GLOBUS MEDICAL INC
Form 10-K
February 21, 2019
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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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

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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.

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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.

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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.

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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;

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- 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

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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

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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.

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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.

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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.

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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

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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.

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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

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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

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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.

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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.

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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.

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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