated losses which may occur when customers cannot make their required payments, we cannot be assured that we will continue to experience the same loss rate in the future given the volatility in the worldwide economy. If our allowance for doubtful accounts is insufficient to address receivables we ultimately determine are uncollectible, we would be required to incur additional charges, which could materially adversely affect our operating results. Moreover, our inability to collect outstanding receivables could adversely affect our financial condition and cash flow from operations.

In addition, adverse economic and financial market conditions may result in future charges to recognize impairment in the carrying value of our goodwill and other intangible assets, which would not directly affect our liquidity but could have a material adverse effect on our reported financial results.

Our strategic initiatives, including acquisitions, may not produce the intended growth in revenue and operating income.

Our strategic initiatives include making significant investments that are designed to achieve revenue growth and margin improvement targets. If we do not achieve the expected benefits from these investments or otherwise fail to execute on our strategic initiatives, we may not achieve the growth improvement we are targeting and our results of operations may be adversely affected.

In addition, as part of our strategy for growth, we have made, and may continue to make, acquisitions and divestitures and enter into strategic alliances such as joint ventures and joint development agreements. However, we may not be able to identify suitable acquisition candidates, complete acquisitions or integrate acquisitions successfully, and our strategic alliances may not prove to be successful. In this regard, acquisitions involve numerous risks, including difficulties in the integration of acquired operations, technologies, services and products and the diversion of management's attention from other business concerns. Even if we are successful in making an acquisition, the products and technologies that we acquire may not be successful or may require significantly greater resources and investments than we originally anticipated. We could also experience negative effects on our results of operations and financial condition from acquisition-related charges, amortization of intangible assets and asset impairment charges, and other issues that could arise in connection with the acquisition of a company or business, including issues related to internal control over financial reporting, regulatory or compliance issues and potential adverse short-term effects on results of operations through increased costs or otherwise. Although our management will endeavor to evaluate the risks inherent in any particular transaction, there can be no assurance that we will identify all such risks or the magnitude of the risks. In addition, prior acquisitions have resulted, and future acquisitions could result, in the incurrence of substantial additional indebtedness and other expenses. Future acquisitions may also result in potentially dilutive issuances of equity securities. There can be no assurance that difficulties encountered with acquisitions will not have a material adverse effect on our business, financial condition and results of operations.

An interruption in our manufacturing or distribution operations or our supply of raw materials may adversely affect our business.

Many of our key products are manufactured at or distributed from single locations, and the availability of alternate facilities is limited. If operations at one or more of our facilities is suspended due to natural disasters or other events, we may not be able to timely manufacture or distribute one or more of our products at previous levels or at all. Furthermore, our ability to establish replacement facilities or to substitute suppliers may be delayed due to regulations and requirements of the FDA and other regulatory authorities regarding the manufacture of our products. In addition, in the event of delays or cancellations in shipments of raw materials by our suppliers, we may not be able to timely manufacture or supply the affected products at previous levels or at all. The manufacture of our products is also highly

exacting and complex, due in part to strict regulatory requirements. Problems in the manufacturing process, including equipment malfunction, failure to follow specific protocols and procedures, defective raw materials and environmental factors, could lead to launch delays, product shortage, unanticipated costs, lost revenues and damage to our reputation. A failure to identify and address manufacturing problems prior to the release of products to our customers may also result in a quality or safety issue. A reduction or interruption in manufacturing or distribution, or our inability to secure suitable alternative sources of raw materials or components, could have a material adverse effect on our business, results of operations and financial condition.

Our ability to attract, train, develop and retain key employees is important to our success.

Our success depends, in part, on our ability to continue to retain our key personnel, including our executive officers and other members of our senior management team. Our success also depends, in part, on our ability to attract, train, develop and retain other key employees, including research and development, sales, marketing and operations personnel. Achieving this objective may be difficult due to many factors, including:

- the intense competition for skilled personnel in our industry;
- fluctuations in global economic and industry conditions;
- changes in our organizational structure;
- our restructuring initiatives;
- competitors' hiring practices; and
- the effectiveness of our compensation programs.

Our inability to attract, train, develop and retain such personnel could have an adverse effect on our results of operations and financial condition.

We are subject to healthcare fraud and abuse laws, regulation and enforcement; our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

We are subject to healthcare fraud and abuse regulation and enforcement by the federal government and the states and foreign governments in which we conduct our business. The laws that may affect our ability to operate include:

- the federal healthcare anti-kickback statute, which prohibits, among other things, persons from knowingly and willfully offering or paying remuneration to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs, or soliciting payment for such referrals, purchases, orders and recommendations;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment from the federal government, including Medicare, Medicaid or other third-party payors;