GLOBUS MEDICAL INC
Form 10-K
February 21, 2019
Table of Contents

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

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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, 2018
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 ¨ 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 ¨ No x

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

Indicate by check mark whether the registrant has submitted electronically , every Interactive Data File required to be submitted 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 such files): Yes x No ¨

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, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller Reporting Company	Emerging Growth Company
x	o	o	o	o

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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, 2018, as reported on the New York Stock Exchange, was approximately $3.8 billion.

The number of shares outstanding of the registrant's common stock (par value $0.001 per share) as of February 18, 2019 was 98,653,450 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our Proxy Statement for our 2019 Annual Meeting of Stockholders, to be filed within 120 days of December 31, 2018, 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.

Table of Contents

Item 1. Business

Overview

Globus Medical, Inc. (together, as applicable, with its consolidated subsidiaries, “Globus,” “we,” “us” or “our”), headquartered in Audubon, Pennsylvania, is a medical device company that develops and commercializes healthcare solutions whose mission is to improve the quality of life of patients with musculoskeletal disorders. Founded in 2003, Globus is committed to medical device innovation and delivering exceptional service to hospitals and physicians to advance patient care and improve efficiency. Since inception, Globus has listened to the voice of the surgeon to develop practical solutions and products to help surgeons effectively treat patients and improve lives. We have expanded our sales operations across the globe and now serve customers in 52 countries worldwide.

Globus is an engineering-driven company with a history of rapidly developing and commercializing advanced products and procedures to address treatment challenges. With over 190 products on the market, we offer a comprehensive portfolio of innovative and differentiated technologies that are used to treat a variety of musculoskeletal conditions of the spine, extremities and pelvis. Although we manage our business globally within one operating segment, we separate our products into two major categories: Musculoskeletal Solutions and Enabling Technologies.

Musculoskeletal Solutions

Musculoskeletal Solutions consist primarily of implantable devices, biologics, accessories, and unique surgical instruments used in an expansive range of spinal, orthopedic and neurosurgical procedures.

Our broad spectrum of spine products addresses the vast majority of conditions affecting the spine including degenerative conditions, deformity, tumors, and trauma. With more than fifteen years in this competitive market, we provide comprehensive solutions that facilitate both open and minimally invasive surgery (“MIS”) techniques. This includes traditional fusion implants such as pedicle screw and rod systems, plating systems, intervertebral spacers and corpectomy devices. We believe we pioneered innovative expandable solutions for interbody fusion, corpectomy and interspinous fixation that allow intraoperative customization of our devices to the patient’s anatomy and save surgical time by eliminating sequential trialing. We have also developed treatment options for motion preservation technologies, such as dynamic stabilization, total disc replacement and interspinous distraction devices, and interventional pain management solutions to treat vertebral compression fractures. Regenerative biologic products such as allografts and synthetic alternatives are adjunctive treatments typically used in combination with stabilizing implant hardware.

Our orthopedic trauma solutions are designed to treat a wide variety of orthopedic fracture patterns and patient anatomies in the upper and lower extremities as well as the hip. To date, Globus has received 510(k) clearance from the U.S. Food and Drug Administration (“FDA”) for several orthopedic trauma and extremity products, covering four major segments of the orthopedic trauma market - fracture plates, compression screws, intramedullary nails, and external fixation. We began marketing these products in 2018 and intend to grow our presence in this field. Fracture plating includes proximal humerus, distal radius, proximal tibia, distal fibula, small fragment, mini-fragment and clavicle plates. Intramedullary nailing includes tibial, trochanteric, and femoral nail systems. Regenerative biologic products such as bone void fillers and allograft struts are also used in orthopedic procedures where applicable.

Table of Contents

Enabling Technologies

Enabling Technologies are advanced computer-assisted intelligent systems designed to enhance a surgeon's capabilities and streamline surgical procedures to be safer, less invasive, more accurate, and more reproducible, to ultimately improve patient care and reduce radiation exposure for all involved.

Our current enabling technologies are comprised of imaging, navigation and robotic ("INR") assisted surgery solutions. This includes the ExcelsiusGPS® platform, a robotic guidance and navigation system that supports minimally invasive and open procedures with screw placement applications. The ExcelsiusGPS® platform has a modular design that can be used for a variety of screw placement applications, and we expect that it will serve as a foundation for future clinical applications using artificial intelligence and augmented reality. Surgimap® pre-planning software is used for effortless and convenient surgical planning at any time.

Globus' innovative Enabling Technologies offer surgeons more information about patient anatomy and surgical options to help them to make well-informed surgical decisions. We believe the advantages of pre-planning implant position and viewing patient anatomy during surgery are self-evident, with significant secondary gains such as eliminating radiation exposure altogether.

Overall Business

While we group our products into two categories, they are not limited to a particular technology, platform or surgical approach. Instead, our goal is to offer a comprehensive product suite that can be used to effectively treat patients based on their specific anatomy and condition, and is customized to the surgeon's training and surgical preference.

To date, the primary market for our products has been the United States, where we sell our products through a combination of direct sales representatives employed by us and distributor sales representatives employed by our exclusive independent distributors, who distribute our products on our behalf for a commission that is generally based on a percentage of sales. We believe there is significant opportunity to strengthen our position in the U.S. market by increasing the size of our U.S. sales force and we intend to add additional direct and distributor sales representatives in the future.

During the year ended December 31, 2018, our international sales accounted for approximately 17% of our total sales. We currently sell our products through a combination of direct sales representatives employed by us and exclusive international distributors. We believe there are significant opportunities for us to increase our presence in both existing and new international markets through the continued expansion of our direct and distributor sales forces and the commercialization of additional products.

Table of Contents

Strategy

Our goal is to become the market leader in providing innovative Musculoskeletal Solutions and Enabling Technologies to promote healing in patients with musculoskeletal disorders. To achieve this goal, we employ the following business strategies:

- Leverage our integrated product development engine. We plan to continue developing new Musculoskeletal Solutions products and Enabling Technologies products, using our product development engine. We believe our team-oriented approach, active surgeon input, and demonstrated capabilities position us to maintain a rapid rate of new product launches. We launched ten new products in 2018, have over 30 potential new products in various stages of development, and expect to regularly launch new products.
- 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 in the spine, trauma, and INR areas. We expect 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.
- Continue to expand into international markets. As of December 31, 2018, we had an existing direct or distributor sales presence in 51 countries outside the United States. We expect to continue to increase our international presence through the commercialization of additional Musculoskeletal Solutions and Enabling Technologies products and through the expansion of our international sales force.
- Pursue strategic acquisitions and alliances. In 2016, we acquired the international operations and distribution channel of Alphatec Holdings, Inc. (“Alphatec International”) to increase our worldwide footprint. In 2017, we acquired KB Medical SA, developer of a computer-assisted robotic guidance system and in 2018, we acquired Nemaris Inc., a privately held company that markets and develops Surgimap®, a leading surgical planning software platform, to further bolster our efforts to advance surgical procedures through Enabling Technologies. We intend to selectively pursue acquisitions and alliances that complement our strategic plan and provide innovative technologies, personnel with significant relevant experience, or increased market penetration. We are currently evaluating possible acquisitions and strategic relationships and believe that our resources and experience make us an attractive acquirer or partner.

Table of Contents

The Musculoskeletal Market

Musculoskeletal disorders are a leading driver of healthcare costs worldwide. Disorders range in severity from mild pain and loss of feeling to extreme pain and paralysis. These disorders are primarily caused by degenerative and congenital conditions, deformity, tumors and traumatic injuries. Treatment alternatives for musculoskeletal disorders range from non-operative conservative therapies to surgical interventions depending on the pathology. Conservative therapies include bed rest, medication, casting, bracing, and physical therapy. When conservative therapies are not indicated, or fail to provide adequate quality of life improvements, surgical interventions may be used. Surgical treatments for musculoskeletal disorders can be instrumented, which include the use of implants, or non-instrumented, which forego the use of any such implants.

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

- Favorable patient demographics. The worldwide population is growing and aging, and improvements in healthcare have led to increasing life expectancies worldwide and the opportunity to lead more active lifestyles. This population is more prone to musculoskeletal degeneration, traumatic fractures, and challenging complications. These trends are expected to generate increased demand for surgical intervention.
- Improving technologies within Musculoskeletal Solutions leading to increased use in surgical procedures. We expect the number of spinal and orthopedic surgery cases to grow as product innovation makes surgery a more attractive option for patients. We also expect these innovations to differentiate Globus products from competitive products and make them more attractive to surgeons.
- Musculoskeletal Solutions driving earlier interventions and creating an expanded patient base. Newer technological innovations have enabled novel surgical procedures, improvements to existing surgical procedures, the treatment of musculoskeletal disorders by new physician specialties, and surgical intervention earlier in the continuum of care, all of which may result in better patient outcomes. As a result, we expect continued advancements within Musculoskeletal Solutions supported by surgical Enabling Technologies, including INR systems, to increase the size of the addressable patient population for spine surgery.
- Shift of MIS procedures performed using Enabling Technology in outpatient settings. The effectiveness and shorter surgical times associated with MIS spine procedures is facilitating a larger number of treatments to be performed in ambulatory surgery centers, which increases availability and access to patients. We believe Enabling Technologies provide more access to MIS surgery and facilitate best-in-class treatment modalities.
- Continued growth of musculoskeletal procedures worldwide. We believe that improvements to the standard of care outside of the United States will increase the international demand for musculoskeletal products.

Table of Contents

The Enabling Technologies Market

The market for Enabling Technologies in spine and orthopedic surgery is still in the infancy stage and consists primarily of imaging, navigation and robotic systems. In spine, a majority of these technologies are limited to surgical planning and assistance in implant placement for increased accuracy and time savings with less intraoperative radiation exposure to the patient and surgical staff. As these Enabling Technologies become more fully integrated with various other Musculoskeletal Solutions, a continued rise in adoption is expected. Furthermore, we believe as new technologies such as augmented reality and artificial intelligence are introduced, Enabling Technologies have the potential to transform the way surgery is performed and most importantly, continue to improve patient outcomes.

We believe that growth in Enabling Technologies will result from the following market influences:

- Demand for minimally invasive surgery. Patients are more actively seeking the least invasive and safest surgical treatment options available. As the benefits of robotic assisted surgery in enabling less invasive surgical techniques become known, we believe hospitals will equip themselves with these technologies to satisfy patient demand.
- Hospital cost reduction initiatives. Enabling Technologies products may facilitate less invasive surgical procedures leading to shorter hospital stays with potentially fewer complications rates, which may lead to lower overall treatment costs per patient for the hospital. As hospitals evaluate 30 day readmissions and surgical complication rates for possible cost savings, we expect that the use of Enabling Technologies across multiple surgical specialties will help facilitate less invasive and less costly procedures.
- Integration of robotic training into medical residency programs. As more surgeon trainees, including fellows and residents, participate in programs incorporating imaging, navigation and robotics into their medical training, they are expected to drive widespread adoption of Enabling Technologies within each surgical specialty.
- Increased emphasis on physician and operating room staff safety. Orthopedic surgery currently requires significant intraoperative radiation exposure to facilitate implant placement. Repeated fluoroscopy exposure to patients, surgeons and their staff is hazardous and has been linked to cancer, cataracts, and other side effects. We believe that Enabling Technologies have the potential to significantly reduce and potentially eliminate the need for intraoperative fluoroscopy which we believe will help drive demand for its implementation.

Table of Contents

The Globus Solution

We believe that our focus on actively listening to the needs of our customers, and fostering a culture of urgency throughout the entire organization to quickly respond to these needs with high quality solutions, separates us from our industry peers. Since 2003 we have introduced more than 190 products designed for the treatment of musculoskeletal disorders. Given our robust product portfolio of unique and differentiated products, as well as the numerous disruptive products in various stages of development, we believe we are well positioned for growth in the spine and orthopedic trauma markets.

Musculoskeletal Solution

Our Spine product portfolio includes a wide range of implant and surgical approach options that can be used to treat degenerative, deformity, tumor and trauma conditions affecting the entire spine, from the occiput to the sacrum, while accommodating various surgical techniques preferred by surgeons.

We believe that we have the most comprehensive expandable spacer portfolio in today's market, with over 16 implant options, designed for a wide variety of procedures including Posterior Lumbar Interbody Fusion, Transforaminal Lumbar Interbody Fusion, Lateral Lumbar Interbody Fusion, Anterior Lumbar Interbody Fusion, Endoscopic Lumbar Interbody Fusion and Corpectomy procedures. Expandable product families, which include RISE®, RISE-L®, CALIBER®, CALIBER®-L, ALTERA®, ELSA®, ELSA®-ATP, MAGNIFY®, MAGNIFY®-S, FORTIFY®, and XPand®, among others, are designed to be inserted at a minimized height and then expanded during surgery for optimal fit between vertebral bodies. This expandability feature eases insertion into the disc space following disc removal to help reduce trauma to the vertebral endplates and surrounding tissue, while allowing for restoration of height and lordosis.

Our fixation portfolio, including pedicle screws, rods and plates, provide strength and stability for treating degenerative and more complex spinal deformity procedures. The CREO® thoracolumbar stabilization platform enhances efficiency and ease of use with intuitively designed instruments and a complete array of implant options for treating complex pathologies. Within this platform, CREO® MIS and CREO MCS® provide percutaneous and mini-open midline approach options designed for less invasive surgery and minimal muscle disruption. CREO® Derotation and CREO® Rod Link Reducer systems help to streamline various derotation maneuvers for deformity correction, such as segmental, rib hump correction, and translation of coronally displaced vertebrae. For revision procedures CREO® Addition provides a comprehensive range of connectors, including modular and top-loading styles, which makes extending fixation more streamlined and efficient. In 2018, we launched our first cement augmented pedicle screw system in the United States, CREO® Fenestrated, designed to enhance fixation using bone cement for patients with advanced stage tumors and limited life expectancy.

QUARTEX®, our most advanced Occipito-Cervico-Thoracic ("OCT") stabilization system, is designed to address a number of challenges associated with posterior OCT fusion to aid in easier construct assembly with convenient implant options. The system features a threading locking cap to enable quick and efficient low-torque single step locking and high angle screw heads that accommodate two different diameter rods.

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.

Table of Contents

Interventional spine products, such as the AFFIRM® bone tamp and the SHIELD® barrier implant, allow physicians to customize the treatment plan for vertebral compression fractures and control cement delivery in minimally invasive procedures.

Our Orthopedic Trauma product portfolio features anatomic plating systems, compression screws, nailing systems, and external fixation.

ANTHEM® Fracture Systems are anatomically contoured plates designed for a wide variety of ankle, shoulder, and wrist fractures as well as long and short bony anatomy. Combined with extensive screw options and unique instruments, the plates are designed to match patient anatomy, reduce operative time and minimize soft tissue irritation from implant prominence, a major contributor to revision surgery. They are available in numerous anatomic configurations for adult and pediatric indications. CAPTIVATE® Compression screws have an innovative feature for easy intraoperative compression and reduction of the fracture site. We believe they are a complement to plating for complex trauma.

The AUTOBAHN™ nailing platform is comprised of the Trochanteric Nail designed for trochanteric and femoral neck fractures, Antegrade/Retrograde Femoral Nail that offers both a greater trochanter and piriformis fossa entry points, and the Tibial Nail which includes instruments for infrapatellar and suprapatellar approaches. Each system is designed to help streamline the procedure, increase versatility, reduce procedure time, and ultimately improve patient care.

The ARBOR® External Fixation System provides a streamlined set of external fixation devices including clamps, pins, and bars. This system offers a one-clamp design for every procedure regardless of pin size. Innovative instruments allow surgeons to quickly create the frame of their choice.

Enabling Technologies

ExcelsiusGPS®, a robotic guidance and navigation system, is our first INR technology product to market. FDA-cleared in 2017 and CE-marked in 2016, our first commercial sale of ExcelsiusGPS® came in the fourth quarter of 2017. The ExcelsiusGPS® technology supports minimally invasive and open orthopedic and neurosurgical procedures, with potential applications ranging from the cervical spine to the sacroilium, long bones, and occiput. ExcelsiusGPS® seamlessly integrates with Globus implants and instruments and is compatible with pre-operative CT, intraoperative CT, and fluoroscopic imaging modalities. The system is designed to reproducibly assist in implant placement, streamline workflows, and minimize radiation exposure.

In 2018, we acquired Nemaris Inc., a privately held company that markets and develops Surgimap®, a leading surgical planning software platform. Surgimap®'s intuitive, patient-specific surgical planning and cloud-based infrastructure with predictive algorithms and visual guides enable healthcare professionals to plan and simulate potential surgical outcomes in treating complex deformities. The software also enables medical professionals to share medical imaging technology globally to improve procedural workflow and patient care.

We believe that our innovative Musculoskeletal Solutions and Enabling Technologies products, combined with our ability to provide world-class service through a highly trained and exclusive sales force, reimbursement education and assistance, and corporate account management, create significant value for our customers.

Table of Contents

Product Development and Research

Globus believes in bringing products to market quickly by reducing the time from product conception to launch. We believe our approach to product development is unique and highly efficient. We employ an integrated team approach to product development involving collaboration among surgeons, our engineers, our dedicated researchers, our highly-skilled machinists, and our regulatory personnel. We believe that this team approach, as well as our extensive in-house facilities, allows us to design, test and obtain regulatory clearance and approvals of our products more effectively. We also believe that our product development engine provides us with a competitive advantage in developing solutions to challenging clinical problems for surgeons and improving 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 more rapidly. Research resources available in-house include a mechanical testing laboratory, spinal kinematics laboratory, tribology laboratory, cadaveric laboratory, materials characterization laboratory, computational laboratory, and clinical and biomechanical research experts.

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.

Sales and Marketing

We market and sell our products through our exclusive global sales force. As of December 31, 2018, we had a direct or distributor sales presence in the United States and in 51 countries outside the United States. We have dedicated spinal implant, orthopedic trauma and INR sales teams in place. We expect to continue to increase the number of our direct and distributor sales representatives in each of these three areas, 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 implant 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 U.S. 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 for members of our direct sales force to move toward a compensation model based solely on commission as they become familiar with our products and drive higher sales.

Table of Contents

Advancement of Musculoskeletal Care

We are committed to the advancement of musculoskeletal care through our support of numerous educational and research programs geared towards 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.

We devote significant resources to training and educating surgeons on 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 have 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 dedicated research team, these efforts range from basic biomechanical testing conducted internally with our six-degrees-of-freedom machine to major clinical outcomes studies. We are committed to providing the orthopedic surgeon community with high quality research to support new or improved surgical techniques and novel product designs that we develop.

Competition

We believe that our significant competitors are Medtronic, DePuy Synthes, Stryker, Zimmer Biomet, Smith and Nephew, and NuVasive. Wright Medical Group, Orthofix International, Integra, 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 musculoskeletal 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.

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 a 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 successfully compete is dependent 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

Table of Contents

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 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. The ExcelsiusGPS® robotic guidance and navigation system is assembled in our facility in Methuen, Massachusetts.

Of our implant and instrument products that are not manufactured in-house, a majority are generally manufactured through a network of over 100 third-party suppliers. Our suppliers use 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 are ISO-13485 certified, meaning they meet the International Organization for Standardization ("ISO") requirements for the manufacture of medical devices. 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 on site 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.

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, 2018, we owned 855 issued U.S. patents (838 utility patents; 17 design patents) and had applications pending for 480 U.S. patents (471 utility patents; 9 design patents), and we owned 301 issued foreign patents and had applications pending for 373 foreign patents. Our issued patents expire between November 2019 and December 2036.

Table of Contents

Our trademark portfolio contains 196 registered trademarks and 70 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, hospital outpatient departments, and Ambulatory Surgery Centers (ASCs) 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.

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 all providers including physicians and facilities for reporting patient diagnosis(es) (ICD-10-CM codes) and hospitals for reporting inpatient procedures (ICD-10-PCS codes). ICD-10-CM/PCS was implemented in the U.S. on October 1, 2015. This represented 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 vary from payor to payor and contract to contract. There are thousands of payor medical policies which are continually reviewed and revised at the discretion of payors. Payor medical policies may 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. Additionally, many private payors use coverage decisions and payment amounts established by CMS for the Medicare program as guidelines in setting their coverage and reimbursement policies. Medicare may establish National Coverage Determinations (NCDs) or Medicare Administrative Contractors (MACs) may establish Local Coverage Determinations (LCDs) that provide coverage information and determine whether services are reasonable and necessary. 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.

Table of Contents

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 musculoskeletal procedures. Additionally, more musculoskeletal 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:

- 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.

Table of Contents

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 request, 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 request process, under which the FDA may determine that the product can be appropriately regulated as a Class I or II device. 510(k) pre-market notifications, de novo requests, and PMAs are subject to the payment of user fees, paid at the time of submission for FDA review. 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.

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;

Table of Contents

- 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's Office of Regulatory Affairs, Office of Compliance, Center for Devices and Radiological Health, and 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.

On October 31, 2018, we received a warning letter from the FDA resulting from an inspection of the facilities of our subsidiary Human Biologics of Texas, located in San Antonio, Texas, in April 2018. The letter described observed non-conformities to regulations for human cells, tissues, and cellular and tissue-based products relating to one allograft tissue product processed by Human Biologics of Texas and sold to end users by us. We take the matters identified in the warning letter seriously and are working diligently to address the FDA's observations. We responded to the FDA's warning letter on November 20, 2018, and subsequently have provided periodic updates regarding our progress towards addressing the FDA's observations. As of December 31, 2018, this warning letter remains pending.

We believe that the FDA's concerns set forth in the warning letter can be resolved without a material impact to our financial results. We cannot, however, give any assurances that the FDA will be satisfied with our response or as to the expected date of the resolution of the matters included in the warning letter. Until the issues cited in the warning letter are resolved to the FDA's satisfaction, additional legal or regulatory action may be taken without further notice. Any adverse action by the FDA, depending on its magnitude, may restrict us from effectively producing, marketing and selling the product that is the subject matter of the warning letter and could have a material adverse effect on our business, financial condition and results of operations.

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. To demonstrate

Table of Contents

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.

In 2020, the EEA Member States will implement the EU Medical Device Regulation (MDR 2017/745), which will replace the current EU Medical Device Directive that governs medical devices in the EEA. All medical device companies manufacturing and/or marketing products in the EEA, including Globus, will be required to comply with the new regulation, which increases technical documentation requirements and may alter the classification of some products. Most devices that are CE marked under the EU Medical Device Directive prior to 2020 will continue to be marketed in the EU under certain conditions until 2024, at which point these products must comply with the new regulation.

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 U.S. Foreign Corrupt Practices Act ("FCPA") and similar anti-bribery laws in non-U.S. jurisdictions, such as the United Kingdom's Bribery Act, generally prohibit companies and their intermediaries from making improper payments to non-U.S. government officials for the purpose of obtaining or retaining business. Because of the predominance of government-administered healthcare systems in many jurisdictions around the world, many of our customer relationships outside of the U.S. are with governmental entities and are therefore potentially subject to such laws. Global enforcement of anti-corruption laws has increased considerably in recent years, with more frequent voluntary self-disclosures by companies, aggressive investigations and enforcement proceedings by U.S. and non-U.S. governmental agencies, and assessment of significant fines and penalties against companies and

Table of Contents

individuals. It is our policy to implement safeguards to educate our employees and agents on these legal requirements and prohibit improper practices. The government may seek to hold us liable for FCPA violations committed by companies that we acquire. Violations of these laws may be punishable by criminal or civil sanctions, including substantial fines, imprisonment of current or former employees and exclusion from participation in governmental healthcare programs.

Additionally, we must comply with a variety of other laws that protect the privacy of individually identifiable healthcare information and impose extensive tracking and reporting related to transfers of value provided to certain healthcare professionals. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively "PPACA") imposes 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 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 of Musculoskeletal Solutions products may be influenced by summer vacation and winter holiday periods during which we have experienced fewer surgeries taking place, as well as more surgeries taking place later in the year when patients have met the deductibles under insurance plans. Our sales of Enabling Technologies products may be influenced by longer capital purchase cycles and the timing of budget approvals for major capital purchases.

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.

Employees

As of December 31, 2018, we had over 1,800 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.

Table of Contents

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 fifteen additional countries, all of which are leased.

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. 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.

Table of Contents

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 surgeons and hospitals that our products are an attractive alternative to our competitors' products and that our Enabling Technologies and Musculoskeletal Solutions products are an attractive alternative to existing surgical treatments of musculoskeletal disorders.

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 surgeons and hospitals that our products are attractive alternatives to competing products for use in procedures. Acceptance of our products depends on educating 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 surgeons in the proper application of our products. If we are not successful in convincing 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.

Furthermore, we believe surgeons will not widely adopt certain of our most novel Musculoskeletal Solutions or Enabling Technologies products unless they determine, based on experience, clinical data and published peer-reviewed journal articles, that MIS techniques, our motion preservation, regenerative biologics, and INR technologies provide benefits or are an attractive alternative to conventional treatments of musculoskeletal 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, motion preservation, regenerative biologics or INR 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 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.

Table of Contents

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 musculoskeletal devices industry is characterized by intense competition and 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 Musculoskeletal Solutions products, we may not be able to sell our Musculoskeletal Solutions 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 Musculoskeletal Solutions 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 Musculoskeletal Solutions 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 Musculoskeletal Solutions 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 Musculoskeletal Solutions products, our profitability may be negatively impacted.

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 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 Musculoskeletal Solutions products. For example, Aetna 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 Musculoskeletal Solutions products designed for lumbar fusion procedures. Our

Table of Contents

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 Musculoskeletal Solutions 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 Musculoskeletal Solutions products will be adequately incorporated into the overall cost of the procedure. Therefore, we cannot be certain that the procedures performed with our Musculoskeletal Solutions products will be reimbursed at a sufficiently profitable level, or at all.

To the extent we sell our Musculoskeletal Solutions 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 Musculoskeletal Solutions 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.

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. 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.

Table of Contents

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.
Our 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, DePuy Synthes, Stryker, Zimmer Biomet, Smith and Nephew, and NuVasive. Wright Medical Group, Orthofix International, Integra, 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 musculoskeletal 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 musculoskeletal 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.
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 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 musculoskeletal implant and device 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 our Musculoskeletal Solutions products and components used in our Enabling Technologies products, 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 many of our Musculoskeletal Solutions products and the components used in our Enabling Technologies 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

Table of Contents

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 and components. 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 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 that might prove wrong. We believe that various demographics and industry-specific trends will help drive growth in our markets 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 musculoskeletal surgery products, find new applications for and improve our existing products, obtain regulatory clearance or approval for new products and applications and educate surgeons about the clinical and cost benefits of our products, all of which we believe could increase acceptance of our products by surgeons. Our strategy of focusing exclusively on the medical devices 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

Table of Contents

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 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.

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 Executive Chairman, David C. Paul, and our Chief Executive Officer, David M. Demski. 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. 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, except our SECURE®-C device which was prospectively studied through seven-year postoperative clinical study as part of the Post-Market Approval (PMA) process. 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, 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 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.

Table of Contents

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

In order to increase our market share, 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:

- 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 and product 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.

We recently introduced the ExcelsiusGPS® platform as well as orthopedic trauma products. Prior to launching, we had no prior experience marketing these new products and we may launch new products in the future that we have no prior experience marketing. We will need to convince a new audience of surgeons and hospital personnel that our new products are attractive alternatives to competing products for use in applicable procedures. If we are not successful in convincing surgeons and hospitals of the merit of new 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.

Table of Contents

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.

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 operations account for approximately 17% 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 Japan, 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.

Table of Contents

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;
- 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 Musculoskeletal Solutions 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 Musculoskeletal Solutions 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.

We rely on information technology systems and network infrastructure to operate and manage our business, if we experience a breach, cyber-attack or other disruption to these systems or data, our business, results of operations and financial condition could be adversely affected.

We are increasingly dependent on sophisticated information technology systems to operate our business, including to process, transmit and store sensitive data, and many of our products and services include or use integrated software and information technology that may collect data regarding customers, patients, suppliers and third parties, or connects to our systems. Given the nature of our business, we also may maintain personally identifiable information ("PII") or access to protected health information ("PHI"). Specifically, 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

Table of Contents

business therefore depends on the continuous, effective, reliable, and secure operation of our computer hardware, software, networks, Internet servers, and related infrastructure.

Although our computer and communications hardware is protected through physical and software safeguards, it is still vulnerable to system malfunction, computer viruses, and cyber-attacks. These events could lead to the unauthorized access of our information technology systems and result in the misappropriation or unauthorized disclosure of confidential information belonging to us, our employees, patients, partners, customers, or our suppliers. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. Additionally, the regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. If our information technology systems are compromised, we could be subject to fines, damages, litigation and enforcement actions and we could lose trade secrets or other confidential information, the occurrence of which could harm our reputation, business, results of operations and financial condition.

Our information systems, and those of third-parties with whom we contract, also require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information technology. The failure of our information technology systems to perform as we anticipate or our failure to effectively implement new systems could disrupt our operations 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.

We are subject to data privacy laws and our failure to comply with them could subject us to substantial liabilities.

Our business relies on the secure electronic transmission, storage and hosting of sensitive information, including personal information, PHI, financial information, intellectual property and other sensitive information related to our customers and workforce. The collection, maintenance, protection, use, transmission, disclosure and disposal of certain personal information and the security of medical devices are regulated at the U.S. federal and state, international and industry levels. U.S. federal and state laws, such as the Health Insurance Portability and Accountability Act of 1996, protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information. In addition to the regulation of personal health information, a number of states have also adopted laws and regulations that may affect our privacy and data security practices for other kinds of PII, such as state laws that govern the use, disclosure and protection of sensitive personal information, such as social security numbers, or that are designed to protect credit card account data. State consumer protection laws may also establish privacy and security standards for use and management of PII, including information related to customers, suppliers, and care providers.

Outside the U.S., we are impacted by the privacy and data security requirements at the international, national and regional level, and on an industry specific basis. Legal requirements in the countries we serve relating to the collection, storage, handling and transfer of personal data and potentially intellectual property continue to evolve with increasingly strict enforcement regimes. More privacy and security laws and regulations are being adopted, and more are being enforced, with potential for significant financial penalties. In the E.U., increasingly stringent data protection and privacy rules that will have substantial impact on the use of patient data across the healthcare industry became effective in May 2018. The E.U. General Data Protection Regulation (GDPR) applies uniformly across the E.U. and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR also requires companies processing personal data of individuals residing in the E.U. to comply with E.U. privacy and data protection rules.

30

Table of Contents

Compliance with these laws and regulations may require significant additional costs or changes in our business which could adversely affect our results of operations or financial condition. Noncompliance with these laws and regulations could result in the imposition of fines and penalties or could result in significant civil and other liabilities.

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 or other cybersecurity attacks or breaches;
- 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.

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

Table of Contents

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.

If our Enabling Technologies products require significant amounts of service after sale or we receive a significant number of warranty claims, our costs may increase and our financial results may be adversely affected.

Sales of certain of our Enabling Technologies products that are capital equipment typically include a warranty and maintenance obligation on our part for services for a period of twelve months from the date the equipment is installed at a customer's facility. Customers may also purchase a supplemental service plan for technical and other services for any required service beyond the initial warranty and service period. If product warranty claims or required service under the service plans exceed our expectations, we may incur additional expenditures for parts and service. In addition, our reputation could be damaged and our products may not achieve market acceptance and could result in reductions in sales.

We are exposed to the credit risk of some of our customers, which could result in material losses.

Our business is subject to the risk of nonpayment by our customers. We sell our Enabling Technologies products through various credit and installment payment arrangements. We may experience loss from a customer's failure to make payments according to the contractual terms.

Although we have systems in place to monitor and mitigate the associated risk, there can be no assurance that such systems will be effective in reducing the credit risk relating to the sale of our Enabling Technologies products. If the level of credit losses we experience in the future exceed our expectations, such losses could have a material adverse effect on our financial condition or results of operations.

We experience long and variable capital sales cycles for our Enabling Technologies products, which may cause fluctuations in our financial results.

The sales and purchase order cycle of our Enabling Technologies capital equipment products, currently the ExcelsiusGPS® platform, is lengthy because they are major capital items and their purchase generally requires the approval of senior management of hospitals, their parent organizations, purchasing groups, and government bodies, as applicable. In addition, sales to some of our customers are subject to competitive bidding or public tender processes. These approval and bidding processes can be lengthy. Further, the introduction of new products could adversely impact our sales cycle as customers take additional time to assess the benefits and costs of such products. As a result, it is difficult for us to predict the length of capital sales cycles and, therefore, the exact timing of capital sales.

The above factors may contribute to fluctuations in our quarterly operating results. Because of these fluctuations, it is possible that in future periods our operating results will fall below the expectations of securities analysts or investors. If that happens, the market price of our stock would likely decrease.

Table of Contents

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;
- 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 costlier and more 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.

Table of Contents

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. 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 may issue a Section 522 Order to conduct postmarketing studies. 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 withdrawal of the product, which could prevent us from generating sales from that product in the United States.

Similarly, we must comply with numerous international laws and regulations in order to market our products outside of the United States; see "Item 1. Business; Government Regulation; International" above for a summary of certain international laws and regulations to which we are subject. As is the case in the United States, the applicable regulatory body 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. Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating revenue from these products or achieving profitability. Conducting clinical studies to obtain clinical data that might be required as part of the clinical evaluation process can be expensive and time-consuming. Additionally, the 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 the perceived safety and efficacy of our products and our reputation.

Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;

Table of Contents

- total or partial suspension of production;
- refusal of the FDA or other regulator to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products;
- refusal to grant export approvals; and/or
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

Modifications to our products may require new 510(k) or de novo clearances, PMAs or PMA supplements, or may require us to cease marketing or recall the modified products until clearances or approvals are obtained.

Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness or that would constitute a major change in its intended use, requires a new 510(k) clearance or, possibly, a de novo petition or approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510(k)-cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances new 510(k) clearances or PMAs are not required. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications, de novo petitions, PMAs or PMA supplements for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Our HCT/P products are subject to extensive government regulation and our failure to comply with these requirements could cause our business to suffer.

In the United States, we are marketing our human tissue products as Section 361 HCT/Ps, which are not subject to FDA premarket clearance or approval requirements. The FDA could disagree with our determination that our human tissue products are Section 361 HCT/Ps and could determine that these products are biologics requiring a biological license application approval or medical devices requiring 510(k) or de novo clearance or PMA approval, or NDA (New Drug Application) approval. The FDA may then require that we cease marketing our human tissue products and/or recall the products unless and until we receive the appropriate clearance or approval from the FDA.

HCT/Ps also are subject to donor eligibility and screening, CGTP, product labeling, and postmarket reporting requirements. If we or our suppliers fail to comply with these requirements, we could be subject to FDA enforcement action, including, for example, warning letters, fines, injunctions, product recalls or seizures, and, in the most serious cases, criminal penalties.

We received an FDA warning letter on October 31, 2018 related to observed non-conformities to FDA's HCT/P regulations. See "Item 1. Business; Government Regulation."

Table of Contents

We may fail to obtain or maintain foreign regulatory approvals to market our products in other countries.

We currently market our products internationally and intend to expand our international marketing. International jurisdictions require separate regulatory approvals and compliance with numerous and varying regulatory requirements. For example, we intend to continue to seek regulatory clearance to market our primary products in the EEA, Japan, Brazil, Canada and other key markets. The approval procedures vary among countries and may involve requirements for additional testing, and the time required to obtain approval may differ from country to country and from that required to obtain FDA clearance or approval.

Clearance or approval by the FDA does not ensure approval or certification by regulatory authorities in other countries or jurisdictions, and approval or certification by one foreign regulatory authority does not ensure approval or certification by regulatory authorities in other foreign countries or by the FDA. The foreign regulatory approval or certification process may include all of the risks associated with obtaining FDA clearance or approval. We may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals or certifications and may not receive necessary approvals to commercialize our products in any market. If we fail to receive necessary approvals or certifications to commercialize our products in foreign jurisdictions on a timely basis, or at all, our business, results of operations and financial condition could be adversely affected.

Additionally, in the EEA, we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned substantial changes to our quality system or changes to our devices which could affect compliance with the essential requirements or the devices' intended use. The Notified Body will then assess the changes and verify whether they affect the products' conformity. If the assessment is not favorable, it could prevent us from selling that product in the EEA, which could adversely impact our business and results of operations.

We are subject to risks associated with our non-U.S. operations.

The FCPA and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our operations, involve significant management distraction and result in a material adverse effect on our business, results of operations and financial condition. We also could suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures, including further changes or enhancements to our procedures, policies and controls, as well as potential personnel changes and disciplinary actions.

Furthermore, we are subject to the export controls and economic embargo rules and regulations of the United States, including, but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries or persons. A determination that we have failed to comply, whether knowingly or inadvertently, may result in substantial penalties, including fines and enforcement actions and civil and/or criminal sanctions, the disgorgement of profits and the imposition of a court-appointed monitor, as well as the denial of export privileges, and may have an adverse effect on our reputation.

Table of Contents

These and other factors may have a material adverse effect on our international operations or on our business, results of operations and financial condition generally.

If we or our suppliers fail to comply with the FDA's good manufacturing practice regulations and similar international regulations, this could impair our ability to market our products in a cost-effective and timely manner.

We and our third-party suppliers are required to comply with the FDA's Quality System Regulation ("QSR"), which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. In addition, suppliers and processors of allograft must comply with the CGTP, which govern the methods used in and the facilities and controls used for the manufacture of human cell tissue and cellular and tissue-based products, record-keeping and the establishment of a quality program. The FDA audits compliance with the QSR and CGTP requirements through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time. If we or our suppliers have significant non-compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) or de novo clearance or PMA of new products or modified products;
- withdrawing 510(k) or de novo clearances or PMAs that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

Any of these sanctions could have a material adverse effect on our reputation, business, results of operations and financial condition.

Outside the United States, our products and operations are also often required to comply with standards set by industrial standards bodies, such as the ISO. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. We intend to comply with the standards enforced by such foreign regulatory bodies as needed to commercialize our products. If we fail to adequately comply with any of these standards, a foreign regulatory body may take adverse actions similar to those within the power of the FDA. Any such action may harm our reputation and business, and could have an adverse effect on our business, results of operations and financial condition.

Table of Contents

A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. Even if voluntary, the FDA requires that a medical device manufacturer report to the FDA any corrective action or removal of a device initiated to reduce a risk to health posed by the device. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation, results of operations and financial condition, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

In the EEA, we must comply with the EU Medical Device Vigilance System. Under this system, manufacturers are required to take Field Safety Corrective Actions ("FSCAs") to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include the recall, modification, exchange, destruction or retrofitting of the device.

Any adverse event involving our products, whether in the United States or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

We may be subject to enforcement action if we engage in the off-label promotion of our products.

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of off-label use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if the FDA determines that our promotional efforts constitutes promotion of an off-label use, it could request that we modify our training or promotional efforts or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities, such as the Department of Justice ("DOJ"), might take action if they consider our promotional or training materials to constitute promotion of an unapproved/off-label use, which could result in significant criminal and/or civil fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement (e.g., the False Claims Act). In that event, our reputation could be damaged and adoption of the products would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

Governmental regulation and limited sources and suppliers could restrict our procurement and use of tissue.

In the United States, the procurement and transplantation of allograft bone tissue is subject to federal law pursuant to the 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

Table of Contents

associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. We provide services in all of these areas in the United States, with the exception of removal and implantation, and receive payments for all such services. We make payments to tissue banks for their services related to recovering allograft bone tissue on our behalf. If NOTA is interpreted or enforced in a manner that prevents us from receiving payment for services we render or that prevents us from paying tissue banks or certain of our clients for the services they render for us, our business could be materially adversely affected.

We depend on a limited number of sources of human tissue for use in some of our regenerative biologics products and a limited number of entities to process the human tissue for use in those regenerative biologics products, and any failure to obtain tissue from these sources or to have the tissue processed by these entities for us in a timely manner will interfere with our ability to effectively meet demand for our regenerative biologics products incorporating human tissue. Less than five third-party suppliers currently supply all of our needs for allograft implants and products, other than those implants and products that we process ourselves. The processing of human tissue into our regenerative biologics products is very labor-intensive and it is therefore difficult to maintain a steady supply stream. In addition, due to seasonal changes in mortality rates, some scarce tissues used in our regenerative biologics products are at times in particularly short supply. We cannot be certain that our current supply of human tissue and allograft implants, plus any additional source that we identify in the future, will be sufficient to meet our needs. Our dependence on a small number of third-party suppliers and the challenges we may face in obtaining adequate supplies of human tissue involve several risks, including limited control over pricing, availability, quality and delivery schedules. In addition, any interruption in the supply of any human tissue component could materially harm our and our third-party suppliers' ability to manufacture our regenerative biologics products until a new source of supply, if any, could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have a material adverse effect on our business, results of operations and financial condition.

Negative publicity concerning methods of tissue recovery and screening of donor tissue in our industry could reduce demand for our regenerative biologics products and impact the supply of available donor tissue.

Media reports or other negative publicity concerning both alleged improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of some of our regenerative biologics products. Unfavorable reports of improper or illegal tissue recovery practices, both in the United States and internationally, as well as incidents of improperly processed tissue leading to the transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of technologies incorporating human tissue. In addition, such negative publicity could cause the families of potential donors to become reluctant to agree to donate tissue to for-profit tissue processors. For example, the media has reported examples of alleged illegal harvesting of body parts from cadavers and resulting recalls conducted by certain companies selling human tissue based products affected by the alleged illegal harvesting. These reports and others could have a negative effect on our tissue regeneration business.

We are subject to environmental laws and regulations that can impose significant costs and expose us to potential financial liabilities.

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. A failure to comply with current or future

Table of Contents

environmental laws and regulations could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations and financial condition.

We or our suppliers may be the subject of claims for non-compliance with FDA regulations in connection with the processing, manufacturing or distribution of our proposed allograft or other regenerative biologics implants and products.

Allegations may be made against us or against donor recovery groups or tissue banks, including those with which we have a contractual supplier relationship, claiming that the acquisition or processing of tissue for allograft implants and products or other regenerative biologics products does not comply with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to take investigative or other action against us or our suppliers, or could cause negative publicity for us or our industry generally. These actions or any negative publicity could cause us to incur substantial costs, divert the attention of our management from our business and harm our reputation.

We and our distributor sales representatives might be subject to claims for failing to comply with U.S. federal, state and foreign fraud and abuse laws, including anti-kickback laws and other anti-referral laws.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Our relationships with surgeons, hospitals and our independent distributors are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs. Because of the broad and far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws.

Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. Examples of laws that may affect our ability to operate include:

- the Federal Anti-Kickback Statute, which prohibits, 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 for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;
- the FCPA, which prohibits corrupt payments, gifts or transfers of value to foreign officials;
- foreign and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; and
- the Physician Payment Sunshine Act, which requires medical device companies to report all compensation, gifts and benefits they have provided to certain healthcare professionals.

Table of Contents

Possible sanctions for violation of these laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting, royalty and other agreements with surgeons, including some who make referrals to us. In addition, some of our referring surgeons own our stock, which they either purchased in an arm's length transaction on terms identical to those offered to non-referral sources or received from us as fair market value consideration for consulting services performed. While these transactions were structured with the intention of complying with all applicable laws, including the federal ban on physician self-referrals, commonly known as the "Stark Law," state anti-referral laws and other applicable anti-kickback laws, it is possible that regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. Regulators also could prohibit us from accepting payment for products ordered or recommended by these surgeons. We would be materially and adversely affected if regulatory agencies interpret our financial relationships with surgeons who order our products to be in violation of applicable laws and we were unable to comply with applicable laws. This could subject us to monetary penalties for non-compliance, the cost of which could be substantial, or we may be unable to accept referrals from such surgeons.

To enforce compliance with the federal laws, the DOJ has increased its scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming and can divert management's attention from the business. Additionally, if an investigation were initiated involving us and we decided to settle that investigation with the DOJ or other law enforcement agencies, we may be forced to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business, financial condition and results of operations.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of commercial compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the possibility that a healthcare company may run afoul of one or more of the requirements.

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. In addition to the penalties described above, any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming and could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to our Financial Results and Need for Financing

We will need to generate significant sales to remain profitable.

We intend to increase our operating expenses substantially as we add sales representatives and distributors to increase our geographic sales coverage, submit additional investigational device exemption ("IDE") applications to the FDA, increase our marketing capabilities, conduct clinical trials and increase our general and administrative functions to support our growing operations. We will need to generate significant sales to maintain profitability

Table of Contents

and we might not be able to do so. Even if we do generate significant sales, we might not be able to sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we anticipate or if our operating expenses exceed our expectations, our business, financial condition and results of operations will likely be adversely affected.

We may be unable to grow our revenue or earnings as anticipated, which may have a material adverse effect on our results of operations.

We have experienced rapid growth since our inception and have increased our revenues to $713.0 million in 2018. Our ability to achieve future growth will depend upon, among other things, the success of our growth strategies, which we cannot assure will be successful. In addition, we may have more difficulty maintaining our historical or prior rate of growth of revenues, profitability or cash flows. Our future success will depend upon numerous factors, including the strength of our brand, the market success of our current and future products, competitive conditions, our ability to attract and retain our employees and our ability to manage our business and implement our growth strategy. If we are unable to achieve future growth, our business, financial condition and results of operations could be adversely affected. In addition, we anticipate significantly expanding our infrastructure and adding personnel in connection with our anticipated growth, which we expect will cause our selling, general and administrative expenses to increase, which could adversely impact our results of operations.

Our quarterly and annual operating results may fluctuate significantly.

Our operating results are difficult to predict and may be subject to periodic fluctuations. Our sales and results of operations will be affected by numerous factors, including:

- our ability to drive increased sales of our products;
- our ability to establish and maintain an effective and dedicated sales force;
- pricing pressure applicable to our products, including adverse third-party coverage and reimbursement outcomes;
- results of clinical research and trials on our existing products and products in development;
- the mix of our products sold because profit margins differ amongst our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- the ability of our suppliers to timely provide us with an adequate supply of materials and components;
- the evolving product offerings of our competitors;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
- interruption in the manufacturing or distribution of our products;
- the effect of competing technological, industry and market developments;
- changes in our ability to obtain regulatory clearance or approval for our products; and
- our ability to expand the geographic reach of our sales and marketing efforts.

Many of the products we may seek to develop and introduce in the future will require FDA approval or clearance before commercialization in the United States, and commercialization of such products outside of the United States would likely require additional regulatory approvals and import licenses. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. In addition, we will be increasing our operating expenses as we expand our commercial capabilities. Accordingly, we may experience significant, unanticipated quarterly or annual losses. If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our Class A common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our Class A common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Table of Contents

The availability of funding under existing credit arrangements might be limited, and our cash and cash equivalents are subject to volatility.

Any lender that is obligated to provide funding to us under any now existing or future credit agreement with us may not be able to provide funding in a timely manner, or at all, when we require it. The cost of, or lack of, available credit or equity financing could impact our ability to develop sufficient liquidity to maintain or grow our company, which in turn may adversely affect our business, results of operations or financial condition. We also manage cash and cash equivalents and short-term investments through various institutions. There may be a risk of loss on investments based on the volatility of the underlying instruments that will prevent us from recovering the full principal of our investments. Negative changes in domestic and global economic conditions or disruptions of either or both of the financial and credit markets may also affect third-party payors and may have a material adverse effect on our stock price, business, results of operations, financial condition and liquidity.

Our future capital needs are uncertain and we may need to raise funds in the future, and such funds may not be available on acceptable terms or at all.

Continued expansion of our business will be expensive and we may seek funds from public and private stock offerings, borrowings under our existing or future credit facilities or other sources. Our capital requirements will depend on many factors, including:

- the revenues generated by sales of our products;
- the costs associated with expanding our sales and marketing efforts;
- the expenses we incur in manufacturing and selling our products;
- the costs of developing and commercializing new products or technologies;
- the cost of obtaining and maintaining regulatory approval or clearance of our products and products in development;
- the number and timing of acquisitions and other strategic transactions;
- the costs associated with our planned international expansion;
- the costs associated with increased capital expenditures, including fixed asset purchases of instrument sets which we loan to hospitals to support surgeries; and
- unanticipated general and administrative expenses.

As a result of these factors, we may seek to raise capital, and such capital may not be available on favorable terms, or at all. Furthermore, if we issue equity or debt securities to raise capital, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise capital on acceptable terms, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures, changes in our supplier relationships, or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our development and commercialization goals, which could have a material adverse effect on our business, results of operations and financial condition.

Our existing revolving credit facility contains restrictive covenants that may limit our operating flexibility.

Our existing revolving credit facility contains certain restrictive covenants that limit our ability to transfer or dispose of assets, merge with other companies or consummate certain changes of control, acquire other companies, pay dividends, incur additional indebtedness and liens, experience changes in management and enter into new businesses. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lender or terminate the revolving credit facility. There is no guarantee that we will be able to

Table of Contents

generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest on any such debt. Furthermore, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance any such debt.

Risks Related to our Intellectual Property and Potential Litigation

Our ability to protect our intellectual property and proprietary technology is uncertain.

We rely primarily on patent, copyright, trademark and trade secret laws, as well as confidentiality and non-disclosure agreements and other methods, to protect our proprietary technologies and know-how. We have applied for patent protection relating to certain existing and proposed products and processes. While we generally apply for patents in those countries where we intend to make, have made, use or sell patented products, we may not accurately predict all of the countries where patent protection will ultimately be desirable. If we fail to timely file a patent application in any such country, we may be precluded from doing so at a later date. Furthermore, we cannot assure you that any of our patent applications will be approved. The rights granted to us under our patents, including prospective rights sought in our pending patent applications, may not be meaningful or provide us with any commercial advantage and they could be opposed, contested or circumvented by our competitors or be declared invalid or unenforceable in judicial or administrative proceedings. The failure of our patents to adequately protect our technology might make it easier for our competitors to offer the same or similar products or technologies. Competitors may be able to design around our patents or develop products that provide outcomes which are comparable to ours without infringing on our intellectual property rights. We have entered into confidentiality agreements and intellectual property assignment agreements with our officers, employees, consultants and advisors regarding our intellectual property and proprietary technology. In the event of unauthorized use or disclosure or other breaches of such agreements, we may not be provided with meaningful protection for our trade secrets or other proprietary information. Due to differences between foreign and U.S. patent laws, our patented intellectual property rights may not receive the same degree of protection in foreign countries as they would in the United States. Even if patents are granted outside the United States, effective enforcement in those countries may not be available. Since most of our issued patents and pending patent applications are for the United States only, we lack a corresponding scope of patent protection in other countries. In countries where we do not have significant patent protection, we may not be able to stop a competitor from marketing products in such countries that are the same as or similar to our products.

We rely on our trademarks, trade names and brand names to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. We cannot assure you that our trademark applications will be approved. Third parties may also oppose our trademark applications, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

If a competitor infringes upon one of our patents, trademarks or other intellectual property rights, enforcing those patents, trademarks and other rights may be difficult and time consuming. Even if successful, litigation to defend our patents and trademarks against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management’s attention from managing our business. Moreover, we may not have sufficient resources or desire to defend our patents or trademarks against challenges or to enforce our intellectual property rights.

Table of Contents

The medical device industry is characterized by patent litigation and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, and/or prevent us from marketing our existing or future products.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of third parties. Significant litigation regarding patent rights exists in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make and sell our products. We have not conducted an independent review of patents issued to third parties. The large number of patents, the rapid rate of new patent issuances, the complexities of the technology involved and uncertainty of litigation increase the risk of business assets and management's attention being diverted to patent litigation. We have received in the past, and expect to receive in the future, communications from various industry participants alleging our infringement of their patents, trade secrets or other intellectual property rights and/or offering licenses to such intellectual property. We are currently subject to lawsuits, and have received other written allegations, claiming that we have infringed certain patents of others in the spine industry. A summary of these cases is provided under "Item 3. Legal Proceedings" below. Any lawsuits resulting from such allegations could subject us to significant liability for damages, and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop selling products or using technology that contains the allegedly infringing intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others;
- incur significant legal expenses;
- pay substantial damages to the party whose intellectual property rights we may be found to be infringing;
- redesign those products that contain the allegedly infringing intellectual property, which could be costly and disruptive; or
- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all.

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. Further, as the number of participants in the musculoskeletal industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (including treble, or triple, damages if an infringement is found to be willful) and/or royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

Table of Contents

Further, in the course of our regular review of pending legal matters, we determine whether it is probable that a potential loss relating to a legal proceeding may have a material impact on our business, financial performance or cash position. However, estimates of probable losses are inherently uncertain, and even if we determine that a loss is probable, in accordance with authoritative accounting guidance, if we are unable to estimate the possible loss or range of loss, we do not record an accrual related to such litigation. As a result of this accounting policy, we may experience variability in our results of operations if damages for which we are found liable exceed the amounts we have accrued. For example, on January 17, 2014, the jury in a misappropriation of trade secret suit filed against us in the Federal District Court for the Eastern District of Texas by Sabatino Bianco returned a verdict in favor of Bianco. In prior periods, we were unable to determine the probable outcome in that case or estimate the potential loss. As a result of that verdict, we incurred $4.3 million in damages, which reduced our 2013 U.S. GAAP diluted earnings per share by approximately $0.03. See further discussion under “Part II; Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations; Non-GAAP Financial Measures” below.

In addition, we generally indemnify our customers and distributors with respect to infringement by our products of the proprietary rights of third parties. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or distributors or may be required to obtain licenses for the products they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our customers may be forced to stop using our products.

We may be subject to damages resulting from claims that we, our employees or our independent distributors have wrongfully used or disclosed alleged trade secrets, proprietary or confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other medical device companies, including our competitors or potential competitors, in some cases until recently. Many of our independent distributors sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees, or our independent distributors have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable personnel. There can be no assurance that this type of litigation will not continue, and any future litigation or the threat thereof may adversely affect our ability to hire additional direct sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

We may incur product liability losses and insurance coverage may be inadequate or unavailable to cover these losses.

Our business exposes us to potential product liability claims that are inherent in the testing, design, manufacture and sale of medical devices for surgical procedures. The development of allograft implants and technologies for human tissue repair and treatment may entail particular risk of transmitting diseases to human recipients, which could result in the assertion of substantial product liability claims against us. Surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. In addition, if longer-term patient results and experience indicates that our products or any component of a product cause tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. Furthermore, if surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products,

Table of Contents

which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients. The medical devices industry has been particularly prone to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices and products for surgery procedures.

A product liability or other damages claim, product recall or product misuse, regardless of the outcome, could require us to spend significant time and money in litigation or to pay significant damages or costs, and could seriously harm our business. If our product liability insurance is inadequate to pay a damages award, we may have to pay the excess out of our cash reserves, which may harm our financial condition. Any product liability claim brought against us, with or without merit, could result in the increase of the costs we incur to obtain product liability insurance or our inability to secure product liability coverage in the future. If any of our products are found to cause tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. Even a meritless or unsuccessful product liability claim could harm our reputation in the industry, impair our ability to sell one or more of our products in the future, result in significant legal fees and cause significant diversion of management's attention from managing our business. A product liability or other claim, product recall, or product misuse involving any of our products, whether or not meritorious, could also materially and adversely harm our reputation and our ability to attract and retain customers.

In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance rates. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all.

Risks Related to the Ownership of our Class A Common Stock

Because of their significant stock ownership, our Executive Chairman, our chief executive officer, our other executive officers, and our directors and principal stockholders will be able to exert control over us and our significant corporate decisions.

Because of their significant stock ownership, our Executive Chairman, our chief executive officer, our other executive officers, and our directors will be able to exert substantial control over us and our significant corporate decisions. Based on an aggregate of 98,573,354 shares of our Class A and Class B common stock outstanding as of December 31, 2018, our executive officers and directors and their affiliates beneficially owned, in the aggregate, approximately 75% of the voting power of our outstanding capital stock. In particular, as of December 31, 2018, David C. Paul, our Executive Chairman and his family members, controlled approximately 22.8% of our Class A and Class B common stock, representing approximately 74.7% of the voting power of our outstanding capital stock as of that date.

As a result, David C. Paul has, and these persons acting together have, the ability to significantly influence or determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. Furthermore, as of December 31, 2018, we had 192,602,552 shares of Class B common stock available for issuance. This amount exceeds 5% of our outstanding common stock, meaning our Board of Directors ("Board") could issue Class B common stock without necessarily triggering the automatic conversion of that Class B common stock to Class A common stock that, pursuant to our charter, will occur when any holder's shares of Class B common stock represents less than 5% of the aggregate number of all outstanding shares of our common stock, thereby further concentrating the voting power of our capital stock in a limited number of stockholders.

The interests of our executive officers, directors and principal stockholders might not coincide with the interests of the other holders of our capital stock. This concentration of ownership may harm the value of our Class A common stock by, among other things:

Table of Contents

- delaying, deferring or preventing a change in control of our company;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- causing us to enter into transactions or agreements that are not in the best interests of all stockholders.

We are a "controlled company" within the meaning of the New York Stock Exchange Rules, and we take, and intend to continue to take, advantage of exemptions from certain corporate governance requirements.

David C. Paul, alone, and our management, directors and significant stockholders, collectively, beneficially own a majority of the voting power of our outstanding common stock. Under the New York Stock Exchange Rules, a company of which more than 50% of the voting power is held by an individual, group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements, including the requirement that a majority of our directors be independent, as defined in the New York Stock Exchange Rules, and the requirement that our compensation and nominating and corporate governance committees consist entirely of independent directors. We rely, and intend to continue to rely, on the "controlled company" exemption under the New York Stock Exchange Rules. As a result, a majority of the members of our Board may not be independent directors and our nominating and corporate governance and compensation committees will not consist entirely of independent directors. Accordingly, while we remain a controlled company and during any transition period following a time when we are no longer a controlled company, you will not have the same protections afforded to stockholders of companies that are subject to all of the New York Stock Exchange's corporate governance requirements.

Our Board is authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation authorizes our Board, without the approval of our stockholders, to issue 35 million shares of our preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, and to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of preferred stock may be senior to or on parity with our Class A common stock, which may reduce its value.

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could depress the price of our Class A common stock and prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain other provisions that could delay or prevent a change of control of our company or changes in our Board that our stockholders might consider favorable.

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers, which may restrict or prohibit certain business combination transactions with stockholders owning 15% or more of our outstanding voting stock, including discouraging takeover attempts that might result in a premium over the market price for shares of our Class A common stock.

Section 203 and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our Board or initiate actions that are opposed by our then-current Board, including delay or impede a merger, tender offer, or proxy contest involving our company. The existence of these provisions could negatively affect the price of our Class A common stock and limit opportunities for you to realize value in a corporate transaction.

Table of Contents

Item 1B. Unresolved Staff Comments
None.

Item 2. 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 fifteen additional countries all of which are leased.

Item 3. Legal Proceedings
We are involved in a number of proceedings, legal actions and claims. Such matters are subject to many uncertainties, and the outcomes of these matters are not within our control and may not be known for prolonged periods of time. In some actions, the claimants seek damages, as well as other relief, including injunctions prohibiting us from engaging in certain activities, which, if granted, could require significant expenditures and/or result in lost revenues. For further details on the material legal proceedings to which we are currently a party, please refer to “Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 15. Commitments and Contingencies” below.
In addition, we are subject to legal proceedings arising in the ordinary course of business.

Item 4. Mine Safety Disclosures
Not applicable.

Table of Contents

PART II

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

Class A Common Stock

Our Class A common stock trades on The New York Stock Exchange, under the symbol "GMED." We had approximately 56 stockholders of record as of February 18, 2019. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our Class A common stock is held of record through brokerage firms in "street name."

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, for development of our business and do not anticipate that we will declare or pay cash dividends on our capital stock in the foreseeable future.

Table of Contents

Comparative Stock Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our Class A common stock from December 31, 2013 through December 31, 2018 to two indices: the S&P 500 Index and the S&P 500 Health Care Equipment Index. The graph assumes an initial investment of $100 on December 31, 2013, in each of our Class A common stock, the stocks comprising the S&P 500 Index, and the stocks comprising the S&P 500 Health Care Equipment Index, including reinvestment of dividends, if any. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.

The following graph and related information shall not be deemed “soliciting material” or to be “filed” with the SEC, nor shall such information be incorporated by reference into any future filing, except to the extent that we specifically incorporate it by reference into such filing.

Company/Index	December 31, 2013	December 31, 2014	December 31, 2015	December 31, 2016	December 31, 2017	December 31, 2018
Globus Medical, Inc.	$100	$118	$138	$123	$204	$214
S&P 500 Index	$100	$114	$115	$129	$157	$150
S&P 500 Health Care Equipment	$100	$126	$134	$143	$187	$217

Table of Contents

Item 6. Selected Financial Data

The selected consolidated financial data set forth in the table below has been derived from our audited financial statements. The data set forth below should be read in conjunction with “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Item 8. Financial Statements and Supplementary Data” below.

Statement of Income Data:	Year Ended December 31,				
(In thousands, except per share amounts)	2018	2017	2016	2015	2014
Sales	$712,969	$635,977	$563,994	$544,753	$474,371
Cost of goods sold	159,410	150,453	134,705	132,333	110,769
Gross profit	553,559	485,524	429,289	412,420	363,602
Operating expenses:					
Research and development	55,496	43,679	44,532	36,312	31,166
Selling, general and administrative	311,591	267,817	222,156	210,241	188,632
Provision for litigation	5,878	2,668	3,156	(11,268)	5,667
Amortization of intangibles	9,588	7,909	3,478	1,561	712
Acquisition related costs	1,681	1,611	1,826	3,352	(937)
Total operating expenses	384,234	323,684	275,148	240,198	225,240
Operating income	169,325	161,840	154,141	172,222	138,362
Other income/(expense), net	19,280	8,088	3,138	583	280
Income before income taxes	188,605	169,928	157,279	172,805	138,642
Income tax provision	32,131	62,580	52,938	60,021	46,157
Net income	$156,474	$107,348	$104,341	$112,784	$92,485
Net income per common share:					
Basic	$1.60	$1.12	$1.09	$1.19	$0.98
Diluted	$1.54	$1.10	$1.08	$1.17	$0.97
Weighted average number of common shares:					
Basic	97,884	96,243	95,647	95,046	94,227
Diluted	101,316	97,887	96,432	96,073	95,457

Balance Sheet Data:	As of December 31,				
(In thousands)	2018	2017	2016	2015	2014
Cash, cash equivalents, restricted cash, and marketable securities	$602,801	$429,840	$350,756	$329,791	$304,051
Working capital	534,563	527,269	433,874	462,108	380,613
Total assets	1,300,670	1,078,502	927,637	834,100	703,547
Business acquisition liabilities, including current portion [(1)]	10,118	15,919	20,080	33,314	26,276
Stockholders’ equity	$1,185,516	$967,778	$832,078	$715,324	$585,454

(1) In connection with certain acquisitions completed in 2018 through 2011, we have certain contingent consideration obligations payable to the sellers in these transactions upon the achievement of certain regulatory and sales milestones. The maximum aggregate undiscounted amounts potentially payable were $24.1 million, $20.6 million, $29.1 million, $35.9 million and $38.9 million as of December 31, 2018, 2017, 2016, 2015 and 2014, respectively. The December 31, 2018 amount includes contingent consideration related to an asset acquisition for which no liability has been recognized in the financial statements.

Table of Contents

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included elsewhere in this Annual Report. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. You should review the "Risk Factors" and "Cautionary Note Concerning Forward-Looking Statements" sections of this Annual Report for a discussion of certain of the important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements described in the following discussion and analysis. Certain amounts and percentages in this discussion and analysis have been rounded for convenience of presentation.

Overview

We are an engineering-driven company with a history of rapidly developing and commercializing advanced products and procedures to address treatment challenges. With over 190 products on the market, we offer a comprehensive portfolio of innovative and differentiated technologies that treat a variety of musculoskeletal conditions of the spine, extremities and pelvis. Although we manage our business globally within one operating segment, we separate our products into two major categories: Musculoskeletal Solutions and Enabling Technologies.

Musculoskeletal Solutions

Musculoskeletal Solutions consist primarily of implantable devices, biologics, accessories, and unique surgical instruments used in an expansive range of spinal, orthopedic and neurosurgical procedures.

Our broad spectrum of spine products addresses the vast majority of conditions affecting the spine including degenerative conditions, deformity, tumors, and trauma. With more than fifteen years in this competitive market, we provide comprehensive solutions that facilitate both open and minimally invasive surgery ("MIS") techniques. This includes traditional fusion implants such as pedicle screw and rod systems, plating systems, intervertebral spacers and corpectomy devices. We believe we pioneered innovative expandable solutions for interbody fusion, corpectomy and interspinous fixation that allow intraoperative customization of our devices to the patient's anatomy and save surgical time by eliminating sequential trialing. We have also developed treatment options for motion preservation technologies, such as dynamic stabilization, total disc replacement and interspinous distraction devices; and interventional pain management solutions to treat vertebral compression fractures. Regenerative biologic products such as allografts and synthetic alternatives are adjunctive treatments typically used in combination with stabilizing implant hardware.

Our orthopedic trauma solutions are designed to treat a wide variety of orthopedic fracture patterns and patient anatomies in the upper and lower extremities as well as the hip. To date, Globus has received 510(k) clearance from the U.S. Food and Drug Administration ("FDA") for numerous orthopedic trauma and extremity products, covering four major segments of the orthopedic trauma market - fracture plates, compression screws, intramedullary nails, and external fixation. We began marketing these products in 2018 and intend to grow our presence in this field. Fracture plating includes proximal humerus, distal radius, proximal tibia, distal fibula, small fragment, mini-fragment and clavicle plates. Intramedullary nailing includes tibial, trochanteric, and femoral nail systems. Regenerative biologic products such as bone void fillers and allograft struts are also used in orthopedic procedures where applicable.

Table of Contents

Enabling Technologies

Enabling Technologies are advanced computer-assisted intelligent systems designed to enhance a surgeon's capabilities and streamline surgical procedures to be safer, less invasive, more accurate, and more reproducible, to ultimately improve patient care and reduce radiation exposure for all involved.

Our current enabling technologies are comprised of imaging, navigation and robotic ("INR") assisted surgery solutions. This includes the ExcelsiusGPS® platform, a robotic guidance and navigation system that supports minimally invasive and open procedures with screw placement applications. The ExcelsiusGPS® platform has a modular design that can be used for a variety of screw placement applications, and we expect that it will serve as a foundation for future clinical applications using artificial intelligence and augmented reality.

Globus' innovative Enabling Technologies products offer surgeons more information about patient anatomy and surgical options to help them to make well-informed surgical decisions. We believe the advantages of pre-planning implant position and viewing patient anatomy during surgery are self-evident, and also create significant secondary gains such as eliminating radiation exposure altogether.

While we group our products into two categories, they are not limited to a particular technology, platform or surgical approach. Instead, our goal is to offer a comprehensive product suite that can be used to effectively treat patients based on their specific anatomy and condition, and is customized to the surgeon's training and surgical preference.

To date, the primary market for our products has been the United States, where we sell our products through a combination of direct sales representatives employed by us and distributor sales representatives employed by our exclusive independent distributors, who distribute our products on our behalf for a commission that is generally based on a percentage of sales. We believe there is significant opportunity to strengthen our position in the U.S. market by increasing the size of our U.S. sales force and we intend to add additional direct and distributor sales representatives in the future.

During the year ended December 31, 2018, our international sales accounted for approximately 17% of our total sales. We currently sell our products in 51 countries outside the United States through a combination of direct sales representatives employed by us and exclusive international distributors. We believe there are significant opportunities for us to increase our presence in both existing and new international markets through the continued expansion of our direct and distributor sales forces and the commercialization of additional products.

Table of Contents

Components of our Results of Operations

We manage our business globally within one operating segment, which is consistent with how our management reviews our business, makes investment and resource allocation decisions and assesses operating performance.

Sales

Today, we sell primarily implants and related disposables, primarily to hospitals, for use by surgeons to treat musculoskeletal disorders. We generally consign our surgical sets, which contain our implants, disposables, surgical instruments and cases to our sales representatives, and the sets are maintained with the sales representatives or at our hospital customers that purchase the implants and related disposables used in the surgeries. We recognize revenue when the consigned implants and related disposables have been implanted or used, or for sets that are sold directly and not consigned, when title to the goods and risk of loss are transferred to customers with no remaining performance obligations which affect the customer's final acceptance of the sale.

We completed our first sale of ExcelsiusGPS™ in the fourth quarter of 2017. We generally recognize revenue when control transfers to the customer, which occurs at the time the product is shipped or delivered. Depending on the terms of the arrangement, we may also defer the recognition of a portion of the consideration received as we have to satisfy a future performance obligation to provide maintenance and support.

We expect to expand our U.S. and international sales forces, which will provide us with significant opportunity to continue to increase our penetration in existing markets and to enter new international markets. We also expect to increase sales by commercializing new products, but expect the increase of sales from new products to be partially offset by decreased sales of earlier-generation products.

Cost of Goods Sold

While we have increased our in-house implant product manufacturing capacity and assemble the ExcelsiusGPS™ system in-house, we also have products manufactured by third-party suppliers. Substantially all of our suppliers manufacture our products in the United States. Our cost of goods sold consists primarily of costs from our in-house manufacturing, costs of products purchased from third-party suppliers, excess and obsolete inventory charges, depreciation of surgical instruments and cases, royalties, shipping, inspection and related costs incurred in making our products available for sale or use. Beginning in January 2013, our cost of goods sold increased as a result of a medical device excise tax ("MDET") of up to 2.3% on the sale of certain medical devices in the United States. On December 18, 2015, the MDET was suspended for two years effective January 1, 2016. In January 2018, Congress further extended the moratorium on the medical device excise tax through January 1, 2020.

Research and Development Expenses

Our research and development expenses primarily consist of engineering, product development, clinical and regulatory expenses, consulting services, outside prototyping services, internal and external research activities, materials, depreciation, and other costs associated with development of our products. Research and development expenses also include related personnel and consultants' compensation and stock-based compensation expense. We expense research and development costs as they are incurred.

Table of Contents

We expect to incur additional research and development costs as we continue to develop new products. These costs will increase in absolute terms as we continue to expand our product pipeline and add personnel.

Selling, General and Administrative Expenses

Selling, general and administrative expenses primarily consist of salaries, benefits and other related costs, including stock-based compensation for personnel employed in sales, marketing, finance, legal, compliance, administrative, information technology, medical education and training, quality and human resource departments. Our selling, general and administrative expenses also include commissions, generally based on a percentage of sales, to direct sales representatives and distributors. We expect our selling, general and administrative expenses will increase in absolute terms with the continued expansion of our sales force and commercialization of our current and pipeline products. We plan to hire more personnel to support the growth of our business.

Provision for Litigation

We record a provision for litigation settlements when a loss is known or considered probable and the amount can be reasonably estimated and in the case of a favorable settlement, income when realized.

Amortization of Intangibles

We amortize finite lived intangible assets over the period of estimated benefit using the straight-line method and estimated lives ranging from one to seventeen years. Indefinite lived intangible assets are tested for impairment annually or whenever events or circumstances indicate that the carrying amount of the asset (asset group) may not be recoverable. If impairment is indicated, we measure the amount of the impairment loss as the amount by which the carrying amount exceeds the fair value of the asset. Fair value is generally determined using a discounted future cash flow analysis.

Acquisition Related Costs

Acquisition related costs represent: the change in fair value of business-acquisition-related contingent consideration; costs related to integrating recently acquired businesses, including but not limited to costs to exit or convert contractual obligations, severance, and information system conversion; and specific costs related to the consummation of the acquisition process such as banker fees, legal fees, and other acquisition related professional fees.

Income Tax Provision

We are taxed at the rates applicable within each jurisdiction. The composite income tax rate, tax provisions, deferred tax assets and deferred tax liabilities will vary according to the jurisdiction in which profits arise. Tax laws are complex and subject to different interpretations by management and the respective governmental taxing authorities, and require us to exercise judgment in determining our income tax provision, our deferred tax assets and liabilities, and the valuation allowance recorded against our net deferred tax assets.

Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not that the future realization of all or some of the deferred tax assets will not be achieved. See “Note 13. Income Taxes” below for further discussion on the impact of the U.S. Tax Cuts and Jobs Act in the current year.

Table of Contents

Critical Accounting Policies and Estimates

The preparation of the consolidated financial statements requires us to make assumptions, estimates and judgments that affect the reported amounts of assets and liabilities, the disclosures of contingent assets and liabilities as of the date of the consolidated financial statements, and the reported amounts of sales and expenses during the reporting periods. Certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. On an ongoing basis, we evaluate our judgments, including but not limited to those related to inventories, recoverability of long-lived assets and the fair value of our common stock. We use historical experience and other assumptions as the basis for our judgments and making these estimates. Because future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Any changes in those estimates will be reflected in our consolidated financial statements as they occur. While our significant accounting policies are more fully described in “Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 1. Background and Summary of Significant Accounting Policies” below in this Annual Report, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results. The critical accounting policies addressed below reflect our most significant judgments and estimates used in the preparation of our consolidated financial statements. We have reviewed these critical accounting policies with the audit committee of our Board.

Revenue Recognition. Revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration we expect to receive in exchange for those products or services. Sales and other taxes we collect concurrent with revenue-producing activities are excluded from revenue. Incidental items that are immaterial in the context of the contract are recognized as expense. For purposes of disclosing disaggregated revenue, we disaggregate our revenue, into two categories, Musculoskeletal Solutions and Enabling Technologies, based on the timing of revenue recognition. Our Musculoskeletal Solutions products consist primarily of the implantable devices, disposables, and unique instruments used in an expansive range of spine, orthopedic trauma and extremity procedures. The majority of our Musculoskeletal Solutions contracts have a single performance obligation and revenue is recognized at a point in time. Our Enabling Technologies products are the advanced hardware and software systems and related technologies that are designed to enhance a surgeon’s capabilities and streamline surgical procedures by making them less invasive, more accurate, and more reproducible to improve patient care. The majority of our Enabling Technologies product contracts typically contain multiple performance obligations, including maintenance and support, and revenue is recognized as we fulfill each performance obligation. For contracts with multiple performance obligations, we allocate the contract’s transaction price to each performance obligation using our best estimate of the standalone selling price of each distinct good or service in the contract. Our policy is to classify shipping and handling costs billed to customers as sales and the related expenses as cost of goods sold.

Excess and Obsolete Inventory. We state inventories at the lower of cost or market. We determine cost on a first-in, first-out basis. The majority of our inventory is finished goods. We periodically evaluate the carrying value of our inventories in relation to the estimated forecast of product demand, which takes into consideration the estimated life cycle of product releases. When quantities on hand exceed estimated sales forecasts, we record a write-down for excess inventories, which results in a corresponding charge to cost of goods sold. Charges incurred for excess and obsolete inventory were $10.5 million, $11.5 million and $12.8 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Table of Contents

The need to maintain substantial levels of inventory impacts the risk of carrying excess inventory. Many of our Musculoskeletal Solutions products come in sets which feature components in a variety of sizes so that the implant or device may be customized to the patient's needs. In order to market our Musculoskeletal Solutions products effectively, we must often maintain and provide surgeons and hospitals with consignment implant sets, back-up products and products of different sizes. For each surgery, fewer than all of the components of the set are used, and therefore certain portions of the set may be considered excess inventory since they are not likely to be used. One of our primary business goals is to focus on continual product innovation. Though we believe this provides us with a competitive advantage, it also increases the risk that our products will become excess or obsolete inventory prior to sale or prior to the end of their anticipated useful lives. When we introduce new products or next-generation products, we may be required to take charges for excess and obsolete inventory that have a significant impact on the value of our inventory or on our operating results.

Goodwill and Intangible Assets. Goodwill represents the excess purchase price over the fair values of the identifiable assets acquired less the liabilities assumed. We acquired goodwill in connection with the various acquisitions completed. Goodwill is tested for impairment at a minimum on an annual basis. The fair value is estimated using an income and discounted cash flow approach. We performed our qualitative goodwill and indefinite-lived intangible assets impairment tests in the fourth quarter of 2018 and determined that fair value of our reporting units is substantially in excess of carrying value.

Intangible assets consist of purchased in-process research and development ("IPR&D"), developed technology, supplier networks, patents, customer relationships and non-compete agreements. Intangible assets with finite useful lives are amortized over the period of estimated benefit using the straight-line method and estimated useful lives ranging from one to seventeen years. Intangible assets are tested for impairment annually or whenever events or circumstances indicate that a carrying amount of an asset (asset group) may not be recoverable. If impairment is indicated, we measure the amount of the impairment loss as the amount by which the carrying amount exceeds the fair value of the asset. Fair value is generally determined using a discounted future cash flow analysis.

IPR&D has an indefinite life and is not amortized until completion and development of the project at which time the IPR&D becomes an amortizable asset. If the related project is not completed in a timely manner, we may have an impairment related to the IPR&D, calculated as the excess of the asset's carrying value over its fair value. During 2016, we recorded an impairment charge of $3.5 million as a component of acquisition related costs.

Long-Lived Assets. We periodically evaluate the recoverability of the carrying amount of long-lived assets, which include property and equipment, whenever events or changes in circumstances indicate that the carrying amount of an asset may not be fully recoverable. We assess impairment when the undiscounted future cash flows from the use and eventual disposition of an asset are less than its carrying value. If impairment is indicated, we measure the amount of the impairment loss as the amount by which the carrying amount exceeds the fair value of the asset. We base our fair value methodology on quoted market prices, if available. If quoted market prices are not available, we estimate fair value based on prices of similar assets or other valuation techniques including present value techniques.

Income Taxes. We recognize deferred tax assets and liabilities for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. We measure deferred tax assets and liabilities using enacted tax rates expected to apply to taxable income in the year in which such items are expected to be received or settled. We recognize the effect on deferred tax assets and liabilities of a change in tax rates in the period that includes the enactment date. We establish a valuation allowance to offset any deferred tax assets if, based upon available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

Table of Contents

While we believe that our tax positions are fully supportable, there is a risk that certain positions could be challenged successfully. In these instances, we look to establish reserves. If we determine that a tax position is more likely than not of being sustained upon audit, based solely on the technical merits of the position, we recognize the benefit. We measure the benefit by determining the amount that has likelihood greater than 50% of being realized upon settlement. We presume that all tax positions will be examined by a taxing authority with full knowledge of all relevant information. We regularly monitor our tax positions, tax assets and tax liabilities. We reevaluate the technical merits of our tax positions and recognize an uncertain tax benefit or reverse a previously recorded tax benefit when (i) a tax audit is completed, (ii) applicable tax law, including a tax case or legislative guidance, changes or (iii) the statute of limitations expires. Significant judgment is required in accounting for tax reserves.

Legal Proceedings. We are involved in a number of legal actions involving both product liability and intellectual property disputes. The outcomes of these legal actions are not within our complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, that could require significant expenditures or result in lost sales. In accordance with authoritative guidance, we record a liability in our consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible, but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed in the notes to the consolidated financial statements. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded. While it is not possible to predict the outcome for these matters, we believe it is possible that costs associated with them could have a material adverse impact on our consolidated earnings, financial position or cash flows.

Stock-Based Compensation Expense. We measure the cost for employee and non-employee awards at the grant date based on the fair value of the award. For employee awards, we amortize the expense, which is the fair value of the portion of the award that is ultimately expected to vest, over the requisite service periods (generally the vesting period of the equity award). We record the awards issued to non-employees at their fair value as determined in accordance with authoritative guidance, and we periodically revalue the awards as they vest, recognizing the expense over the requisite service period. We estimate the fair value of stock options using a Black-Scholes option-pricing model. Our determination of the fair value is affected by our stock price and a number of assumptions, including expected volatility, expected term, risk-free interest rate and expected dividends.

As we became a publicly traded entity in 2012, historic volatility for our common stock is insufficient to estimate expected volatility. As a result, we estimate volatility based on a consistently defined peer group of public companies that we believe collectively provides a reasonable basis for estimating volatility. We intend to continue to use the consistently defined group of publicly traded peer companies to determine volatility in the future until sufficient information regarding volatility of the price of our shares of Class A common stock becomes available or the selected companies are no longer suitable for this purpose.

We also do not have sufficient history of stock option exercises as a public company available that is indicative of future exercise and post-vesting behavior to estimate the expected term after our initial public offering (“IPO”). As a result, we use the simplified method of estimating the expected term, under which the expected term is presumed to be the mid-point between the vesting date and the contractual end of the term. We base the risk-free interest rate on observed interest rates of U.S. Treasury securities equivalent to the expected terms of the stock options. We estimate our pre-vesting forfeiture rate based on our historical experience. Our dividend yield assumption is based on the history and expectation of no dividend payouts.

We estimate the weighted-average fair value of the options granted using a Black-Scholes option-pricing model, which requires the input of subjective assumptions, including the expected stock price volatility, the

Table of Contents

calculation of expected term and fair value of the underlying common stock on the date of grant, among other inputs. To the extent that further evidence regarding these variables is available and provides estimates that we believe are more indicative of actual trends, we may refine or change our approach to deriving these input estimates. Any such changes could materially affect the stock-based compensation expense we record in the future.
We expect to continue to grant stock options in the future, and to the extent that we do, our actual stock-based compensation expense recognized may increase.

Results of Operations
Year Ended December 31, 2018 Compared to the Year Ended December 31, 2017
Sales
The following table sets forth, for the periods indicated, our sales by geography expressed as dollar amounts and the changes in sales between the specified periods expressed in dollar amounts and as percentages:

	Year Ended		Change	
(In thousands, except percentages)	December 31, 2018	December 31, 2017	$	%
United States	$593,878	$ 529,882	$63,996	12.1%
International	119,091	106,095	12,996	12.2%
Total sales	$712,969	$ 635,977	$76,992	12.1%

In the United States, the increase in sales of $64.0 million was due primarily to increased spine product sales due to penetration in existing territories, INR product sales, and associated implant and robotic instrument sales. Internationally, the increase in sales of $13.0 million was due primarily to increased sales in Japan and other existing countries as well as sales of INR product and associated robotic instrument sales. On a constant currency basis, our international sales grew $11.5 million, or by 10.8%, and our worldwide sales increased by 11.9%.
Cost of Goods Sold

	Year Ended		Change	
(In thousands, except percentages)	December 31, 2018	December 31, 2017	$	%
Cost of goods sold	$159,410	$ 150,453	$8,957	6.0%
Percentage of sales	22.4 %	23.7 %		

The increase in cost of goods sold was primarily due to higher volumes and was partially offset by a decrease in depreciation of $5.7 million primarily resulting from the change in accounting estimate for the depreciable lives of our instruments and cases.

Table of Contents

Research and Development Expenses

(In thousands, except percentages)	Year Ended December 31, 2018	December 31, 2017	Change $	%
Research and development	$55,496	$ 43,679	$11,817	27.1%
Percentage of sales	7.8 %	6.9 %		

The increase in research and development expenses was due primarily to an increase in employee compensation costs from additional headcount, including our INR technology group, increased supplies for furthering research activities and developing new innovative products, and an increase of $1.8 million from one-time technology licensing fees.

Selling, General and Administrative Expenses

(In thousands, except percentages)	Year Ended December 31, 2018	December 31, 2017	Change $	%
Selling, general and administrative	$311,591	$ 267,817	$43,774	16.3%
Percentage of sales	43.7 %	42.1 %		

The increase in selling, general and administrative expenses was primarily due to increases of $18.1 million of costs to build the INR technology and orthopedic trauma sales forces, and a $12.6 million increase in the U.S. sales force expenses. Additionally, there were increases in stock based compensation expenses of $5.1 million.

Provision for Litigation

(In thousands, except percentages)	Year Ended December 31, 2018	December 31, 2017	Change $	%
Provision for litigation	$5,878	$ 2,668	$3,210	120.3%
Percentage of sales	0.8 %	0.4 %		

The increase in the provision for litigation was primarily due to the settlement of the L5 litigation, as well as other settlement payments and costs recorded in the period.

For additional information regarding litigation, please refer to “Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 15. Commitments and Contingencies.”

Amortization of Intangibles

(In thousands, except percentages)	Year Ended December 31, 2018	December 31, 2017	Change $	%
Amortization of intangibles	$9,588	$ 7,909	$1,679	21.2%
Percentage of sales	1.3 %	1.2 %		

The increase in the amortization of intangibles is primarily due to the developed technology intangible asset acquired in connection with the Nemaris acquisition.

Table of Contents

Acquisition Related Costs

(In thousands, except percentages)	Year Ended December 31, 2018	Year Ended December 31, 2017	Change $	Change %
Acquisition related costs	$1,681	$ 1,611	$70	4.3%
Percentage of sales	0.2 %	0.3 %		

Acquisition related costs remained consistent for the year ended December 31, 2018 as compared to the year ended December 31, 2017.

Other Income, Net

(In thousands, except percentages)	Year Ended December 31, 2018	Year Ended December 31, 2017	Change $	Change %
Other income, net	$19,280	$ 8,088	$11,192	138.4%
Percentage of sales	2.7 %	1.3 %		

The increase in other income, net, is due primarily to the gain on sale of assets of $4.6 million and increases in interest income from marketable securities and the Alphatec Credit Agreement of $6.7 million. For additional information regarding the note receivable with Alphatec Spine Inc., please refer to “Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 3. Note Receivable.”

Income Tax Provision

(In thousands, except percentages)	Year Ended December 31, 2018	Year Ended December 31, 2017	Change $	Change %
Income tax provision	$32,131	$ 62,580	$(30,449)	(48.7)%
Effective income tax rate	17.0 %	36.8 %		

The change in the effective income tax rate between the current year and prior year periods is primarily driven by the impact of the U.S. Tax Cuts and Jobs Act (“Tax Reform Act”) as further described in “Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 13. Income Taxes.” and stock option exercise benefit.

Year Ended December 31, 2017 Compared to the Year Ended December 31, 2016

Sales

The following table sets forth, for the periods indicated, our sales by geography expressed as dollar amounts and the changes in sales between the specified periods expressed in dollar amounts and as percentages:

(In thousands, except percentages)	Year Ended December 31, 2017	Year Ended December 31, 2016	Change $	Change %
United States	$529,882	$ 500,226	$29,656	5.9 %
International	106,095	63,768	42,327	66.4%
Total sales	$635,977	$ 563,994	$71,983	12.8%

Table of Contents

In the United States, the increase in sales of $29.7 million was due primarily to expansion into new territories and increased penetration in existing territories.

Internationally, the increase in sales of $42.3 million was primarily due to incremental sales from the Alphatec International acquisition. On a constant currency basis, our international sales grew $41.1 million, or by 66.9%, due to expansion into new international territories. Our worldwide sales increased 12.8% on a constant currency basis.

Cost of Goods Sold

(In thousands, except percentages)	Year Ended December 31, 2017	Year Ended December 31, 2016	Change $	Change %
Cost of goods sold	$150,453	$134,705	$15,748	11.7%
Percentage of sales	23.7%	23.9%		

The increase in cost of goods sold was primarily due to increases from higher volumes, product mix and inventory write offs. Partially offsetting these increases was a cost benefit of $4.0 million from in-house manufacturing.

Research and Development Expenses

(In thousands, except percentages)	Year Ended December 31, 2017	Year Ended December 31, 2016	Change $	Change %
Research and development	$43,679	$44,532	$(853)	(1.9)%
Percentage of sales	6.9%	7.9%		

The decrease in research and development expenses was due primarily to $4.0 million of one-time licensing costs incurred in 2016, which was partially offset by increased investment into INR technology and orthopedic trauma for additional headcount to further research activities and development of new innovative products.

Selling, General and Administrative Expenses

(In thousands, except percentages)	Year Ended December 31, 2017	Year Ended December 31, 2016	Change $	Change %
Selling, general and administrative	$267,817	$222,156	$45,661	20.6%
Percentage of sales	42.1%	39.4%		

The increase in selling, general and administrative expenses was due primarily to increases of $15.8 million of costs to support Alphatec International sales, $9.5 million of costs to build the INR technology and orthopedic trauma sales forces, and a $10.1 million increase in the U.S. sales force expenses. In addition, there were cost increases of $6.5 million related to general and administrative compensation costs.

Table of Contents

Provision for Litigation

(In thousands, except percentages)	Year Ended December 31, 2017	Year Ended December 31, 2016	Change $	Change %
Provision for litigation	$2,668	$ 3,156	$(488)	(15.5)%
Percentage of sales	0.4 %	0.6 %		

The current year provision for litigation, which is relatively consistent with the prior year provision, includes legal settlement and verdict costs.

Amortization of Intangibles

(In thousands, except percentages)	Year Ended December 31, 2017	Year Ended December 31, 2016	Change $	Change %
Amortization of intangibles	$7,909	$ 3,478	$4,431	127.4%
Percentage of sales	1.2 %	0.6 %		

The increase in the amortization of intangibles is primarily due to intangible assets acquired in connection with the Alphatec International acquisition.

Acquisition Related Costs

(In thousands, except percentages)	Year Ended December 31, 2017	Year Ended December 31, 2016	Change $	Change %
Acquisition related costs	$1,611	$ 1,826	$(215)	(11.8)%
Percentage of sales	0.3 %	0.3 %		

Acquisition related costs remained consistent for the year ended December 31, 2017 as compared to the year ended December 31, 2016. The current year balance primarily consists of costs associated with the KB Medical acquisition.

Other Income, Net

(In thousands, except percentages)	Year Ended December 31, 2017	Year Ended December 31, 2016	Change $	Change %
Other income, net	$8,088	$ 3,138	$4,950	157.7%
Percentage of sales	1.3 %	0.6 %		

The increase in other income, net is due primarily to increases in interest income from increased average investment balances and the note receivable with Alphatec Spine Inc., coupled with increases in foreign exchange transaction gains. For additional information regarding the note receivable with Alphatec Spine Inc., please refer to “Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 3. Note Receivable.”

Table of Contents

Income Tax Provision

(In thousands, except percentages)	Year Ended December 31, 2017	December 31, 2016	Change $	Change %
Income tax provision	$62,580	$ 52,938	$9,642	18.2%
Effective income tax rate	36.8 %	33.7 %		

Our tax provision and effective tax rate for the year ended December 31, 2017 was higher than the prior year due primarily to the impact of the U.S. Tax Cuts and Jobs Act ("Tax Reform Act"), as further described in "Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 13. Income Taxes."

Non-GAAP Financial Measures

To supplement our financial statements prepared in accordance with U.S. generally accepted accounting principles ("U.S. GAAP"), management uses certain non-GAAP financial measures. For example, non-GAAP Adjusted EBITDA, which represents net income before interest income, net and other non-operating expenses, provision for income taxes, depreciation and amortization, stock-based compensation expense, provision for litigation, acquisition related costs/licensing and prior period adjustment excluding depreciation, is useful as an additional measure of operating performance, and particularly as a measure of comparative operating performance from period to period, as it is reflective of changes in pricing decisions, cost controls and other factors that affect operating performance, and it removes the effect of our capital structure, asset base, income taxes and interest income and expense. Our management also uses non-GAAP Adjusted EBITDA for planning purposes, including the preparation of our annual operating budget and financial projections. Provision for litigation represents costs incurred for litigation settlements or unfavorable verdicts when the loss is known or considered probable and the amount can be reasonably estimated, or in the case of a favorable settlement, when income is realized. Acquisition related costs/licensing represents the change in fair value of business-acquisition-related contingent consideration; costs related to integrating recently acquired businesses, including but not limited to costs to exit or convert contractual obligations, severance, and information system conversion; and specific costs related to the consummation of the acquisition process such as banker fees, legal fees, and other acquisition related professional fees, as well as one-time licensing fees. Prior period adjustment excluding depreciation represents the cumulative impact of prior year adjustments primarily related to a decrease in scrap adjustments of instruments and cases, none of which were individually material to the related year's financial position or results of operations.

Table of Contents

The following is a reconciliation of Net income to Adjusted EBITDA for the periods presented:

(In thousands, except percentages)	Year Ended December 31, 2018	December 31, 2017	December 31, 2016
Net income	$156,474	$ 107,348	$ 104,341
Interest income, net	(13,278)	(6,608)	(3,057)
Provision for income taxes	32,131	62,580	52,938
Depreciation and amortization	41,630	42,067	*38,771
EBITDA	216,957	205,387	192,993
Stock-based compensation expense	21,899	14,686	11,382
Provision for litigation	5,878	2,668	3,156
Acquisition related costs/licensing	4,488	3,391	6,931
Net gain from sale of assets	(3,593)	—	—
Prior period adjustment, excluding depreciation	—	—	(3,697)
Adjusted EBITDA	$245,629	$ 226,132	$ 210,765
Net income as a percentage of sales	21.9%	16.9%	18.5%
Adjusted EBITDA as a percentage of sales	34.5%	35.6%	37.4%

* Included in this amount for the year ended December 31, 2016 is $5.5 million related to depreciation amounts recognized in the current year related to the prior period adjustment.

For additional information regarding the prior period adjustment, please refer to “Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 1. Background and Summary of Significant Accounting Policies; (b) Basis of Presentation.”

In addition, for the year ended December 31, 2018 and for other comparative periods, we are presenting non-GAAP net income and non-GAAP Diluted Earnings Per Share, which represents net income and diluted earnings per share excluding the provision for litigation, amortization of intangibles, acquisition related costs/licensing, prior period adjustment and the tax effects of all of the foregoing adjustments. The tax effect adjustment represents the tax effect of the pre-tax non-GAAP adjustments excluded from non-GAAP net income. The tax impact of the non-GAAP adjustments is calculated based on the consolidated effective tax rate on a GAAP basis, applied to the non-GAAP adjustments, unless the underlying item has a materially different tax treatment, in which case the estimated tax rate applicable to the adjustment is used. At December 31, 2017, we calculated the tax effect of adjusting items utilizing our effective tax rate prior to the one-time Tax Reform Act adjustment. The effective tax rate applied was 30.3%. We believe these non-GAAP measures are also useful indicators of our operating performance, and particularly as additional measures of comparative operating performance from period to period as they remove the effects of litigation, amortization of intangibles, acquisition related costs/licensing, and the tax effects of all of the foregoing adjustments, which we believe are not reflective of underlying business trends.

Table of Contents

The following is a reconciliation of net income computed in accordance with U.S. GAAP to non-GAAP net income for the periods presented.

(In thousands)	Year Ended December 31, 2018	December 31, 2017	December 31, 2016
Net income	$156,474	$ 107,348	$ 104,341
Provision for litigation	5,878	2,668	3,156
Amortization of intangibles	9,588	7,909	3,478
Acquisition related costs/licensing	4,488	3,391	6,931
Net gain from sale of assets	(3,593)	—	—
Prior period adjustment	—	—	1,765
Tax reform impact	—	11,014	—
Tax effect of adjusting items	(3,437)	(4,239)	(5,166)
Non-GAAP net income	$169,398	$ 128,091	$ 114,505

The following is a reconciliation of Diluted Earnings Per Share as computed in accordance with U.S. GAAP to non-GAAP Diluted Earnings Per Share for the periods presented.

(Per share amounts)	Year Ended December 31, 2018	December 31, 2017	December 31, 2016
Diluted earnings per share, as reported	$1.54	$ 1.10	$ 1.08
Provision for litigation	0.06	0.03	0.03
Amortization of intangibles	0.09	0.08	0.04
Acquisition related costs/licensing	0.05	0.03	0.07
Net gain from sale of assets	(0.04)	—	—
Prior period adjustment	—	—	0.02
Tax reform impact	—	0.11	—
Tax effect of adjusting items	(0.03)	(0.04)	(0.05)
Non-GAAP diluted earnings per share	$1.67	$ 1.31	$ 1.19

We also define the non-GAAP measure of Free Cash Flow as the net cash provided by operating activities, adjusted for the impact of restricted cash, less the cash impact of purchases of property and equipment. We believe that this financial measure provides meaningful information for evaluating our overall financial performance for comparative periods as it facilitates an assessment of funds available to satisfy current and future obligations and fund acquisitions. Below is a reconciliation of net cash provided by operating activities as computed in accordance with U.S. GAAP to Free Cash Flow for the periods presented.

(Per share amounts)	Year Ended December 31, 2018	December 31, 2017	December 31, 2016
Net cash provided by operating activities	$181,643	$ 159,058	$ 147,823
Purchases of property and equipment	(59,697)	(51,303)	(40,909)
Free cash flow	$121,946	$ 107,755	$ 106,914

Table of Contents

Furthermore, the non-GAAP measure of constant currency sales growth is calculated by translating current year sales at the same average exchange rates in effect during the applicable prior year period. We believe constant currency sales growth provides insight to the comparative increase or decrease in period sales, in dollar and percentage terms, excluding the effects of fluctuations in foreign currency exchange rates.

Below is a reconciliation of sales growth as reported in accordance with U.S. GAAP compared to constant currency sales growth for the periods presented.

(In thousands, except percentages)	Year Ended December 31, 2018	December 31, 2017	Reported Sales Growth	Currency Impact on 2018 Sales	Constant Currency Sales Growth
United States	$593,878	$ 529,882	12.1 %	—	12.1 %
International	119,091	106,095	12.2 %	$(1,494)	10.8 %
Total sales	$712,969	$ 635,977	12.1 %	$(1,494)	11.9 %

(In thousands, except percentages)	Year Ended December 31, 2017	December 31, 2016	Reported Sales Growth	Currency Impact on 2017 Sales	Constant Currency Sales Growth
United States	$529,882	$ 500,226	5.9 %	—	5.9 %
International	106,095	63,768	66.4 %	$ 346	66.9 %
Total sales	$635,977	$ 563,994	12.8 %	$ 346	12.8 %

Non-GAAP Adjusted EBITDA, non-GAAP net income, non-GAAP Diluted Earnings Per Share, Free Cash Flow and constant currency sales growth are not calculated in conformity with U.S. GAAP within the meaning of Item 10(e) of Regulation S-K. Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for financial measures prepared in accordance with U.S. GAAP. These measures do not include certain expenses that may be necessary to evaluate our liquidity or operating results. Our definitions of non-GAAP Adjusted EBITDA, non-GAAP net income, non-GAAP Diluted Earnings Per Share, Free Cash Flow and constant currency sales growth may differ from that of other companies and therefore may not be comparable. Additionally, we have recast prior periods for non-GAAP net income and non-GAAP Diluted Earnings Per Share to conform with current period presentation.

Cash Flows

The following table summarizes, for the periods indicated, cash flows from operating, investing and financing activities:

(In thousands)	Year Ended December 31, 2018	December 31, 2017	December 31, 2016	2018 - 2017 Change $	2017 - 2016 Change $
Net cash provided by operating activities	$181,643	$ 159,058	$ 147,823	$22,585	$11,235
Net cash used in investing activities	(193,027)	(111,277)	(162,738)	(81,750)	51,461
Net cash provided by financing activities	$32,570	$ 1,626	$ 470	$30,944	$1,156
Effect of foreign exchange rate changes on cash	(256)	1,979	(1,894)	(2,235)	3,873
Increase/(decrease) in cash, cash equivalents, and restricted cash	$20,930	$ 51,386	$ (16,339)	$(30,456)	$67,725

Table of Contents

Our cash, cash equivalents, and marketable securities at December 31, 2018 and 2017 were $602.8 million and $429.8 million, respectively. We assess our liquidity in terms of our ability to generate cash to fund our operating, investing and financing activities, whereby our principal source of liquidity is operating cash flows. Excess operating cash is primarily used to fund acquisitions to advance the strategic growth of the Company, as well as continue our cash management program to generate returns on our cash and cash equivalents through investing in marketable securities, which include municipal bonds, corporate debt securities, commercial paper, securities of government, federal agency, and other sovereign obligations and asset-backed securities. Our overall cash position reflects our strong business results and a cash management strategy that takes into account liquidity, economic factors and tax considerations. We believe our future operating cash flows will be sufficient to meet our future operating cash needs. See “Liquidity and Capital Resources” below for further discussion of cash flow results.

Cash Provided by Operating Activities

The increase in net cash provided by operating activities for the year ended December 31, 2018 was due primarily to increased operational cash flows in 2018 related to timing of spending and cash receipts.

The decrease in net cash provided by operating activities for the year ended December 31, 2017 was due primarily to the timing of collection and billing of trade accounts receivable, which was partially offset by an increase in depreciation and amortization expense.

Cash Used in Investing Activities

The increase in net cash used in investing activities for the year ended December 31, 2018 was due primarily to higher investment in marketable securities and increased purchases of property and equipment, which was partially offset by the cash received from collection of the note receivable.

The increase in net cash used in investing activities for the year ended December 31, 2017 was due primarily to higher investment in marketable securities and increased purchases of property and equipment, which was partially offset by the decrease in cash used for the acquisition of businesses.

Cash Provided by Financing Activities

The increase in cash provided by financing activities for the year ended December 31, 2018 was due primarily to higher proceeds from exercises of stock options, which was partially offset by payments for business acquisition liabilities.

The increase in cash provided by financing activities for the year ended December 31, 2017 was due primarily to proceeds from exercises of stock options, which was partially offset by payments for business acquisition liabilities.

Liquidity and Capital Resources

The following table highlights certain information related to our liquidity and capital resources:

(In thousands)	December 31, 2018	December 31, 2017
Cash, cash equivalents, and restricted cash	$ 139,747	$ 118,817
Short-term marketable securities	199,937	254,890
Long-term marketable securities	263,117	56,133
Total cash, cash equivalents, restricted cash, and marketable securities	$ 602,801	$ 429,840

Table of Contents

During the year ended December 31, 2018, our total cash, cash equivalents, restricted cash, and marketable securities increased $173.0 million, primarily as a result of our cash provided by operating activities and increased investment in marketable securities. Our investment in marketable securities includes municipal bonds, corporate debt securities, commercial paper, U.S. treasuries, securities of government, federal agency, and other sovereign obligations and asset-backed securities, and are classified as available-for-sale as of December 31, 2018.

During the fourth quarter of 2017, the Company identified and recorded an adjustment to its December 31, 2016 consolidated balance sheet to correct the presentation of $65.8 million of its Variable Rate Demand Notes ("VRDNs") as short-term marketable securities instead of cash and cash equivalents (see "Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 1. Background and Summary of Significant Accounting Policies.")

On June 13, 2017, we acquired the international operations and distribution channel of KB Medical SA for $31.5 million in cash, subject to certain closing adjustments (see "Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 2. Acquisitions.")

In May 2011, we entered into a credit agreement with Wells Fargo Bank related to a revolving credit facility that provides for borrowings up to $50.0 million. In June 2018, we amended the credit agreement to increase the revolving credit facility amount from $50.0 million to $125.0 million. At our request, and with the approval of the bank, the amount of borrowings available under the revolving credit facility can be increased to $150.0 million. The revolving credit facility includes up to a $25.0 million sub-limit for letters of credit. As amended to date, the revolving credit facility expires in May 2019. Cash advances bear interest at our option either at a fluctuating rate per annum equal to the daily LIBOR in effect for a one-month period plus 0.75%, or a fixed rate for a one- or three-month period equal to LIBOR plus 0.75%. The credit agreement governing the revolving credit facility also subjects us to various restrictive covenants, including the requirement to maintain maximum consolidated leverage. The covenants also include limitations on our ability to repurchase shares, to pay cash dividends or to enter into a sale transaction. As of December 31, 2018, we were in compliance with all financial covenants under the credit agreement, there were no outstanding borrowings under the revolving credit facility and available borrowings were $125.0 million. We may terminate the credit agreement at any time on ten days' notice without premium or penalty.

In addition to our existing cash and marketable securities balances, our principal sources of liquidity are cash flow from operating activities and our revolving credit facility, which was fully available as of December 31, 2018. We believe these sources will provide sufficient liquidity for us to meet our liquidity requirements for the foreseeable future. Our principal liquidity requirements are to meet our working capital, research and development, including clinical trials, and capital expenditure needs, principally for our surgical sets required to maintain and expand our business and potential future business or intellectual property acquisitions. We expect to continue to make investments in surgical sets as we launch new products, increase the size of our U.S. sales force, and expand into international markets. We may, however, require additional liquidity as we continue to execute our business strategy. Our liquidity may be negatively impacted as a result of a decline in sales of our products, including declines due to changes in our customers' ability to obtain third-party coverage and reimbursement for procedures that use our products, increased pricing pressures resulting from intensifying competition, cost increases and slower product development cycles resulting from a changing regulatory environment; and unfavorable results from litigation which will affect our cash flow. We anticipate that to the extent that we require additional liquidity, it will be funded through the incurrence of other indebtedness, additional equity financings or a combination of these potential sources of liquidity. The sale of additional equity may result in dilution to our stockholders. There is no assurance that we will be able to secure such additional funding on terms acceptable to us, or at all.

Table of Contents

Contractual Obligations and Commitments

The following table summarizes our outstanding contractual obligations as of December 31, 2018. There have been no material changes in our remaining contractual obligations since that time.

	Payments Due by Period				
(In thousands)	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases	$2,794	$1,581	$1,098	$115	$—
Purchase obligations[1]	9,973	2,158	2,515	2,500	2,800
Total[2]	$12,767	$3,739	$3,613	$2,615	$2,800

(1) Reflects minimum annual volume commitments to purchase inventory under certain of our supplier contracts as well as costs related to service agreements.

(2) In connection with certain acquisitions completed in 2011 through 2018, we have certain contingent consideration obligations payable to the sellers in these transactions upon the achievement of certain regulatory and sales milestones. The maximum aggregate undiscounted amounts potentially payable not included in the table above total $24.1 million.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Related-Party Transactions

We do not have any related-party transactions.

Recently Issued Accounting Pronouncements

For further details on recently issued accounting pronouncements, please refer to “Part II; Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 1. Background and Summary of Significant Accounting Policies; (x) Recently Issued Accounting Pronouncements.”

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

Market risk is the potential loss arising from adverse changes in the financial markets. We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes and do not believe we are exposed to material market risk with respect to our cash, cash equivalents and marketable debt securities. Except for the foreign exchange risk described below, we believe there has been no material quantitative changes in our market risk exposure between December 31, 2018 and December 31, 2017.

Interest Rate Risk

Our exposure to interest rate risk relates primarily to our revolving credit facility and our investments in cash equivalents and marketable debt securities portfolio. At December 31, 2018, we had no debt outstanding under our revolving credit facility and therefore were not exposed to interest rate risk with respect to interest payable under that facility.

Table of Contents

In general, our investments in cash equivalents and marketable debt securities are governed by our investment policy, which has been approved by our Board of Directors. Our investment policy seeks to preserve the value of capital, consistent with maximizing return on our investments while maintaining adequate liquidity. To achieve our investment objectives, we maintain a portfolio of various holdings, types and maturities and invest in securities that meet or exceed our investment policy standards, such as high credit quality debt securities.

We continue to be exposed to interest rate risk related to our cash equivalents and marketable securities. Generally, our interest rate risk with respect to these investments is limited due to yields earned. Changes in the overall level of interest rates affect the interest income generated by our cash, cash equivalents and marketable securities. Our investment policy limits the amount of credit exposure to any one issue, issuer or type of security. Our securities all have maturity dates within three years of the date of purchase and are designated as available for sale. As of December 31, 2018, we believe that a hypothetical 10% change in interest rates would not materially affect the underlying valuation of our marketable securities.

Foreign Exchange Risk

We operate in countries other than the United States and, therefore, we are exposed to foreign currency risks. Most of our direct sales outside of the United States are billed in local currencies. We expect that the percentage of our sales and certain operating expenses denominated in foreign currencies will increase in the foreseeable future as we continue to expand into international markets. When our sales or expenses are not denominated in U.S. dollars, a fluctuation in exchange rates could affect our net income. We do not currently hold derivatives to hedge our exposure to foreign currency exchange rate fluctuations; however, we may choose to hedge our exposure in the future.

Table of Contents

Item 8. Financial Statements and Supplementary Data

GLOBUS MEDICAL, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

Report of Independent Registered Public Accounting Firm
To the shareholders and the Board of Directors of Globus Medical, Inc.

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of Globus Medical, Inc. and subsidiaries (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of income, comprehensive income, equity, and cash flows, for the years ended December 31, 2018 and 2017, and the related notes and the schedule listed in the Index at Item 15(a)(2) (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years ended December 31, 2018 and 2017, in conformity with accounting principles generally accepted in the United States of America.
We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 21, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.
Basis for Opinion
These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP
Philadelphia, Pennsylvania
February 21, 2019
We have served as the Company's auditor since 2017.

Table of Contents

Report of Independent Registered Public Accounting Firm
To the shareholders and the Board of Directors of Globus Medical, Inc.

Opinion on Internal Control over Financial Reporting
We have audited the internal control over financial reporting of Globus Medical, Inc. and subsidiaries (the "Company") as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control - Integrated Framework (2013) issued by COSO.
We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements and financial statement schedule as of and for the year ended December 31, 2018, of the Company and our report dated February 21, 2019, expressed an unqualified opinion on those financial statements and financial statement schedule.
Basis for Opinion
The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.
Definition and Limitations of Internal Control over Financial Reporting
A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.
Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.
/s/ DELOITTE & TOUCHE LLP
Philadelphia, Pennsylvania
February 21, 2019

Table of Contents

Report of Independent Registered Public Accounting Firm
Board of Directors and Stockholders
Globus Medical, Inc.

We have audited the consolidated balance sheet of Globus Medical, Inc. (a Delaware corporation) and subsidiaries (the “Company”) as of December 31, 2016 (not presented herein), and the related accompanying consolidated statements of income, comprehensive income, equity, and cash flows for the year then ended. Our audit of the basic consolidated financial statements included the financial statement schedule listed in the index appearing under Item 15(a)(2). These financial statements and financial statement schedule are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Globus Medical, Inc. and subsidiaries as of December 31, 2016, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

/s/ GRANT THORNTON LLP
Philadelphia, Pennsylvania
March 16, 2017

Table of Contents

GLOBUS MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

(In thousands, except par value)	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash, cash equivalents, and restricted cash	$ 139,747	$ 118,817
Short-term marketable securities	199,937	254,890
Accounts receivable, net of allowances of $4,226 and $3,963, respectively	137,067	116,676
Inventories	131,254	108,409
Prepaid expenses and other current assets	15,387	11,166
Current portion of note receivable	—	1,667
Income taxes receivable	7,289	8,717
Total current assets	630,681	620,342
Property and equipment, net of accumulated depreciation of $216,809 and $191,760, respectively	171,873	143,167
Long-term marketable securities	263,117	56,133
Note receivable	—	28,333
Intangible assets, net	87,323	78,659
Goodwill	123,734	123,890
Other assets	10,364	7,947
Deferred income taxes	13,578	20,031
Total assets	$ 1,300,670	$ 1,078,502
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 25,895	$ 25,039
Accrued expenses	59,878	52,594
Income taxes payable	917	3,274
Business acquisition liabilities	6,830	11,411
Deferred revenue	2,598	755
Total current liabilities	96,118	93,073
Business acquisition liabilities, net of current portion	3,288	4,508
Deferred income taxes	8,114	10,669
Other liabilities	7,634	2,474
Total liabilities	115,154	110,724
Commitments and contingencies (Note 15)		
Equity:		
Class A common stock; $0.001 par value. Authorized 500,000 shares; issued and outstanding 76,143 and 72,780 shares at December 31, 2018 and 2017, respectively	76	73
Class B common stock; $0.001 par value. Authorized 275,000 shares; issued and outstanding 22,430 and 23,878 shares at December 31, 2018 and 2017, respectively	22	24
Additional paid-in capital	299,869	238,341
Accumulated other comprehensive loss	(7,172)	(6,907)
Retained earnings	892,721	736,247
Total equity	1,185,516	967,778
Total liabilities and equity	$ 1,300,670	$ 1,078,502

See accompanying notes to consolidated financial statements.

77

Table of Contents

GLOBUS MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share amounts)	Year Ended December 31, 2018	December 31, 2017	December 31, 2016
Sales	$712,969	$ 635,977	$ 563,994
Cost of goods sold	159,410	150,453	134,705
Gross profit	553,559	485,524	429,289
Operating expenses:			
Research and development	55,496	43,679	44,532
Selling, general and administrative	311,591	267,817	222,156
Provision for litigation	5,878	2,668	3,156
Amortization of intangibles	9,588	7,909	3,478
Acquisition related costs	1,681	1,611	1,826
Total operating expenses	384,234	323,684	275,148
Operating income	169,325	161,840	154,141
Other income, net:			
Interest income/(expense), net	13,278	6,608	3,057
Foreign currency transaction gain/(loss)	360	909	(482)
Other income/(loss)	5,642	571	563
Total other income/(expense), net	19,280	8,088	3,138
Income before income taxes	188,605	169,928	157,279
Income tax provision	32,131	62,580	52,938
Net income	$156,474	$ 107,348	$ 104,341
Earnings per share:			
Basic	$1.60	$ 1.12	$ 1.09
Diluted	$1.54	$ 1.10	$ 1.08
Weighted average shares outstanding:			
Basic	97,884	96,243	95,647
Dilutive stock options	3,432	1,644	785
Diluted	101,316	97,887	96,432
Anti-dilutive stock options excluded from weighted average calculation	2,451	2,873	5,481

See accompanying notes to consolidated financial statements.

Table of Contents

GLOBUS MEDICAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
Year
Ended