GLOBUS MEDICAL INC
Form 10-K
March 16, 2017
Table of Contents

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

_____

FORM 10-K

(Mark One)
x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016
or
o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File No. 001-35621

GLOBUS MEDICAL, INC.
(Exact name of registrant as specified in its charter)

DELAWARE	04-3744954
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2560 General Armistead Avenue, Audubon, PA	19403
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including Area Code:
(610) 930-1800

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

Title of each class	Name of each exchange on which registered
Class A Common Stock, par value $.001 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 o No x

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 o No x

Table of Contents

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 o

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files):
Yes x No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) 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:
o

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. (check one):

Large accelerated filer x	Accelerated filer o	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

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 voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing sales price for the registrant's common stock on the last business day of the registrant's most recently completed second quarter, June 30, 2016, as reported on the New York Stock Exchange, was approximately $1.7 billion.

The number of shares outstanding of the registrant's common stock (par value $0.001 per share) as of February 28, 2017 was 95,972,637 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our Proxy Statement for our 2017 Annual Meeting of Stockholders, to be filed within 120 days of December 31, 2016, are incorporated by reference in Part III, Items 10, 11, 12, 13 and 14 herein of this Annual Report. Such Proxy Statement, except for the parts therein which have been specifically incorporated by reference, shall not be deemed "filed" for the purposes of this Annual Report on Form 10-K.

Table of Contents

GLOBUS MEDICAL, INC. AND SUBSIDIARIES
TABLE OF CONTENTS

Table of Contents

PART I

CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical fact are forward-looking statements. We have tried to identify forward-looking statements by using words such as "believe," "may," "might," "could," "will," "aim," "estimate," "continue," "anticipate," "intend," "expect, similar words. These forward-looking statements are based on our current assumptions, expectations and estimates of future events and trends. Forward-looking statements are only predictions and are subject to many risks, uncertainties and other factors that may affect our businesses and operations and could cause actual results to differ materially from those predicted. These risks and uncertainties include, but are not limited to, factors affecting our quarterly results, our ability to manage our growth, our ability to sustain our profitability, demand for our products, our ability to compete successfully (including without limitation our ability to convince surgeons to use our products and our ability to attract and retain sales and other personnel), our ability to rapidly develop and introduce new products, our ability to develop and execute on successful business strategies, our ability to comply with changes and applicable laws and regulations that are applicable to our businesses, our ability to safeguard our intellectual property, our success in defending legal proceedings brought against us, trends in the medical device industry, general economic conditions, and other risks set forth throughout this Annual Report, including under "Item 1, Business," "Item 1A, Risk Factors," and "Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations," and those discussed in other documents we file with the Securities and Exchange Commission (the "SEC"). Moreover, we operate in an evolving environment. New risk factors and uncertainties emerge from time to time and it is not possible for us to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.

Given these risks and uncertainties, readers are cautioned not to place undue reliance on any forward-looking statements. Forward-looking statements contained in this Annual Report speak only as of the date of this Annual Report. We undertake no obligation to update any forward-looking statements as a result of new information, events or circumstances or other factors arising or coming to our attention after the date hereof.

Item 1. Business

Overview

Globus Medical, Inc. ("Globus," "we," "us" or "our") is a medical device company focused on developing products that promote healing in patients with musculoskeletal disorders. We are currently focused on products to treat patients with spine disorders. We have also developed a robotic surgical navigation device as well as products to treat patients who have experienced orthopedic trauma and expect to begin selling these products in 2017, but development efforts for these products are still ongoing and we currently have no robotic or orthopedic trauma products cleared for sale by the U.S. Food and Drug Administration ("FDA").

We are an engineering-driven company with a history of rapidly developing and commercializing innovative products and procedures to assist surgeons in effectively treating their patients. Since our inception in 2003, we have launched over 170 products and offer a comprehensive portfolio of innovative and differentiated products addressing a broad array of spinal pathologies, anatomies and surgical approaches.

Table of Contents

We continue to devote significant efforts to the development of new and innovative technologies for the treatment of patients with spine disorders. In 2016, those efforts resulted in the launch of seventeen new products.

All of our current products fall into one of two categories: Innovative Fusion or Disruptive Technologies. Our Innovative Fusion products comprise fusion products designed to treat a wide variety of spinal disorders for the entire spine and can be used in a variety of surgical approaches. We believe our Innovative Fusion products have features and characteristics that provide advantages for surgeons and potentially contribute to better outcomes for patients as compared to competing traditional fusion products.

We define Disruptive Technologies as those that represent a significant shift in the treatment of spinal disorders by allowing for novel surgical procedures, improvements to existing surgical procedures and/or the treatment of spinal disorders earlier in the continuum of care. We believe the use of Disruptive Technologies may improve patient outcomes and reduce costs given the expected lower morbidity rates, shorter patient recovery times and shorter hospital stays associated with these procedures. Additionally, Disruptive Technologies may help patients avoid progression of spinal disc disease sometimes caused by traditional surgical options such as spinal fusion. Our current portfolio of approved and pipeline Disruptive Technology products includes products that allow for minimally invasive surgical ("MIS") techniques, as well as new treatment alternatives, including motion preservation technologies, such as dynamic stabilization, total disc replacement and interspinous process spacer products; regenerative biologics technologies; and interventional pain management solutions, including treatments for vertebral compression fractures.

While we group our products into two categories, our products are not limited to a particular technology, platform or surgical approach. Instead, our goal is to offer spine surgeons a complete suite of products they can use to most effectively treat their patients, based on the patient's specific anatomy and condition and the surgeon's particular training and surgical preference.

On September 1, 2016, we acquired the international operations and distribution channels of Alphatec Holdings, Inc. ("Alphatec"), a publicly traded medical devices company, for $80.1 million in cash, subject to certain closing adjustments (the "Alphatec International Transaction"). This acquisition provides us immediate access to Japan and increased presence and penetration in other key geographies, roughly doubling our international sales. We also acquired a talent pool of international sales professionals as well as an extensive network of international distributors. We also agreed to extend a 5-year senior secured credit facility of up to $30.0 million to Alphatec to support their working capital needs. Globus intends to offer its own products through the sales channels acquired from Alphatec, but for some period of time we will continue to sell Alphatec products. The Alphatec International transaction included a supply agreement through which Alphatec will supply its products to Globus Medical for up to five years as we seek to transition those customers to Globus products.

Strategy

Our goal is to become the leader in providing innovative solutions to promote healing in patients with musculoskeletal disorders. To achieve this goal, we are employing the following business strategies:

- Leverage our integrated product development engine. We plan to continue developing new spine products as well as additional robotic and trauma products using our product development engine. We believe our team-oriented approach, active surgeon input and demonstrated product development capabilities position us to maintain a rapid rate of new product launches. We launched seventeen new products in 2016, have over 30 potential new products in various stages

Table of Contents

of development, and expect to launch approximately five to ten new products in each of the next three years.

- Increase the size, scope and productivity of our exclusive U.S. sales force. We believe there is significant opportunity for us to further penetrate existing markets and to enter new markets by increasing the size and geographic scope of our exclusive U.S. sales force. We expect to continue to increase the number of our direct and distributor sales representatives in the United States to expand into new geographic territories and to deepen our penetration in existing territories. We will also continue to provide our sales representatives with specialized development programs designed to improve their productivity. In addition, we have begun to build exclusive sales forces in the U.S. and internationally to support the anticipated launch of our robotics and trauma products.
- Continue to expand into international markets. In 2016, we significantly increased our international presence through the acquisition of the international operations and distribution channels of Alphatec Holdings, Inc. As of December 31, 2016, we had an existing direct or distributor sales presence in 49 countries outside the United States. We expect to continue to increase our international presence through the commercialization of additional products, including our robotics and trauma products, and through the expansion of our international sales force.
- Pursue strategic acquisitions and alliances. We intend to selectively pursue acquisitions and alliances in the future that will provide us with new or complementary technologies, personnel with significant relevant experience, or increased market penetration. We are currently evaluating a number of possible acquisitions or strategic relationships and believe that our resources and experience make us an attractive acquirer or partner.

The Spine Market

Spine disorders are a leading driver of healthcare costs worldwide. Spine disorders range in severity from mild pain and loss of feeling to extreme pain and paralysis. These disorders are primarily caused by degenerative conditions in the spine, deformity, tumors and trauma.

Treatment alternatives for spine disorders range from non-operative conservative therapies to surgical interventions. Conservative therapies include bed rest, medication and physical therapy. When conservative therapies fail to provide adequate quality of life improvements, surgical interventions may be used to address pain. Surgical treatments for spine disorders can be instrumented, which include the use of implants, or non-instrumented, which forego the use of any such implants.

We believe the spine market will continue to experience growth as a result of the following market influences:

- Favorable patient demographics. The number of people between 40 to 80 years old is large and growing. Improvements in healthcare have led to increasing life expectancies worldwide and the opportunity to lead more active lifestyles at advanced ages. These trends are expected to generate increased demand for spine surgeries.
- Improving technologies leading to increased use in fusion procedures. Due to the longevity of its practice and acceptable clinical outcomes, fusion has become a standard treatment option for patients presenting more advanced stages of spine disease. We expect that the development of

Table of Contents

improved fusion products will continue to contribute to spinal fusion as a leading treatment for advanced stages of spine disease.

- Disruptive Technologies driving earlier interventions and creating an expanded patient base. Newer technology products and procedures are gaining increasing acceptance among patients and surgeons because they allow for novel surgical procedures, improvements to existing surgical procedures, the treatment of spine disorders by new physician specialties, and surgical intervention earlier in the continuum of care, all of which may result in better outcomes for patients. As a result, we expect Disruptive Technologies to drive accelerated growth and increase the size of the addressable patient population for spine surgery.
- Continued growth of spine procedures worldwide. While the United States comprises approximately 4% of the worldwide population, we believe that approximately one-half of all spine surgeries occur in the United States. We believe that improvements to the standard of care outside of the United States will increase the international demand for spine products.

The Globus Solution

We currently offer over 170 products for the treatment of spine disorders.

Innovative Fusion Products

Our Innovative Fusion products include a range of implant and surgical approach options to treat degenerative, deformity, tumor, and trauma conditions along the entire spine, from the occiput to the sacrum. We believe our products provide advantages over traditional fusion products that may help improve surgical techniques, and may contribute to better outcomes for patients. For example, in 2016 we launched QUARTEX®, our Occipito-Cervico-Thoracic ("OCT") stabilization system. QUARTEX® was designed to address a number of challenges associated with posterior OCT fusion to aid in easier construct assembly. QUARTEX® features a threading locking cap to enable quick and efficient low-torque single step locking and high angle screw heads that accommodate rods of different diameters. The QUARTEX® system also includes a comprehensive range of instruments, including threaded drivers and streamlined reduction tools. Our Innovative Fusion products also include the Alphatec products we began distributing following the Alphatec International Transaction.

We also launched new additions to the CREO® platform in 2016, including the CREO® 4.75 System, designed to address deformity correction via a minimally invasive thoracoscopic or mini-open anterior approach. The CREO® 4.75 System features streamlined instruments, a unique non-threaded locking cap designed specifically for deformity correction, and an extensive selection of hydroxyapatite coated screws to aid in obtaining bicortical purchase and enhanced fixation.

Disruptive Technologies Products

We believe we are well positioned to capitalize on this higher-growth segment of the spine market given our multiple existing commercialized products and several products in various stages of development. We have a broad, comprehensive product portfolio and pipeline of Disruptive Technologies, including our expandable cages, MIS, motion preservation, and regenerative biologics technologies, as well as interventional pain management solutions. Globus markets an innovative line of expandable interbody fusion devices designed to be inserted at a minimized height and then expanded during surgery to obtain optimal fit between vertebral bodies. This

Table of Contents

expandability feature allows for restoration of height following disc removal while easing insertion into the disc space, helping to reduce trauma to the vertebral endplates as well as the surrounding tissue.

Our MIS products enable a surgeon to perform a procedure less invasively to minimize tissue disruption and maximize native anatomy, which may lead to better patient recovery and fewer approach-related complications. For example, COALITION MIS™, a 2016 addition to our COALITION® line of cervical interbody fusion devices, is an integrated plate-spacer designed to deliver fixation in fewer procedural steps through a less invasive surgical corridor than traditional integrated spacers. COALITION MIS™ is compatible with both anchors and screws, providing multiple intraoperative options for securing the spacer to the vertebral bodies. In addition, the innovative instrumentation for COALITION MIS™ allows the introduction of both the spacer and the screws or anchors into the disc space through an access window approximately the same size as the spacer itself. INDEPENDENCE MIS™, also introduced in 2016, is an integrated plate-spacer similar to COALITION MIS™ but designed for the lumbar spine. We offer a variety of additional innovative fixation options including plates and pedicle screw systems designed for minimally invasive insertion.

Similarly, other Disruptive Technology products include our motion preservation offerings, such as SECURE®-C, SECURE®-CR and SECURE®-C3, which are next-generation cervical arthroplasty devices that allow segmental motion, are semi-constrained, and provide alternatives to fusion in the treatment of degenerative conditions.

Regenerative biologics products, including bioactive glass-based KINEX® and SIGNIFY™ bone void fillers and CONDUCT® ceramic-collagen, are well suited for pelvic/extremity and posterolateral spinal fusion procedures. ViaSorb™ Cubes and Strips, launched in 2016, are demineralized cancellous sponges that provide a natural osteoconductive scaffold with unique compressive capabilities that facilitate packing into bony voids and within allograft spacers. The porous structure of ViaSorb™ Sponges allows for adsorption of osteogenic cells from autologous bone marrow aspirate.

Emerging Technologies Products

In January 2017 we announced our European Conformity mark ("CE mark") of Excelsius GPS™, a system providing robotic trajectory guidance and navigation. The Excelsius GPS™ technology supports both minimally invasive and open orthopedic and neurosurgical procedures, with applications ranging from the cervical spine to the sacroilium, long bones and cranium. Excelsius GPS™ integrates with Globus implants and instruments and is compatible with pre-operative CT, intra-operative CT and fluoroscopic imaging modalities. The system is designed to minimize radiation exposure, streamline workflow, and reproducibly assist in implant placement. Excelsius GPS™ is currently not cleared for sale in the United States.

We have also developed products to treat patients who have experienced orthopedic trauma and expect to begin selling these products in 2017, although development efforts for these products are still ongoing and we currently have no orthopedic trauma products with CE marking or cleared for sale by the FDA.

Product Development and Research

Globus was founded with a goal of leveraging our team's extensive experience in the spine industry to use a distinctive product development process that significantly reduces the length of time between a product's conception and commercialization. Our product development engine is the name we give to our particular approach to product development, which we believe is unique and highly efficient. We employ an integrated team approach to product development that involves collaboration among surgeons, our engineers, our dedicated researchers, our highly-skilled machinists, and our regulatory personnel. We believe

Table of Contents

that utilizing these integrated teams, as well as our extensive in-house facilities, allows us to design, test, and obtain timely regulatory clearance and approvals of our products. We also believe that our product development engine enables us to develop products that provide advantages for surgeons and contribute to better outcome for patients.

Our product development efforts are supported by our in-house research capabilities. We believe that centralizing and consolidating the critical elements of the product development and commercialization process in one facility allows us to bring products from the concept stage to the market rapidly in order to respond to surgeon and patient needs. Research resources include a clinical research group, a mechanical testing laboratory, a spinal kinematics laboratory, a tribology laboratory, a cadaveric laboratory, a materials characterization laboratory, and a computational laboratory.

The markets in which we operate are subject to rapid technological advancements. We must constantly improve existing products and introduce new products in order to continue to succeed. Accordingly, we have made significant investments in our product development and research capabilities. For the years ended December 31, 2016, 2015 and 2014, we spent $44.5 million, $36.3 million and $31.2 million, respectively, including costs from our Emerging Technologies group, on research and development.

Sales and Marketing

We market and sell our products through our exclusive global sales force. As of December 31, 2016, we had a direct or distributor sales presence in the United States and in 49 countries outside the United States. We expect to continue to increase the number of our direct and distributor sales representatives, both in the U.S. and internationally, to expand into new geographic territories and to deepen our penetration in existing territories. We believe the expansion of our U.S. and international sales forces provides us with significant opportunities for future growth as we continue to penetrate existing geographic markets and enter new ones.

Our sales representatives are present in the operating room during most surgeries in the United States and in many, but not all, of the other countries in which our products are sold. These representatives have the responsibility to confirm that all of the items needed in the surgery are available and are provided sterile or are capable of being sterilized at the hospital. Various sizes and quantities of implants are made available to be able to satisfy varying surgical requirements and patient anatomy, along with numerous surgical instruments and cases needed to safely perform the surgery and implantation. As products are used in surgeries, replacement items are shipped to our sales representatives and hospitals to replenish their supply.

All of our independent distributors are compensated solely on commission. Most of our new direct sales representatives start with a compensation arrangement that is largely based on salary. Our goal is to have members of our direct sales force move toward a compensation model based solely on commission as they become familiar with our products and drive higher sales.

We are in the process of building exclusive sales forces for our robotic surgical navigation and orthopedic trauma businesses and expect to expand those teams in the U.S. and internationally in 2017 as we grow closer to commercializing products in these areas.

Table of Contents

Advancement of Spine Care

We are committed to the advancement of spine care through our support of numerous educational and research programs geared towards spine surgeons, such as:

- national and regional educational courses;
- intensive hands-on cadaveric training on new products and new techniques;
- research collaboration and support;
- educational support; and
- fellowship support.

Globus devotes significant resources to training and educating surgeons in the safe and effective use of our products and techniques. To that end, we have made significant investments in the creation, staffing and program offerings of our Musculoskeletal Education and Research Center ("MERC"). Through MERC, educational and training programs are offered at our modern bioskills laboratory and 100 person lecture facility, and through regionally-based didactic education and cadaveric bioskills training programs at off-site facilities.

We are highly focused on training through programs such as our Skin-to-Skin® Series programs that feature intensive two day MIS training programs on thoracolumbar interbody fusion procedures and our lateral lumbar interbody fusion labs. To complement these intensive cadaveric bioskills training programs, we also conduct product-based programs providing surgeons with informative didactic sessions coupled with hands-on-lab segments to allow surgeons to learn and experience new instrumentation and techniques. For more complex procedures and techniques, surgeon preceptorships are offered which provide surgeons with one-on-one intraoperative training followed in some instances by focused bioskills labs.

Globus has a strong commitment to research performed in conjunction with surgeons from around the world as well as research opportunities in collaboration with leading academic institutions. Supported by a large, focused research team, these efforts range from basic biomechanical testing conducted internally with our six degrees of freedom machine to support of major clinical outcomes studies. We are committed to providing the spine surgeon community with high quality research to support the new surgical techniques and novel product designs that we develop.

Competition

We believe that our significant competitors are Medtronic, the DePuy Synthes Companies (a division of Johnson & Johnson), Stryker and NuVasive. Alphatec Spine, Orthofix International, Zimmer Biomet, K2M and other smaller public and private companies are also competitors of ours. At any time, these or other market participants may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products. They may also develop and patent processes or products earlier than we can, or obtain regulatory clearance or approvals for competing products more rapidly than we can.

We compete in the marketplace to recruit and retain qualified scientific, management and sales personnel, as well as in acquiring technologies and technology licenses complementary to our products or advantageous to our business.

Table of Contents

Our currently marketed products are, and any future products we commercialize will be, subject to intense competition. Many of our current and potential competitors are major medical device companies that have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. In addition, many of these competitors have significantly longer operating history and more established reputations than we do. The markets we compete in are intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. Our ability to compete successfully depends on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement, and are safer, less invasive and more effective than alternatives available for similar purposes. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing competing products.

Manufacturing and Supply

We have greatly expanded our dedicated in-house implant manufacturing capabilities. A significant portion of our implant products is manufactured in our facilities in Eagleville, Pennsylvania. Most of our regenerative biologics products are processed in our facilities in San Antonio, Texas, and in Audubon, Pennsylvania.

However, most of our products are generally manufactured through a network of over 100 third-party suppliers. Our suppliers utilize high precision, computer-aided manufacturing equipment to manufacture our products. We have focused on developing a strong supplier base as part of our manufacturing strategy. Our relationship with our suppliers enables significant interaction between our design engineers and project managers and the suppliers' engineers and schedulers to work through issues arising during the entire product development cycle. Many of our suppliers are domestic, which affords our engineers and other members of our product development team the opportunity to work closely with them to commercialize our products.

We select our suppliers carefully and generally use a small number of suppliers for each of our key products for added reliability. Our internal quality assurance group evaluates the potential vendor through a formal vendor approval process before we enter into a relationship with the vendor. Suppliers that meet our internal quality assurance standards are added to our approved supplier list. All of our suppliers that provide us with implants or human tissue are ISO-13485 certified, meaning they meet the International Organization for Standardization ("ISO") requirements for the manufacture of medical devices, and/or are accredited by the American Association of Tissue Banks. Our quality assurance group conducts periodic audits to ensure continued compliance with our standards. With every shipment of inventory that we receive, our suppliers provide a certificate of compliance with our quality control standards. Our receiving group also performs inspections, packaging and labeling onsite at our headquarters facility.

We work closely with our suppliers to ensure that our inventory needs are met while maintaining high quality and reliability. To date, we have not experienced significant difficulty in locating and obtaining the materials necessary to fulfill our production requirements, and we have not experienced a meaningful backlog of sales orders. We believe our supplier relationships and facilities will support our potential capacity needs for the foreseeable future.

A majority of our product inventory is held primarily with our sales representatives and at hospitals throughout the United States. We stock inventory in our warehouse facilities and retain title to consigned inventory which is maintained with our field representatives and hospitals in sufficient quantities so that products are available when needed for surgical procedures. Safety stock levels are determined based on a number of factors, including demand, manufacturing lead times and quantities required to maintain service levels.

Table of Contents

Intellectual Property

We protect our proprietary rights through a variety of methods. In particular, we rely on patent, trademark, copyright, trade secret and other intellectual property laws and also utilize nondisclosure agreements and other measures to protect our rights.

As of December 31, 2016, we owned 548 issued U.S. patents (533 utility patents; 15 design patents) and had applications pending for 443 U.S. patents (442 utility patents; 1 design patent), and we owned 140 issued foreign patents and had applications pending for 220 foreign patents. Our issued patents expire between November 2019 and July 2035.

Our trademark portfolio contains 180 registered trademarks and 53 pending trademarks. Our portfolio includes domestic and foreign trademarks with associated logos and tag lines.

Third-Party Coverage and Reimbursement

We expect that, in the future, sales volumes and prices of our spinal implant and orthopedic trauma products may grow to be more dependent on the availability of coverage and reimbursement from third-party payors, such as state and federal programs including Medicare, Medicaid and Worker's Compensation as well as private insurance plans including Blue Cross Blue Shield plans and commercial insurers. Reimbursement is dynamic and is contingent on coding for given services or procedures, coverage by third-party payors, and adequate payment for the services or procedures.

Physicians use Current Procedural Terminology ("CPT®") codes to bill for services and procedures, which are established by the American Medical Association ("AMA"). Specialty societies such as the North American Spine Society, the American Association of Neurological Surgeons, and the American Academy of Orthopaedic Surgeons provide advice to the AMA CPT® Editorial Panel for developing codes. The availability of existing codes to bill for services and procedures may impact the adoption of technology. For example, the deletion of the CPT® code to report spine cages and subsequent addition of three new CPT® codes, two of which include integral anterior instrumentation, may impact the type of devices used by physicians to perform spine procedures.

The Centers for Medicare and Medicaid Services ("CMS") and the National Center for Health Statistics are jointly responsible for overseeing changes and modifications to International Classification of Diseases, Clinical Modification/Procedure Coding System ("ICD-10-CM/PCS") procedure codes used by physicians for reporting diagnosis(es) and hospitals for reporting inpatient procedures. ICD-10-CM/PCS was implemented in the U.S. on October 1, 2015. This represents the first major coding change for ICD coding in over 30 years. The granularity and specificity of the new ICD-10-CM/PCS coding system may impact reimbursement in the future, particularly hospital inpatient reimbursement. Physician and hospital coding is subject to change, which could impact coverage and reimbursement and thus potentially impact physician practice behavior.

Independent of coding status, third-party payors may deny coverage based on their own criteria. Payor medical policies continue to become more restrictive. Payors may deem the clinical efficacy of a device or procedure to be experimental or investigational, not the most cost-effective treatment available, or used for an unapproved indication. For example, Aetna's Clinical Policy Bulletin for invasive back pain procedures includes an Appendix which lists covered and non-covered spine devices by brand name and manufacturer. Aetna continues to revise its policy to include devices as covered and non-covered. Aetna considers "expandable" cages to be covered for only limited indications (e.g., L5-S1 fusions). Additionally, many private payors use coverage decisions and payment amounts established by CMS for the Medicare

Table of Contents

program as guidelines in setting their coverage and reimbursement policies. As the portion of the U.S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. National and local coverage policy decisions are subject to unforeseeable change and have the potential to impact physician behavior. We will continue to provide the appropriate resources to patients, physicians, hospitals, and insurers in order to promote the best patient care, provide clarity regarding coverage and reimbursement policies, and work to reverse any non-coverage policies.

For federal/state programs, such as Medicaid, coverage and reimbursement differ from state to state. Some state Medicaid programs may not reimburse an adequate amount for the procedures performed with our products, if any payment is made at all. In addition, state-level worker's compensation coverage and reimbursement vary from state to state. Payment by Medicare and other third-party payors may not be adequate to cover the cost of medical devices used in spine procedures. Additionally, more spine procedures are being performed in the hospital outpatient and ambulatory surgery center settings, in part due to innovation. Reimbursement levels in these settings are typically lower than for the hospital inpatient setting and may not be adequate to cover the cost of innovative and novel medical devices.

In international markets, reimbursement and healthcare payment systems vary significantly by country and some countries have instituted price ceilings on specific product lines. There can be no assurance that our products will be accepted by third-party payors, that coverage and reimbursement will be available or, if available, that the third-party payors' coverage and reimbursement policies will not adversely affect our ability to sell our products profitably.

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. There can be no assurance that third-party coverage and reimbursement will be available or adequate, or that future legislation, regulation, coding or coverage and reimbursement policies of third-party payors will not adversely affect the demand for our products or our ability to sell these products on a profitable basis.

Government Regulation

Our business is subject to extensive federal, state, local and foreign regulations. Some of the pertinent laws have not been definitively interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of subjective interpretations. In addition, these laws and their interpretations are subject to change.

Both federal and state governmental agencies continue to subject the healthcare industry to intense regulatory scrutiny, including heightened civil and criminal enforcement efforts. We believe that we have structured our business operations and relationships with our customers to comply with all applicable legal requirements. However, it is possible that governmental entities or other third parties could interpret these laws differently and assert otherwise. We discuss below the statutes and regulations that are most relevant to our business.

U.S. Food and Drug Administration Regulation

Our products are medical devices and human tissue products subject to extensive regulation by the FDA and other federal, state, local and foreign regulatory bodies. FDA regulations govern, among other things, the following activities that we or our partners perform and will continue to perform:

Table of Contents

- product design and development;
- product testing, manufacturing and safety;
- post-market surveillance and reporting;
- product labeling;
- complaint handling;
- post-market approval studies; and
- product advertising, marketing and promotion.

FDA's Pre-Market Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States requires either 510(k) clearance, clearance of a de novo classification petition, or a pre-market approval ("PMA") from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose low or moderate risk are placed in either Class I or II. Unless classified as exempt from pre-market notification, Class I and II devices generally require the manufacturer to submit to the FDA a pre-market notification requesting permission for commercial distribution. This process is known as 510(k) clearance. Some low risk devices are exempt from this requirement. Devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a previously cleared 510(k) device are placed in Class III, which typically requires approval of a PMA application. For certain Class III devices that present low to moderate risk, a risk-based classification determination can be requested in accordance with the de novo petition process, under which the FDA may determine that the product can be appropriately regulated as a Class I or II device. Both 510(k) pre-market notification and PMAs are subject to the payment of user fees, paid at the time of submission for FDA review. Future legislation may impose user fees for the submission of de novo classification petitions. The FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

Human Cell, Tissue and Cellular and Tissue Based Products

We currently distribute a number of products processed from human tissue, some of which are manufactured by third-party suppliers. FDA regulates human tissue products as Human Cells and Cellular and Tissue Based Products ("HCT/Ps"). Certain HCT/Ps are regulated solely under Section 361 of the Public Health Service Act and are referred to as "Section 361 HCT/Ps," while other HCT/Ps are subject to FDA's regulatory requirements for medical devices or biologics. Section 361 HCT/Ps do not require 510(k) clearance, PMA approval, or other premarket approvals from FDA before marketing. Tissue banks that handle HCT/Ps must register their establishments with FDA, list their HCT/P products with FDA, and comply with FDA donor eligibility and screening, current Good Tissue Practice ("CGTP"), product labeling, and postmarket reporting requirements for HCT/Ps.

The FDA periodically inspects tissue processors to determine compliance with these requirements. Entities that provide us with allograft bone tissue are responsible for performing donor recovery, donor screening and donor testing and our compliance with those aspects of the CGTP regulations that regulate those functions are dependent upon the actions of these independent entities.

Table of Contents

The procurement and transplantation of allograft bone tissue is subject to U.S. federal law pursuant to the National Organ Transplant Act ("NOTA"), a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for "valuable consideration." NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. With the exception of removal and implantation, we provide services in all of these areas.

The procurement of human tissue is also subject to state anatomical gift acts and some states have statutes similar to NOTA. In addition, some states require that tissue processors be licensed by that state.

FDA Enforcement

The FDA enforces these requirements by inspection and market surveillance. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) or de novo clearance or PMA of new products;
- withdrawing 510(k) clearance or PMAs that are already granted;
- refusal to grant export approval of our products; and
- criminal prosecution.

We are subject to unannounced device inspections by the FDA, the Office of Compliance, the Center for Devices and Radiological Health, and the Center for Biologics Evaluation and Research, as well as other regulatory agencies overseeing the implementation and adherence of applicable state and federal tissue licensing regulations. These inspections may include our suppliers' facilities.

International

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. The European Union/European Economic Area ("EEA") requires a CE mark in order to market medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE or FDA clearance or approval. Other countries, such as Brazil, Canada and Japan, require separate regulatory filings.

In the EEA, our devices are required to comply with the essential requirements of the EU Medical Device Directive (Council Directive 93/42/EEC). Compliance with these requirements entitles us to affix the CE conformity mark to our medical devices, without which they cannot be commercialized in the EEA.

Table of Contents

To demonstrate compliance with the essential requirements and obtain the right to affix the CE conformity mark we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification.

Additionally in the EEA, the procurement, testing, processing, preservation, storage and distribution of human tissues and cells is subject to the requirements of the laws of individual EEA Member States implementing Directive 2004/23/EC, Directive 2006/17/EC and Directive 2006/86/EC.

Further, the advertising and promotion of our products in the EEA is subject to the laws of individual EEA Member States implementing the EU Medical Device Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other EEA Member State laws governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

We are subject to unannounced device inspections by the Notified Body (an organization accredited by a Member State of the EEA to conduct conformity assessments), as well as other regulatory agencies overseeing the implementation and adherence of applicable regulations. These inspections may include our suppliers' facilities.

Sales and Marketing Commercial Compliance

Federal anti-kickback laws and regulations prohibit, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for, or to induce either the referral of an individual, or the purchase, order or recommendation of, any good or service paid for under federal healthcare programs such as the Medicare and Medicaid programs.

In addition, federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Off-label promotion has been pursued as a violation of the federal false claims laws. Pursuant to FDA regulations, we can only market our products for cleared or approved uses. Although surgeons are permitted to use medical devices for indications other than those cleared or approved by the FDA based on their medical judgment, we are prohibited from promoting products for such off-label uses. Additionally, the majority of states in which we market our products have similar anti-kickback, false claims, anti-fee splitting and self-referral laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and violations may result in substantial civil and criminal penalties.

The United States and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including under the United Kingdom's Bribery Act and increased U.S. government oversight and enforcement of the U.S. Foreign Corrupt Practices Act ("FCPA"). Additionally, the commercial compliance environment is continually evolving in the healthcare industry as some states, including California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively "PPACA") also imposes new reporting and disclosure requirements on device manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. The shifting compliance environment and the need to build and maintain

Table of Contents

robust and expandable systems to comply in multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Environmental Matters

The manufacture of certain of our products, including our allograft implants and products, and the handling of materials used in the product testing process, including in our cadaveric laboratory, involve the controlled use of biological, hazardous and/or radioactive materials and wastes. Our business and facilities and those of our suppliers are subject to foreign, federal, state and local laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling and disposal of, and exposure to, such materials and wastes. In addition, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third-party waste disposal sites even if such contamination was not caused by us.

We are not currently aware of any material costs or liabilities relating to environmental matters, including any claims or actions under environmental laws or obligations to perform any cleanups at any of our facilities or any third-party waste disposal sites, that we expect to have a material adverse effect on our business, financial condition or operating results. However, it is possible that material environmental costs or liabilities may arise in the future.

Seasonality and Backlog

Our business is generally not seasonal in nature. However, our sales may be influenced by summer vacation and winter holiday periods during which we have experienced fewer spine surgeries taking place. Our sales generally consist of products that are in stock in our warehouse facilities or maintained at hospitals or with our sales representatives. Accordingly, we do not have a backlog of sales orders.

Employees

As of December 31, 2016, we had over 1,400 employees, including sales and marketing, product development, general administrative and accounting, both domestically and internationally. Our employees are not subject to a collective bargaining agreement except in a single market outside the U.S., and we consider our relationship with our employees to be good.

Properties

Our corporate headquarters are located in Audubon, Pennsylvania and owned by us. We own research and manufacturing facilities in Massachusetts, Pennsylvania and Texas, lease additional research and manufacturing facilities in Texas and also own a distribution center in Heerlen, Netherlands to support our international operations. We maintain sales and administrative offices in twenty-five additional countries, all of which are leased.

Financial Information

For financial information about our business segment and the geographic areas in which we derive revenues, see “Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 18. Segment and Geographic Information” below.

Table of Contents

Corporate and Available Information

We were incorporated in Delaware in March 2003. Our principal executive offices are located at 2560 General Armistead Avenue, Audubon, Pennsylvania 19403, and our telephone number at that location is (610) 930-1800. Our corporate website address is http://www.globusmedical.com. The information contained in or accessible through our website or contained on other websites is not deemed to be part of this Annual Report on Form 10-K.

We are subject to the filing requirements of the Exchange Act. Therefore, we file annual reports, periodic reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information may be obtained by visiting the Public Reference Room of the Securities and Exchange Commission at 100 F Street, NE, Washington, D.C. 20549. You may obtain information regarding the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains a website (www.sec.gov) that contains reports, proxy and information statements, and other information regarding issuers that file electronically.

We make our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to such reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act available free of charge through a link on the Investors section of our website located at http://www.globusmedical.com (under “SEC Filings”) as soon as reasonably practicable after they are filed with or furnished to the SEC.

Item 1A. Risk Factors

Risk factors that could cause our actual results to differ from our expectations and that could negatively impact our business, results of operations and financial condition are discussed below and elsewhere in this Annual Report on Form 10-K. If any of these risks actually occurs, our business, results of operations, financial condition and future growth prospects could be materially and adversely affected. You should carefully read and consider each of these risks, together with all of the other information set forth in this Annual Report on Form 10-K. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also materially adversely affect our business, results of operations, financial condition and future growth prospects, and our stock price.

Risks Related to Our Business and Our Industry

To be commercially successful, we must convince spine surgeons and hospitals that our products are an attractive alternative to our competitors’ products and that our Disruptive Technologies are an attractive alternative to existing surgical treatments of spine disorders.

Spine surgeons play a significant role in determining the course of treatment and, ultimately, the type of product that will be used to treat a patient, so we rely on effectively marketing to them. Hospitals, however, are increasingly involved in the evaluation of products and product purchasing decisions. In order for us to sell our products, we must convince spine surgeons and hospitals that our products are attractive alternatives to competing products for use in spine procedures. Acceptance of our products depends on educating spine surgeons and hospitals as to the distinctive characteristics, perceived benefits, safety and cost-effectiveness of our products as compared to our competitors’ products and on training spine surgeons in the proper application of our products. If we are not successful in convincing spine surgeons and hospitals of the merit of our products or educating them on the use of our products, they may not use our products and we will be unable to increase our sales and sustain growth or profitability.

Table of Contents

Furthermore, we believe spine surgeons will not widely adopt our Disruptive Technology products unless they determine, based on experience, clinical data and published peer-reviewed journal articles, that MIS techniques and our motion preservation and regenerative biologics technologies provide benefits or are an attractive alternative to conventional treatments of spine disorders and incorporate improved technologies that permit novel surgical procedures.

Surgeons, and in certain instances, hospitals, may be hesitant to change their medical treatment practices or the products available for use to treat patients for the following reasons, among others:

- lack of experience with MIS or our motion preservation or regenerative biologics technologies;
- lack or perceived lack of evidence supporting additional patient benefits;
- perceived liability risks generally associated with the use of new products and procedures;
- limited or lack of availability of coverage and reimbursement within healthcare payment systems;
- costs associated with the purchase of new products and equipment; and
- the time commitment that may be required for training.

If we are unable to convince surgeons and hospitals to use our products, we will not achieve expected sales or sustain our growth, and our financial condition and results of operation may be adversely affected.

In addition, we believe recommendations and support of our products by influential spine surgeons are essential for market acceptance and adoption. If we do not receive support from such surgeons or long-term data does not show the benefits of using our products, surgeons may not use our products. In such circumstances, we may not achieve expected sales or sustain our growth and may be unable to maintain profitability.

Pricing pressure from our competitors and our customers may impact our ability to sell our products at prices necessary to support our current business strategies.

The spine industry is characterized by intense competition, and the spine market continues to attract numerous new companies and technologies, which has encouraged more established companies to intensify competitive pricing pressure. As a result of this increased competition, as well as the challenges of third-party coverage and reimbursement practices, we believe there will be continued pricing pressure in the future. If competitive forces drive down the prices we are able to charge for our products, our profit margins will shrink, which will adversely affect our ability to maintain our profitability and to invest in and grow our business.

If our hospital and other healthcare provider customers are unable to obtain adequate coverage and reimbursement for their purchases of our products, we may not be able to sell our products at prices necessary to maintain our profitability or at all.

Maintaining and growing sales of our products depends on the availability of adequate coverage and reimbursement from third party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Hospitals and other healthcare providers that purchase our products generally rely on third party payors to cover all or part of the costs associated with the procedures performed with these products, including the cost to purchase the product. Our customers' access to adequate coverage and reimbursement for the procedures performed with our products by government and private insurance plans is central to the acceptance of our current and future products. We may be unable to sell our products on a profitable basis, or at all, if third party payors deny coverage or reduce their current levels of payment. If our cost of production increases faster than increases in reimbursement levels for the products, our profitability may be negatively impacted.

Table of Contents

Future action by CMS (which administers the Medicare program), other government agencies or private payors, may diminish payments to physicians, outpatient surgery centers and/or hospitals, which could harm our ability to market and sell our products. Private payors may adopt coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. Private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures performed with our products. In addition, for some governmental programs, such as Medicaid, coverage and reimbursement differs from state to state. Medicaid payments to physicians and facilities are often lower than payments by other third party payors and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control rising healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers.

Third party payors, including public and private payors, may develop negative coverage policies impacting our products. For example, Aetna recently changed its medical policy from coverage in all or most cases to coverage only for limited indications for biomechanical devices (e.g., spine cages) for cervical fusion procedures, stating that they have not been proven more effective than bone graft for cervical fusions, which may limit demand for our products. In addition, some payors have changed their coverage policies to be more restrictive as to the criteria under which they will cover and reimburse for vertebral fusions in the lumbar spine to treat multilevel degenerative disc disease (“DDD”), initial primary laminectomy/discectomy for nerve root decompression, or spinal stenosis. Although these coverage policy changes have not had a material impact on our business, other insurers may adopt similar coverage decisions in the future. Patients covered by these insurers may be unwilling or unable to afford lumbar fusion surgeries to treat these conditions, which could materially harm or limit our ability to sell our products designed for lumbar fusion procedures. Our business would be negatively impacted if the trend by governmental agencies or third party payors continues to reduce coverage of and/or reimbursement for procedures using our products.

We cannot be certain that under current and future payment systems, such as those utilized by Medicare and in many private managed care systems, the cost of our products will be adequately incorporated into the overall cost of the procedure. Therefore, we cannot be certain that the procedures performed with our products will be reimbursed at a sufficiently profitable level, or at all.

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government-sponsored healthcare and private insurance. Our products may not obtain international coverage and reimbursement approvals in a timely manner, if at all. Our failure to receive such approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

If we are unable to maintain and expand our network of direct sales representatives and independent distributors, we may not be able to generate anticipated sales.

Our operating results are directly dependent upon the sales and marketing efforts of not only our employees, but also our independent distributors. We expect our direct sales representatives and independent distributors to develop long-lasting relationships with the surgeons they serve. If our direct sales representatives or independent distributors fail to adequately promote, market and sell our products, our sales could significantly decrease.

Table of Contents

We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. If any of our direct sales representatives were to leave us, or if any of our independent distributors were to cease to do business with us, our sales could be adversely affected. Some of our independent distributors account for a significant portion of our sales volume, and if any such independent distributor were to cease to distribute our products, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors or increase our reliance on our direct sales representatives, which may not prevent our sales from being adversely affected. If a direct sales representative or independent distributor were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified independent distributors or to hire additional direct sales representatives to work with us. We may not be able to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified direct sales representatives or independent distributors would prevent us from maintaining or expanding our business and generating sales.

As we launch new products and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives and independent distributors with significant technical knowledge in various areas, such as spinal care practices, spine injuries and disease and spinal health. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales.

If we are unable to expand our sales and marketing capabilities domestically and internationally, we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations and financial condition.

We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow.

The spine industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. We believe that our significant competitors are Medtronic, the DePuy Synthes Companies (a division of Johnson & Johnson), Stryker and NuVasive. Alphatec Spine, Orthofix International, Zimmer Biomet, K2M and other smaller public and private companies are also competitors of ours. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products. They may also develop and patent processes or products earlier than we can or obtain regulatory clearance or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. If alternative treatments are, or are perceived to be, superior to our spine surgery products, sales of our products could be negatively affected and our results of operations could suffer.

Many of our current and potential competitors are major medical device companies that have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive.

Table of Contents

Many of our larger competitors enjoy several competitive advantages over us, including:

- greater financial, human and other resources for product research and development, sales and marketing and litigation;
- significantly greater name recognition;
- established relationships with spine surgeons, hospitals and other healthcare providers;
- large and established sales and marketing and distribution networks;
- products supported by long-term clinical data;
- greater experience in obtaining and maintaining regulatory clearances or approvals for products and product enhancements;
- more expansive portfolios of intellectual property rights; and
- greater ability to cross-sell their products or to incentivize hospitals or surgeons to use their products.

The frequent introduction by competitors of products that compete with our existing or planned products may also make it difficult to market or sell our products. In addition, the entry of multiple new products and competitors, including physician-owned distributorships ("PODs"), may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the spine market generally.

As a result, our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement from third-party payors, and are safer, less invasive and more effective than alternatives available for similar purposes. If we are unable to do so, our sales or margins could decrease, thereby harming our business.

We are dependent on a limited number of third-party suppliers for most of our products and components, and the loss of any of these suppliers, or their inability to provide us with an adequate supply of materials, could harm our business.

We rely on third-party suppliers to supply most of our products. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Our anticipated growth could strain the ability of our suppliers to deliver an increasingly large supply of products, materials and components. Other issues, including shortages of raw materials or components, problems with production yields and quality control and assurance, especially with products such as allograft, which is processed human tissue, could impair a supplier's ability to supply us with product quantities necessary to support our sales. Furthermore, under our supplier agreements, our suppliers generally have no obligation to manufacture for us or sell to us any specific quantity of products. If we are unable to obtain sufficient quantities of high quality components to meet demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

We generally use a small number of suppliers for each of our products. Our dependence on such a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our suppliers cease to provide us with sufficient quantities of manufactured products in a timely manner or on terms acceptable to us, or cease to manufacture components of acceptable quality, we would have to seek alternative sources of supply. Because of the nature of our internal quality control requirements, regulatory requirements and the custom and proprietary nature of the parts, we cannot quickly engage additional or replacement suppliers for many of our critical components. Failure of any of our third-party suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments to our customers and could have a material adverse effect on our

Table of Contents

business. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other foreign regulatory authorities. We could incur delays while we locate and engage qualified alternative suppliers, and we may be unable to engage alternative suppliers on favorable terms or at all. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate sales.

If we do not successfully implement our business strategy, our business and results of operations will be adversely affected.

Our business strategy was formed based on assumptions about the spine market that might prove wrong. We believe that various demographics and industry-specific trends, including the aging of the general population, increasingly active lifestyles, improving fusion technologies and increasing acceptance of Disruptive Technologies leading to earlier interventions, will help drive growth in the spine market and our business, but these demographics and trends are uncertain. Actual demand for our products could differ materially from projected demand if our assumptions regarding these factors prove to be incorrect or do not materialize, or if alternative treatments to those offered by our products gain widespread acceptance.

We may not be able to successfully implement our business strategy. To implement our business strategy we need to, among other things, strengthen our brand, develop and introduce new spine surgery products, find new applications for and improve our existing products, obtain regulatory clearance or approval for new products and applications and educate spine surgeons about the clinical and cost benefits of our products, all of which we believe could increase acceptance of our products by spine surgeons. Our strategy of focusing exclusively on the spine market may limit our ability to grow. In addition, we are seeking to increase our sales and, in order to do so, will need to commercialize additional products and expand our direct and distributor sales forces in existing and new territories, all of which could result in our becoming subject to additional or different foreign and domestic regulatory requirements, with which we may not be able to comply. Moreover, even if we successfully implement our business strategy, our operating results may not improve or may decline. We may decide to alter or discontinue aspects of our business strategy and may adopt different strategies due to business or competitive factors not currently foreseen, such as new medical technologies that would make our products obsolete. Any failure to implement our business strategy may adversely affect our business, results of operations and financial condition.

The proliferation of PODs could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships.

PODs are medical device distributors that are owned, directly or indirectly, by physicians. These physicians derive a proportion of their revenue from selling or arranging for the sale of medical devices for use in procedures they perform on their own patients at hospitals that agree to purchase from or through the POD, or that otherwise furnish ordering physicians with income that is based directly or indirectly on those orders of medical devices.

We do not sell or distribute any of our products through PODs. The number of PODs in the spine industry may continue to grow as economic pressures increase throughout the industry, as hospitals, insurers and physicians search for ways to reduce costs, and, in the case of the physicians, search for ways to increase their incomes. These companies and the physicians who own, or partially own, them have significant market knowledge and access to the surgeons who use our products and the hospitals that purchase our products, and growth in this area may reduce our ability to compete effectively for business from surgeons who own such distributorships.

Table of Contents

Our business could suffer if we lose the services of key members of our senior management, key advisors or personnel.

We are dependent upon the continued services of key members of our senior management and a limited number of key advisors and personnel. In particular, we are highly dependent on the skills and leadership of our Chief Executive Officer ("CEO"), David C. Paul. The loss of any one of these individuals could disrupt our operations or our strategic plans. Additionally, our future success will depend on, among other things, our ability to continue to hire and retain the necessary qualified scientific, technical and managerial personnel, for whom we compete with numerous other companies, academic institutions and organizations. The loss of members of our management team, key advisors or personnel, or our inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on our business, results of operations and financial condition. Though members of our sales force generally enter into noncompetition agreements that restrict their ability to compete with us, most of the members of our executive management team are not subject to such agreements. Accordingly, the adverse effect resulting from the loss of certain executives could be compounded by our inability to prevent them from competing with us.

The safety and efficacy of our products is not yet supported by long-term clinical data, which could limit sales, and our products might therefore prove to be less safe and effective than initially thought.

All of the products we currently market in the United States, other than our SECURE®-C cervical disc, have either received pre-market clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act ("FDCA") or are exempt from pre-market review. The FDA's 510(k) clearance process requires us to show that our proposed product is "substantially equivalent" to another 510(k)-cleared product. This process is shorter and typically requires the submission of less supporting documentation than other FDA approval processes and does not always require long-term clinical studies. We also continue to gather long term follow-up data in our SECURE®-C clinical trial. Additionally, to date, we have not been required to complete long-term clinical studies in connection with the sale of our products outside the United States. As a result, we currently lack the breadth of published long-term clinical data supporting the safety and efficacy of virtually all of our products and the benefits they offer that might have been generated in connection with other approval processes. For these reasons, spine surgeons may be slow to adopt our products, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would slow the adoption of our products by spine surgeons, significantly reduce our ability to achieve expected sales, and could prevent us from sustaining our profitability.

Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to mandatory product recalls, product seizures, suspension or withdrawal of FDA clearance or approval, and significant legal liability or harm to our business reputation.

If we do not enhance our product offerings through our research and development efforts, we may be unable to effectively compete.

In order to increase our market share in the spine market, we must enhance and broaden our product offerings in response to changing customer demands and competitive pressures and technologies. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

Table of Contents

- properly identify and anticipate surgeon and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

If we do not develop and obtain regulatory clearance or approval for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to successfully develop enhancements or new generations of our products, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

In the near future we expect to introduce a robotic surgical navigation device as well as products to treat patients who have experienced orthopedic traumas. We have no prior experience marketing these new products, and we will need to convince a new audience of surgeons and hospital personnel that these products are attractive alternatives to competing products for use in applicable procedures. If we are unable to launch these new products, either in a timely fashion or at all, or we are not successful in convincing surgeons and hospitals of the merit of these products or educating them on their use, our sales and operating results may be negatively affected and we may not grow as quickly as we anticipate.

If we fail to properly manage our anticipated growth, our business could suffer.

Our rapid growth has placed, and will continue to place, a significant strain on our management and on our operational and financial resources and systems. Failure to manage our growth effectively could cause us to over-invest or under-invest in infrastructure, and result in losses or weaknesses in our infrastructure, which could materially adversely affect us. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to carefully monitor for quality assurance. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

Our results of operations could suffer if we are unable to manage our planned international expansion effectively.

Expansion into international markets is an element of our business strategy and involves risk. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subject us to extensive U.S. and foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. Other laws and regulations that can significantly affect us include various anti-bribery laws, including the FCPA and anti-boycott laws. Any failure to comply with applicable legal and regulatory obligations in the United States or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments and restrictions on certain business activities. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities.

Table of Contents

Our international operations expose us and our independent distributors to risks inherent in operating in foreign jurisdictions, including:

- exposure to different legal and regulatory standards;
- lack of stringent protection of intellectual property;
- obstacles to obtaining domestic and foreign export, import and other governmental approvals, permits and licenses and compliance with foreign laws;
- potentially adverse tax consequences and the complexities of foreign value-added tax systems;
- adverse changes in tariffs and trade restrictions;
- foreign exchange rate risk;
- limitations on the repatriation of earnings;
- difficulties in staffing and managing foreign operations;
- transportation delays and difficulties of managing international distribution channels;
- longer collection periods and difficulties in collecting receivables from foreign entities;
- increased financing costs; and
- political, social and economic instability and increased security concerns.

These risks may limit or disrupt our expansion, restrict the movement of funds or result in the deprivation of contractual rights or the taking of property by nationalization or expropriation without fair compensation.

Our goal of succeeding as an international company depends, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole.

We are subject to risks arising from currency exchange rate fluctuations on our international transactions and translation of local currency results into United States dollars, which could adversely affect our profitability.

Our international sales account for approximately 11% of our total net sales, and we intend to continue to expand our international presence. A significant portion of our foreign revenues and expenses are generated in the Euro zone, United Kingdom, Switzerland and Australia. As our reporting currency is the U.S. dollar, significant changes in currency exchange rates can result in increased exposure to foreign exchange effects on our consolidated results of operations. We cannot predict changes in currency exchange rates, the impact of exchange rate changes, nor the degree to which we will be able to manage the impact of currency exchange rate changes.

We may seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on us.

From time to time we expect to consider opportunities to acquire or make investments in other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. Potential and completed acquisitions and strategic investments involve numerous risks, including:

- problems assimilating the purchased technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;

Table of Contents

- diversion of management's attention from our core business;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses and to obtain any necessary financing. These efforts could be expensive and time-consuming, and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to integrate any acquired businesses, products or technologies effectively, our business, results of operations and financial condition will be materially adversely affected.

We are required to maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows.

As a result of the need to maintain substantial levels of inventory, we are subject to the risk of inventory obsolescence. Many of our products come in sets, which feature components in a variety of sizes to satisfy the particular patient's anatomical needs. In order to market our products effectively, we often must maintain implant sets consisting of the full range of product sizes. For each surgery, fewer than all of the components of the set are used, and therefore certain portions of the set, like uncommon sizes, may become obsolete before they can be used. In the event that a substantial portion of our inventory becomes obsolete, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

If we experience significant disruptions in our information technology systems, our business, results of operations and financial condition could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage:

- sales and marketing, accounting and financial functions;
- inventory management;
- engineering and product development tasks; and
- our research and development data.

Our information technology systems are vulnerable to damage or interruption from:

- earthquakes, fires, floods and other natural disasters;
- terrorist attacks and attacks by computer viruses or hackers;
- power losses; and
- computer systems, or Internet, telecommunications or data network failures.

The failure of our information technology systems to perform as we anticipate or our failure to effectively implement new systems could disrupt our entire operation and could result in decreased sales, increased overhead costs, excess inventory and product shortages, all of which could have a material adverse effect on our reputation, business, results of operations and financial condition.

Table of Contents

Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, results of operations or financial condition.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payors to curb these costs have resulted in a consolidation trend in the healthcare industry to aggregate purchasing power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for hospitals. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, results of operations or financial condition.

Fluctuations in insurance cost and availability could adversely affect our profitability or our risk management profile.

We hold a number of insurance policies, including product liability insurance, directors' and officers' liability insurance, property insurance, health insurance and workers' compensation insurance. If the costs of maintaining adequate insurance coverage increase significantly in the future, our operating results could be materially adversely affected. Likewise, if any of our current insurance coverage should become unavailable to us or become economically impractical, we would be required to operate our business without indemnity from commercial insurance providers. If we operate our business without insurance, we could be responsible for paying claims or judgments against us that would have otherwise been covered by insurance, which could adversely affect our results of operations or financial condition.

Risks Related to our Legal and Regulatory Environment

Our medical device products and operations are subject to extensive governmental regulation both in the United States and abroad, and our failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies. The FDA and other U.S. and foreign governmental agencies regulate, among other things, with respect to medical devices:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- pre-market clearance and approval;
- record keeping procedures;
- advertising and promotion;
- recalls and field safety corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;

Table of Contents

- post-market approval studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time; see “Item 1. Business; Government Regulation” above for a summary of certain regulations to which we are subject. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

The processes by which 510(k) clearance, grant of a de novo classification request, or PMA approval is obtained can be expensive and lengthy and require the payment of significant fees. The FDA’s 510(k) clearance process usually takes from three to 12 months, but may last longer. The FDA’s goal is to review de novo classification requests within 120 to 150 days, but presently, less than 50 percent of the requests are reviewed in this time period and it often takes much longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained. The process of obtaining regulatory clearances through the 510(k) process, de novo classification, or approvals through the PMA process to market a medical device in the United States or internationally can be costly and time-consuming, and we may not be able to obtain these clearances, grants of de novo classification, or approvals on a timely basis, if at all.

In the United States, all of our currently commercialized medical device products, other than SECURE®-C have either received pre-market clearance under Section 510(k) of the FDCA or are exempt from pre-market review. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline and potentially harm our ability to compete. In addition, if the FDA disagrees with our determination that a product we currently market is subject to an exemption from pre-market review, the FDA may require us to submit a 510(k), de novo, or PMA and may require us to cease distribution of the product and/or recall the product unless and until we obtain 510(k) or de novo clearance or PMA. Further, even with respect to those future products where a PMA is not required, we cannot assure you that we will be able to obtain the 510(k) or de novo clearances with respect to those products. The FDA may also reclassify devices currently on the market from Class II to Class III, which could result in additional regulatory burden requiring submission and approval of a PMA prior to marketing, or could result in FDA rescinding a 510(k) for a previously cleared device.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA’s satisfaction that our products are safe and effective for their intended uses;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. It is also possible that, if we obtain new FDA regulatory clearances or approvals, the clearances or approvals may contain limitations on the indicated uses or may prohibit certain uses which may impact the marketability of the product.

Table of Contents

Any delay in, or failure to receive or maintain, clearance or approval for our medical device products under development could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could dissuade some surgeons from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

In addition, even after we have obtained the proper regulatory approval to market a product, the FDA has the power to require us to conduct postmarketing studies. For example, the FDA issued a Section 522 Order in October 2009 requiring companies that market dynamic stabilization systems, such as our TRANSITION® system, to conduct postmarketing studies on those systems. These studies can be very expensive and time-consuming to conduct. Failure to comply with those studies in a timely manner could result in the revocation of the 510(k) clearance for the product that is subject to such a Section 522 Order and the recall or withd