

GLOBUS MEDICAL INC
Form 10-K
March 05, 2013
Table of Contents

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

FORM 10-K

(Mark One)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2012
or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission File No. 001-35621

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

DELAWARE (State or other jurisdiction of incorporation or organization)	04-3744954 (I.R.S. Employer Identification No.)
--	--

2560 General Armistead Avenue, Audubon, PA (Address of principal executive offices)	19403 (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 Class A Common Stock, par value \$.001 per share	Name of each exchange on which registered 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 ☒

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 ☒

Table of Contents

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days:

Yes ☒ x

No ☐ o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files):

Yes ☒ x

No ☐ o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K:

☒ x

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (check one):

Large accelerated filer ☐ o

Accelerated filer ☐ o

Non-accelerated filer ☒ x

(Do not check if a smaller reporting company) Smaller reporting company ☐ o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act):

Yes ☐ No ☒ x

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the price at which the common equity last sold, or the average bid and asked price of such common equity, as of June 30, 2012 is not provided because the registrant's common equity did not commence trading on New York Stock Exchange until August 3, 2012.

The number of shares outstanding of the registrant's common stock (par value \$0.001 per share) as of February 28, 2013 was 91,858,583 shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our Proxy Statement for our 2013 Annual Meeting of Stockholders, to be filed within 120 days of December 31, 2012, are incorporated by reference in Part III, Items 10, 11, 12, 13 and 14 herein of this Annual Report. Such Proxy Statement, except for the parts therein which have been specifically incorporated by reference, shall not be deemed "filed" for the purposes of this Annual Report on Form 10-K.

Table of Contents

GLOBUS MEDICAL, INC. AND SUBSIDIARIES
TABLE OF CONTENTS

	Page
PART I	
Item 1. Business	<u>4</u>
Item 1A. Risk Factors	<u>28</u>
Item 1B. Unresolved Staff Comments	<u>64</u>
Item 2. Properties	<u>64</u>
Item 3. Legal Proceedings	<u>64</u>
Item 4. Mine Safety Disclosures	<u>66</u>
PART II	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	<u>67</u>
Item 6. Selected Financial Data	<u>69</u>
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations	<u>71</u>
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	<u>87</u>
Item 8. Financial Statements and Supplementary Data	<u>89</u>
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	<u>121</u>
Item 9A. Controls and Procedures	<u>121</u>
Item 9B. Other Information	<u>122</u>
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	<u>122</u>
Item 11. Executive Compensation	<u>123</u>
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	<u>123</u>
Item 13. Certain Relationships and Related Transactions, and Director Independence	<u>123</u>
Item 14. Principal Accountant Fees and Services	<u>123</u>
PART IV	
Item 15. Exhibits and Financial Statement Schedules	<u>124</u>
SIGNATURES	<u>128</u>

Table of Contents

PART I

CAUTIONARY NOTE CONCERNING FORWARD-LOOKING STATEMENTS

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

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

Item 1. Business

Overview

Globus Medical, Inc. (“Globus,” “we,” “us” or “our”) is a medical device company focused exclusively on the design, development and commercialization of products that promote healing in patients with spine disorders. We are an engineering-driven company with a history of rapidly developing and commercializing products that assist surgeons in effectively treating their patients, respond to evolving surgeon needs and address new treatment options. Since our inception in 2003, we have launched over 110 products and offer a comprehensive portfolio of innovative and differentiated products addressing a broad array of spinal pathologies, anatomies and surgical approaches. We were formed in 2003 and have grown our sales to \$386.0 million in 2012. We have been able to achieve our success while maintaining strong profit margins. For the year ended December 31, 2012, we had \$136.6 million of Adjusted EBITDA, representing an Adjusted EBITDA margin of 35.4%, and \$73.8 million of net income.

Table of Contents

All of our products fall into one of two categories: Innovative Fusion or Disruptive Technologies. Our Innovative Fusion products address a broad range of spinal fusion surgical procedures. Spinal fusion is a surgical procedure to correct problems with the individual vertebrae, the interlocking bones making up the spine, by preventing movement of the affected bones. We believe our Innovative Fusion products demonstrate features and characteristics that provide advantages for surgeons and contribute to better outcomes for patients as compared to traditional fusion products. These advantages have enabled us to grow our sales at a faster rate than the broader spine industry. We define Disruptive Technologies as those that represent a significant shift in the treatment of spine disorders by allowing for novel surgical procedures, improvements to existing surgical procedures, the treatment of spine disorders by new physician specialties, and surgical intervention earlier in the continuum of care. We expect the increased use of Disruptive Technologies to improve patient outcomes and reduce costs given the expected lower morbidity rates, shorter patient recovery times and shorter hospital stays associated with these procedures. Our current portfolio of approved and pipeline products includes a variety of Disruptive Technology products, which we believe offer material improvements to fusion procedures, such as minimally invasive surgical (“MIS”) techniques, as well as new treatment alternatives including motion preservation technologies, such as dynamic stabilization, total disc replacement and interspinous process spacer products and advanced biomaterials technologies, as well as interventional pain management solutions, including treatments for vertebral compression fractures. For the year ended December 31, 2012, our sales were \$238.7 million from Innovative Fusion products and \$147.3 million from Disruptive Technology products, representing year-over-year growth rates of 6.4% and 37.5%, respectively.

We expect the market for Disruptive Technologies to grow faster than the traditional fusion market and to expand the overall addressable population of patients seeking surgical treatment for spine disorders. We believe we are well positioned to capitalize on this higher-growth segment of the spine market given our multiple existing commercialized products and several products in various stages of development. In addition, we believe we are well positioned to increase sales of our Innovative Fusion products at a rate faster than the broader spine industry because of the advantages our products offer compared to traditional fusion products.

Our product development engine is the name we give to our particular approach to product development, which we believe is unique and highly efficient. It employs an integrated team approach to product development that involves collaboration among surgeons, our engineers, our dedicated researchers, our highly-skilled machinists, and our clinical and regulatory personnel. We believe that utilizing these integrated teams, as well as our extensive in-house facilities, enables us to design, test, and obtain regulatory approvals of our products at a faster rate than our competitors. We emphasize the importance of developing new products that are improvements to existing technologies and offerings, including our own, which we believe results in superior offerings that drive the demand for our products.

Our product development engine allows us to develop products that we believe provide advantages for surgeons and contribute to better outcomes for patients. We also believe the use of our products reduces costs as a result of lower morbidity rates, shorter patient recovery times and shorter hospital stays.

We market and sell our products through our exclusive global sales force. As of December 31, 2012, we had a direct or distributor sales presence in the United States and in 24 countries outside the United States. In addition, we have hired a separate sales force to market and sell our current and planned interventional pain management products, including our existing AFFIRM® kyphoplasty product, which we market under the trade name Algea Therapies®. We expect to continue to increase the number of our direct and distributor sales representatives, both in the United States and internationally, to expand into

Table of Contents

new geographic territories and to deepen our penetration in existing territories. We believe the planned 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.

Recent Developments

During the year ended December 31, 2012, we launched 14 new products, achieved a new milestone and completed an acquisition, all in furtherance of our strategic initiatives. In September 2012, we received our first U.S. Food and Drug Administration (“FDA”) pre-market approval (“PMA”), for our SECURE[®] Cervical Artificial Disc (see “Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations - Recent Developments” below). Clinical data from a 380 patient investigational device exemption (“IDE”) study demonstrated that SECURE[®] is statistically superior to anterior cervical discectomy and fusion in terms of overall success, subsequent surgery at the index level, device-related adverse events, and patient satisfaction at 24 months.

In July 2012, we acquired the assets of a small company with operations in the United States and Germany, including a new product designed to treat vertebral compression fractures (“VCFs”). For more information about this acquisition, see “Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 3. Business Acquisitions.”

Industry Overview

Overview of Spine Anatomy

The spine consists of interlocking bones, called vertebrae, stacked on top of one another. Vertebrae are separated from each other by intervertebral discs, which act as shock absorbers, and are connected to each other by facet joints, which provide flexibility. Supportive soft tissues including ligaments, tendons and muscles are attached to two laminae, which provide stability to the vertebral segment. The spinal cord runs through the center of the spine, or spinal canal, carrying nerves that exit through openings between the vertebrae, referred to as foramen, and deliver sensation and control to the entire body.

The spine is comprised of five regions, of which there are three primary regions: the cervical, thoracic and lumbar regions. The cervical region consists of the first seven vertebrae (C1-C7) extending from the base of the skull to the shoulders and facilitates movement of the head and neck. The thoracic region consists of the 12 vertebrae in the middle of the back (T1-T12) and each vertebra is connected to two ribs that protect the body's vital organs. The lumbar region consists of five vertebrae in the lower back (L1-L5) and is the primary load-bearing region of the spine. The final two regions of the spine, the sacrum (S1-S5) and coccyx, consist of naturally fused vertebrae connected to the hip bones to provide support and protect organs in the pelvic area. With regard to anatomical terms of surgical location, anterior refers to access from the front, posterior refers to access from the back and lateral refers to access from the side.

Overview of Spine Disorders

Spine disorders are a leading driver of healthcare costs worldwide. Spine disorders range in severity from mild pain and loss of feeling to extreme pain and paralysis. These disorders are primarily caused by degenerative disc disease (“DDD”), stenosis, deformity, osteoporosis, tumors and trauma.

DDD describes the most common type of spine disorder, which primarily results from repetitive stresses experienced during the normal aging process. Disc degeneration occurs as the inner cores of

Table of Contents

Intervertebral discs lose elasticity and shrink. Over time, these changes can cause the discs to lose their normal height and shock-absorbing characteristics, which leads to back pain and reduced flexibility. Herniated discs are a common form of degenerative disc disease and occur when the intervertebral disc material protrudes from the annulus. Symptomatic cervical disc disease (“SCDD”) is a gradual deterioration of the spongy discs in the neck leading to problems related to nerve function that can cause pain and limit movement.

Spinal stenosis is a condition attributed to the narrowing of the space around the nerves in the lumbar spine. The resulting compression can lead to back and leg pain. This condition is often caused by the degenerative process in the spine and facet joints. Lumbar stenosis is a condition whereby either the spinal canal or vertebral foramen becomes narrowed in the lower back. If the narrowing is substantial, it causes compression of the nerves and the painful symptoms of lumbar spinal stenosis.

Spine deformity is a term used to describe any variation in the natural curvature of the spine. Natural curves help the upper body maintain proper balance and alignment over the pelvis. Common forms of deformity include scoliosis, which is a lateral or side-to-side curvature of the spine, extreme lordosis, which is an abnormal convex curvature of the lumbar spine, and extreme kyphosis, which is an abnormal concave curvature leading to a rounded back.

VCFs are fractures of the vertebrae that result in the collapse of the vertebral body. These fractures, which can be very painful to the patient, are often the result of osteoporosis, which causes the vertebrae to weaken and become brittle, or spine tumors, but can also result from trauma.

Spine tumors are relatively rare. Benign tumors are typically removed surgically while malignant tumors are more difficult to treat and often originate in other areas of the body such as the lungs, thyroid or kidneys.

Treatments for Spine Disorders

Treatment alternatives for spine disorders range from non-operative conservative therapies to surgical interventions. Conservative therapies include bed rest, medication and physical therapy. When conservative therapies fail to provide adequate quality of life improvements, surgical interventions may be used to address pain. Surgical treatments for spine disorders can be instrumented, which include the use of implants, or non-instrumented, which forego the use of any such implants. The most common surgical interventions include non-instrumented treatments such as discectomy, which is the removal of all or part of a damaged disc, and laminectomy, which is the removal of all or part of a lamina. Non-instrumented treatments have typically been used to treat patients earlier in the continuum of care than instrumented treatments. The most common instrumented treatment is spinal fusion, where two or more adjacent vertebrae are fused together with implants to restore disc height and provide stability. As Disruptive Technologies continue to gain acceptance, we expect that they will allow surgeons to use instrumented treatments earlier in the continuum of care as a preferred alternative to non-instrumented surgical intervention or conservative therapies.

Fusions are typically performed on the cervical or lumbar regions of the spine, and implants may include devices such as plates, pedicle screw and rod systems and interbody spacers.

Disruptive Technologies are designed to provide better patient outcomes in certain situations through the use of MIS techniques, by allowing the patient to retain some motion in the affected area, or by using biomaterials or interventional pain management solutions, such as treatments for VCFs to speed healing time or improve patient outcomes. Disruptive Technologies may enable treatment with implants earlier in the

Table of Contents

continuum of care by addressing the shortcomings of traditional surgical interventions, which often include soft tissue disruption, long operating times, extended hospital stays and lengthy patient recovery times. Additionally, Disruptive Technologies may help a patient avoid progression of spinal disc disease sometimes caused by traditional surgical options such as spinal fusion. As a result, we expect the market for Disruptive Technologies to grow faster than the market for traditional fusion and expand the addressable patient population for spine surgery.

Growth Drivers

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

Favorable patient demographics. The number of people over the age of 65 is large and growing. Improvements in healthcare have led to increasing life expectancies worldwide and the opportunity to lead more active lifestyles at advanced ages. These trends are expected to generate increased demand for spine surgeries.

- Improving technologies leading to increased use of fusion procedures. Due to the longevity of its practice and acceptable clinical outcomes, fusion has become a standard treatment option for patients presenting more advanced stages of spine disease. We expect that the development of improved fusion products will continue to contribute to spinal fusion as a leading treatment for advanced stages of spine disease.

Disruptive Technologies driving earlier interventions and creating an expanded patient base. Disruptive Technologies are gaining increasing acceptance among patients and surgeons because they allow for novel surgical procedures, improvements to existing surgical procedures, the treatment of spine disorders by new physician specialties, and surgical intervention earlier in the continuum of care, all of which can result in better outcomes for patients. We believe surgeons and patients who would otherwise choose more conservative nonsurgical treatment plans with sub-optimal results may elect a surgical option utilizing Disruptive Technologies to treat spine disorders. As a result, Disruptive Technologies are expected to drive accelerated growth and increase the size of the addressable patient population for spine surgery.

Continued market penetration internationally. While the United States comprises approximately 5% of the worldwide population, we believe that approximately half of all spine surgeries occur in the United States. We believe that improvements to the standard of care, including the introduction of new products and the expansion of international sales forces, will increase demand for spine products outside of the United States.

Our Competitive Strengths

We are focused exclusively on the spine market, and our senior leadership team has over 200 years of collective experience in the spine and medical device industries. We believe that this focus and experience, combined with the following principal competitive strengths, will allow us to grow our sales faster than our competitors and the overall spine industry:

Comprehensive and broad portfolio of Innovative Fusion products. We have a comprehensive portfolio of Innovative Fusion products that addresses a broad array of spinal pathologies, anatomies and surgical approaches. We believe our Innovative Fusion products demonstrate

Table of Contents

features and characteristics that provide advantages for surgeons and contribute to better outcomes for patients as compared to traditional fusion products. Our differentiated product portfolio allows us to offer a wide variety of treatment options and effectively market our entire product portfolio to surgeons who may initially be familiar with only a subset of our products. In addition, because surgeons and hospitals typically prefer to deal with a limited number of vendors with broad product offerings, our portfolio of products enables us to compete effectively.

Well-positioned Disruptive Technology products. We expect the market for Disruptive Technologies to grow faster than the traditional fusion market. We currently have a comprehensive and broad portfolio of MIS, motion preservation and advanced biomaterials products, with two additional products addressing motion preservation in clinical trials and other pipeline products in various stages of development. We believe our current portfolio and pipeline of Disruptive Technology products provide improved patient outcomes, reduce overall costs and position us to capitalize on the growth in this market.

Integrated product development engine. We believe that we have a unique and highly efficient approach to product development that significantly reduces the time required to advance a potential product from concept to commercialization. We have historically utilized our product development engine to bring substantially all of our products to market and have not relied upon acquisitions to grow our business. Our integrated teams of surgeons, engineers, dedicated researchers, highly-skilled machinists, and clinical and regulatory personnel work together to conceptualize, evaluate, and develop potential new products through an iterative process that allows for rapid product development. In addition, our regulatory and clinical affairs teams have a proven ability to work effectively with regulatory agencies worldwide to obtain approvals to market our products. The combination of our research, development, clinical and regulatory expertise allows us to react quickly to evolving surgeon and patient needs, address new treatment options, and introduce several new products annually.

Exclusive U.S. sales force with broad geographic scope. We have made, and intend to continue to make, significant investments in our exclusive U.S. sales force. Our direct and distributor sales representatives are highly trained in the clinical benefits of our products and frequently consult with surgeons and surgical staff inside the operating room regarding the use of our products. We believe the size, expertise and exclusive nature of our U.S. sales force enable us to maximize our market penetration and continue to expand our geographic presence.

Demonstrated track record of profitability with established scale. We have made investments in our infrastructure that have allowed us to accelerate development and commercialization of our products, and maintain strong profit margins typically associated with our larger competitors. We have launched over 110 products and experienced significant growth in sales since our founding in 2003, while remaining focused on generating operating cash flow and net income. We were formed in 2003 and have grown our sales to \$386.0 million in 2012. Our disciplined approach has contributed to Adjusted EBITDA of \$136.6 million and net income of \$73.8 million for the year ended December 31, 2012.

Our Strategy

Our goal is to become the leader in providing innovative solutions across the continuum of care in the spine market. To achieve this goal, we are employing the following business strategies:

Table of Contents

Leverage our product development engine. We plan to continue to develop both Innovative Fusion products and Disruptive Technology products using what we believe to be a unique and highly efficient product development engine. We believe our team-oriented approach, active surgeon input and demonstrated product development and commercialization capabilities position us to maintain a rapid rate of new product launches. As of the date of this Annual Report, we had over 30 potential new products in various stages of development and we expect to launch approximately five to ten new products in each of the next three years.

Increase the size, scope and productivity of our exclusive U.S. sales force. We believe there is significant opportunity to further penetrate existing markets and to enter new markets by increasing the size and geographic scope of our U.S. sales force. We expect to continue to increase the number of our direct and distributor sales representatives in the United States to expand into new geographic territories and to deepen our penetration in existing territories. We also intend to continue recruiting additional sales representatives strategically to grow our Algea Therapies® sales force. In addition to focusing our recruitment efforts on individuals with previous spine industry experience and demonstrated sales success, we will continue to provide our sales representatives with specialized development programs designed to improve their productivity.

Continue to expand into international markets. We have historically focused our commercialization efforts primarily on the U.S. market. However, we began selling our products in international markets in 2005 and sales generated from outside the United States of \$30.4 million for the year ended December 31, 2012, a 48.6% increase from 2011. We expect to continue to increase our international presence through the commercialization of additional products and through the expansion of our direct and distributor sales force. As of December 31, 2012, we had an existing direct or distributor sales presence in 24 countries outside the United States.

Pursue strategic acquisitions and alliances. We intend to selectively pursue acquisitions and alliances in the future that will provide us with new or complementary technologies, personnel with significant relevant experience, or increased market penetration. We are currently evaluating a number of possible acquisitions or strategic relationships and believe that our resources and experience make us an attractive acquirer or partner.

Products

We currently offer over 110 Innovative Fusion and Disruptive Technology products. We summarize below a selection of these products.

Innovative Fusion

Our products address the entire spine with Innovative Fusion products for use in cervical, thoracolumbar, sacral, and interbody/corpectomy fusion procedures to treat degenerative, deformity, tumor, and trauma conditions. We believe that our Innovative Fusion products demonstrate features and characteristics that enable us to provide advantages over traditional fusion products that help improve surgical techniques and may contribute to better outcomes for patients. For example, our comprehensive REVERE® pedicle screw and rod system incorporates a convenient non-threaded locking cap design that eases building of thoracolumbar fixation constructs to readily adapt to the patient's anatomy and condition, for a range of clinical applications. Certain other of our products, such as our XPAND® and FORTIFY® corpectomy devices that incorporate smooth expansion capability, have a range of size options for optimal fit, and are manufactured from radiolucent polyetheretherketone ("PEEK") to allow for postoperative radiographic

Table of Contents

visualization. Certain of our other products, such as our COALITION® and INDEPENDENCE® stand-alone interbody fusion devices, simplify the surgical technique by reducing steps and hardware while providing confident stabilization. The depth of our Innovative Fusion portfolio encompasses treatment modalities from the occiput to the sacrum, with novel designs and features that provide key improvements to the standards of care. We also build on proven technologies to continuously upgrade our offerings, including multiple cervical plating systems, both top-loading and posted screw systems, and a range of interbody implant and approach options.

Disruptive Technologies

We believe we are well positioned to capitalize on this higher-growth segment of the spine market given our multiple existing commercialized products and several products in various stages of development. We have a comprehensive and broad product portfolio and pipeline of Disruptive Technologies, including MIS, motion preservation, and advanced biomaterials technologies, as well as interventional pain management solutions, including treatments for VCFs. Our MIS products enable a surgeon to perform a procedure less invasively to minimize tissue disruption and maximize native anatomy, which may lead to better patient recovery and fewer approach-related complications. For example, our MARSTM 3V retractor system facilitates smaller incisions with the use of positionable radiolucent retractor blades to access the surgical site and to allow both direct and radiographic visualization. Our CALIBER®, RISE® and SIGNATURE® interbody spacers are designed for reliable delivery through smaller MIS incisions with streamlined implants and instruments. Our REVOLVE® pedicle screw system is designed for MIS screw and rod insertion through small incisions, and utilizes a convenient non-threaded locking cap design. Other Disruptive Technology products, such as TRANSITION®, provide for stabilization that is less rigid than traditional pedicle screw systems for more natural load distribution to help promote fusion while maintaining stability. Similarly, our motion preservation products, such as SECURE®-C and SECURE®-CR, are next-generation arthroplasty devices that allow segmental motion, are semi-constrained to enhance stability, and provide alternatives to fusion in the treatment of degenerative conditions. Our advanced biomaterials products, including MICROFUSE® resorbable bone void filler and CONDUCT® ceramic-collagen, are well suited for posterolateral fusion procedures in which our innovative stabilization systems are also used. Our AFFIRM® product allows for the treatment of painful VCFs earlier in the continuum of care.

Table of Contents

A selection of the 14 new products we launched in 2012 is presented below:

Selected Product	Description	Region
MARS™ Anterior Retractor	Retractor system for a minimal access retroperitoneal approach	United States International
RISE®	Expandable lumbar interbody fusion device that may be implanted using open or endoscopic techniques	United States International
CALIBER®-L	Expandable lateral lumbar interbody fusion device with PEEK endplates	United States International
AFFIRM®	Minimally invasive vertebral augmentation system for the treatment of VCFs	United States International
CANOPY™	Plate and spacer system for posterior laminoplasty	United States International
SECURE®-C	Selectively constrained dual articulating cervical disc replacement device	United States International
XEMPLIFI® DBM	Osteoinductive and osteoconductive demineralized bone matrix in several forms	United States International
PLYMOUTH®	Minimally invasive cervical plate system designed to provide stabilization through a lateral approach.	United States International
FORTIFY®	PEEK and titanium self-locking expandable corpectomy device with modular endplates	United States
REVERE® 4.5	Comprehensive pedicle screw and rod system with non-threaded locking mechanism, to treat complex spinal deformities in pediatric and small stature, skeletally mature patients.	United States International

Clinical Development Programs

In addition to the products we currently market, we continue to develop and test novel spine products. As we focus our attention on developing more Disruptive Technologies, we are required to conduct clinical trials in order to obtain FDA approval or clearance to market some of those Disruptive Technologies. We recently received our first FDA PMA for our SECURE®-C cervical artificial disc and are currently conducting various clinical trials under FDA-approved IDEs, including the following:

ACADIA® Facet Replacement System

The current treatment for spinal stenosis calls for removal of bone around the affected nerve including the facet joints and fusing the posterior of the spine to ensure the segments remain stable. The ACADIA® Facet Replacement System allows for an anatomic reconstruction of the facet joint after the degenerated facet is decompressed and removed.

ACADIA® has been designed on the principles that have allowed other total joint replacement procedures to provide significant patient benefits. These guiding principles include an anatomically based implant design, a reproducible surgical technique, and the preservation of motion while addressing the clinical concern. Like the original facet joint, the replacement implant is designed to reproduce facet motion while restoring normal stability and motion.

We acquired the assets of Facet Solutions, developers of ACADIA®, in January 2011. Two U.S. IDE studies are in progress to study the use of ACADIA® in patients suffering from spinal stenosis. A 20-patient pilot study was enrolled prior to the acquisition, and a pivotal study was underway with 130 patients enrolled at the time of the acquisition. The prospective randomized pivotal study of ACADIA® may enroll

Table of Contents

and treat up to 750 patients randomly selected for the treatment or control arm in a 2:1 ratio. As of December 31, 2012, 214 patients have been enrolled and treated in the study. Postoperative follow-up data is obtained at six weeks, three months, six months, 12 months, 24 months and annually thereafter. ACADIA® is CE marked and is available for sale in certain jurisdictions outside the United States.

TRIUMPH® Lumbar Disc

The TRIUMPH® Lumbar Disc, which is used in the treatment of lumbar DDD, is a posterolateral artificial disc that permits motion and is the first device of its kind to be inserted from a posterolateral approach.

TRIUMPH® is an articulating device comprised of two cobalt-chrome alloy components with multiple serrated keels for fixation, and titanium plasma spray coating to promote bony ingrowth. The two endplate surfaces are biconvex to conform to the vertebral endplates. The device allows for motion in all planes regardless of insertion angle, which can vary depending on surgical needs. This approach enables a surgeon to address the patient's posterior pathology, as needed, and to maintain important anterior anatomical structures. The device is placed obliquely across the disc space, and has features that guide alignment in the anteroposterior and lateral planes.

An IDE pilot study is being conducted on TRIUMPH® in patients suffering from back and/or leg pain associated with DDD. A total of 20 patients have been enrolled and treated with TRIUMPH®. We plan to submit the required data obtained through the IDE pilot study to the FDA to gain support for a larger randomized pivotal study comparing TRIUMPH® to traditional fusion in the control arm. TRIUMPH® is CE marked and is available for sale in certain jurisdictions outside the United States.

Product Development and Research

The markets in which we operate are subject to rapid technological advancements. We must constantly improve our existing products and introduce new products in order to continue to succeed. Accordingly, we have made significant investments in our product development and research capabilities. For the years ended December 31, 2012, 2011 and 2010, we spent \$27.9 million, \$23.5 million and \$21.3 million, respectively, on research and development.

Our senior management team founded Globus with a goal of leveraging their experience in the spine industry to develop a distinctive product development process that could significantly reduce the length of time between a product's concept stage and commercialization. We have created what we believe to be a unique and highly efficient product development engine that employs an integrated team approach to product development that involves collaboration between surgeons, our engineers, our dedicated researchers and our highly-skilled machinists, as well as our clinical and regulatory personnel. This product development team formulates a design for the product and then builds and tests prototypes in our in-house prototype development and testing facility. As part of the development process, spine surgeons test the implantation of the product in our cadaveric laboratory to ensure it meets the needs of both surgeon and patient. Our team quickly refines or redesigns the prototype as necessary based on the results of the product testing, allowing us to perform rapid iterations of the design-prototype-test development cycle. We believe that our product development engine allows us to provide solutions that effectively respond to the needs of spine surgeons and their patients.

Our regulatory and clinical affairs department works in parallel with our product development teams, allowing us to anticipate and resolve issues at early stages in the development cycle. Our regulatory and

Table of Contents

clinical affairs personnel are committed to timely and responsive communication with regulatory agencies. Though regulatory requirements are constantly changing and continued success cannot be assured, we have demonstrated an ability to gain rapid regulatory approvals of our Innovative Fusion products and Disruptive Technologies. We have demonstrated success in rapid product development, as we have successfully introduced over 110 products since we were founded in 2003 and intend to continue to launch five to ten new products in each of the next three years.

Our product development efforts are supported by our in-house research capabilities. We believe that centralizing and consolidating the critical elements of the product development and commercialization process in one facility allows us to bring products from the concept stage to the market rapidly in order to respond to surgeon and patient needs. We have the following resources at our corporate headquarters:

• A mechanical testing laboratory that provides a modern, fully-equipped facility for product testing. This capability is critical to our rapid product development process that relies on multiple iterations of the design-build-test cycle.

• Our clinical research group gathers and performs postmarket clinical research and collects data that supports our product development and sales efforts.

• A spinal kinematics laboratory contains our proprietary six degrees of freedom machine that we developed to biomechanically test cadaveric specimens. The six degrees of freedom machine enables us to simulate accurately and replicate the movement of the human spine. This enables spine surgeons and engineers to study the kinematics and kinetics of the human spine and the effects of various treatments and surgical techniques using our products.

• A tribology laboratory with machines that study the wear behavior of various bearing surfaces. This research is critical to the development of the next generation of Disruptive Technology products using newer bearing surfaces.

A cadaveric laboratory simulates the operating room environment for product testing and training. This allows our product development team, including surgeons, to ensure our products meet all of their specifications and enables surgeons to develop a high level of comfort and aptitude in using the products.

• A materials characterization laboratory including a scanning electron microscope, energy dispersive spectroscopy and differentiated scanning calorimetry that allows us to view images of a device's surface to determine certain of its properties, such as topography and composition. This laboratory enables us to model and analyze failures of certain device mechanisms, such as a material's stress points, in order to improve our products.

A computational laboratory built around a high-powered computer that conducts detailed mathematical modeling of discrete elements of a device in order to determine that device's behavior under various loading conditions. We use this mathematical modeling as a supplement to other testing methods in the design process.

Spine Community Involvement and Education

One of the defining elements of our business is the extent of our involvement in the spine surgeon community. Spine surgeons participate in various aspects of our strategy, research, product development

Table of Contents

and education through formal programs such as our Medical Board of Directors and our Strategic Advisory Board. We also have extensive informal contact with spine surgeons. For example, surgeons are invited to our corporate headquarters to interface with our executive team, review our product portfolio, participate in bioskills labs, observe surgical procedures and interact with our product development teams. Members of all product development groups and other executives routinely conduct field visits with our spine surgeon constituency. Feedback from these interactions helps us understand practitioners' needs and positions us to see key trends ahead of the competition.

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

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

We devote significant resources to training and educating surgeons in the safe and effective use of our products and techniques. In 2012, for example, we sponsored over 40 such programs in which over 500 surgeons participated. We have also made significant investments in the creation, staffing and program offerings of our Musculoskeletal Education and Research Center ("MERC"). Through MERC we offer educational and training programs both internally in our modern bioskills laboratory and 100 person lecture facility and externally through regionally-based didactic education and cadaveric bioskills training programs.

We are highly focused on the training of Disruptive Technologies through programs such as our Skin-to-Skin® Series programs that feature intensive two day MIS training programs on thoracolumbar interbody fusion procedures and our lateral lumbar interbody fusion labs. To complement these intensive cadaveric bioskills training programs, we also conduct a large number of product-based programs providing surgeons with informative didactic sessions coupled with hands-on-lab segments to allow surgeons to learn and experience new instrumentation and techniques.

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

In addition to the programs offered by MERC, we actively participate in trade and industry organizations, including the North American Spine Society, the American Association of Neurological Surgeons and the International Society for the Advancement of Spine Surgery. We annually provide support to such professional organizations in the form of restricted educational grants and support of specific product

Table of Contents

workshop programs. Promising spine surgeons routinely seek educational fellowships as an important part of building strong clinical skills. We annually support these fellowships through academic institutions throughout the United States.

Sales and Marketing

We market and sell our products through our exclusive global sales force. As of December 31, 2012, we had a direct or distributor sales presence in the United States and in 24 countries outside the United States. In addition, we have hired a new sales force to market and sell our current and planned interventional pain management products, which we market under the trade name Algea Therapies®. Algea Therapies has a separate sales force because the physicians who use interventional pain management solutions are not limited to the neurosurgeons and orthopedic surgeons to whom our existing sales force currently markets our other products. In addition to these surgeons, our Algea Therapies® sales force will also call on interventional radiologists and pain management physicians to sell these new products. We intend to recruit additional sales representatives strategically to grow that business. We expect to continue to increase the number of our direct and distributor sales representatives, both in the U.S. and internationally, to expand into new geographic territories and to deepen our penetration in existing territories. We believe the expansion of our U.S. and international sales forces provides us with significant opportunities for future growth as we continue to penetrate existing geographic markets and enter new ones.

We have developed an intensive training program that all members of our direct and independent sales force are required to attend. We expect that they will continue to develop a depth of knowledge and understanding of our products that will allow them to more effectively and efficiently generate sales.

Our sales representatives are present in the operating room during most surgeries in the United States and in many, but not all, of the other countries in which our products are sold. Our representatives have the responsibility to confirm that all of the items needed in the surgery are sterilized and available to the surgeon and surgical staff. 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 our products are used in surgeries, we ship replacement items to our sales representatives and hospitals to replenish their supply.

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

Suppliers and Inventory

Our products are generally manufactured through a network of over 100 international and domestic third-party suppliers. Our suppliers utilize state-of-the-art, 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, including our largest suppliers, are located within a 100-mile radius of the Philadelphia area, which affords our engineers and other members of our product development team the opportunity to work closely with them to commercialize our products.

Table of Contents

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

We generally use a small number of suppliers for each of our key products for added reliability. A small percentage of our products, chiefly some of our advanced biomaterials, are manufactured in-house at our headquarters. We also use our facilities for inspection, packaging and labeling a large percentage of our inventory. A majority of our product inventory is held primarily with our sales representatives and at hospitals throughout the United States. We believe our supplier relationships and facilities will support our potential capacity needs for the foreseeable future.

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 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 proactively protect our innovations by filing numerous U.S. and foreign patent applications and our growing intellectual property portfolio reflects significant investment. Complementing our internally-developed intellectual property holdings, we have also acquired intellectual property via the strategic purchase of patents in areas in which we have wished to commercialize products. We employ in-house intellectual property lawyers who oversee the maintenance of our intellectual property assets. As of December 31, 2012, we owned 135 issued U.S. patents (122 utility patents; 13 design patents) and had applications pending for 279 U.S. patents (272 utility patent applications; seven design patent applications), and we owned 51 issued foreign patents and had applications pending for 94 foreign patents. One of our issued patents expires in March 2015 and the rest of our issued patents expire between November 2019 and October 2031.

Our trademark portfolio contains 87 registered trademarks and 45 pending trademarks. Our portfolio includes domestic and foreign trademarks with associated logos and tag lines. The following list includes all registered marks and pending marks. All other trademarks or trade names referred to in this Annual Report are the property of their respective owners.

We also rely upon trade secrets, know-how, continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information.

Table of Contents

Although we believe our patents are valuable, we also believe that our knowledge and experience and our trade secret information with respect to development and manufacturing processes, materials and product design have been equally important in maintaining our proprietary product lines. As a condition of employment, we generally require employees to execute a confidentiality agreement relating to proprietary information and assigning patents and other intellectual property to us.

Competition

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

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

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

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.

Table of Contents

U.S. Food and Drug Administration Regulation

Our products are medical devices and tissues 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;
- product manufacturing;
- product safety;
- post-market adverse event reporting;
- post-market surveillance;
- product labeling;
- product storage;
- record keeping;
- pre-market clearance or approval;
- post-market approval studies;
- advertising and promotion; and
- product sales and distribution.

FDA's Pre-market Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the United States will require either prior 510(k) clearance or prior approval of a PMA application from the FDA. The FDA classifies medical devices into one of three classes. Devices deemed to pose lower risk are placed in either Class I or II, which requires 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, requiring approval of a PMA application. Both pre-market clearance and PMA applications 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.

Table of Contents

510(k) Clearance Pathway

To obtain 510(k) clearance, we must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMA applications. The FDA's 510(k) clearance pathway usually takes from three to 12 months from the date the application is completed, but it can take significantly longer and clearance is never assured. Although many 510(k) pre-market notifications are cleared without clinical data, in some cases, the FDA requires significant clinical data to support substantial equivalence. In reviewing a pre-market notification, the FDA may request additional information, including clinical data, which may significantly prolong the review process. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance or could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination regarding whether a new pre-market submission is required for the modification of an existing device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. If the FDA requires us to seek 510(k) clearance or approval of a PMA application for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant regulatory fines or penalties for failure to submit the requisite PMA application. We have made and plan to continue to make minor additional product enhancements that we believe do not require new 510(k) clearances. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k)s and additional requirements that may significantly impact the process.

Pre-market Approval Pathway

A PMA application must be submitted if the device cannot be cleared through the 510(k) process and requires proof of the safety and effectiveness of the device to the FDA's satisfaction. Accordingly, a PMA application must be supported by extensive data including, but not limited to, technical information regarding device design and development, preclinical and clinical trials, data and manufacturing and labeling to support the FDA's determination that the device is safe and effective for its intended use. After a PMA application is complete, the FDA begins an in-depth review of the submitted information, which generally takes between one and three years, but may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with Quality System Regulations ("QSRs") which impose elaborate design development, testing, control, documentation and other quality assurance procedures in the design and manufacturing process. The FDA may approve a PMA application with post-approval conditions intended to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported approval. Failure to comply with the conditions of approval can result in materially adverse enforcement action, including the loss or withdrawal of the approval. New PMA applications or PMA application supplements are required for significant modifications to the manufacturing process, labeling and design of a device that is approved through the PMA process. PMA supplements often require submission of the

Table of Contents

same type of information as a PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials

A clinical trial is almost always required to support a PMA application and may be required for a 510(k) pre-market notification. These trials generally require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to evaluate the device in humans and that the testing protocol is scientifically sound. The IDE application must be approved in advance by the FDA for a specified number of subjects, unless the product is deemed a non-significant risk device and eligible for more abbreviated IDE requirements. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the responsible institutional review boards. There can be no assurance that submission of an IDE will result in the ability to commence clinical trials. Additionally, after a trial begins, the FDA may place it on hold or terminate it if, among other reasons, it concludes that the clinical subjects are exposed to an unacceptable health risk. During a study, we are required to comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting, record keeping and prohibitions on the promotion of investigational devices or making safety or efficacy claims for them. We are also responsible for the appropriate labeling and distribution of investigational devices. The investigators must also obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and record keeping requirements. The FDA's grant of permission to proceed with clinical testing does not constitute a binding commitment that the FDA will consider the study design adequate to support clearance or approval. In addition, there can be no assurance that the data generated during a clinical study will meet chosen safety and effectiveness endpoints or otherwise produce results that will lead the FDA to grant marketing clearance or approval. ACADIA® and TRIUMPH® are currently in human clinical trials under IDEs. We expect to launch additional clinical trials under IDEs for devices which we also expect will be required to undergo the PMA process. Our clinical trials must be conducted in accordance with FDA regulations and other federal regulations and state laws concerning human subject protection and privacy. The results of our clinical trials may not be sufficient to obtain clearance or approval of our product.

Human Cell, Tissue and Cellular and Tissue Based Products

We currently distribute MAINTAIN® machined allograft and XEMPLIFI® demineralized bone matrix, both of which are manufactured by third-party suppliers. Tissue-only products are regulated by the FDA as Human Cell, Tissue and Cellular and Tissue Based Products. FDA regulations do not currently require 510(k) clearance or approval of a PMA application before marketing these products. Tissue banks must register their establishments, list products with the FDA and comply with Current Good Tissue Practices for Human Cell, Tissue and Cellular and Tissue Based Product Establishments.

The FDA periodically inspects tissue processors to determine compliance with these requirements. Violations of applicable regulations noted by the FDA during facility inspections could adversely affect the continued marketing of our products. We believe we comply with all aspects of the Current Good Tissue Practices ("CGTPs"), although there can be no assurance that we will comply, or will comply on a timely basis, in the future. 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 CGTPs regulations that regulate those functions are dependent upon the actions of these independent entities.

Table of Contents

The procurement and transplantation of allograft bone tissue is subject to U.S. federal law pursuant to the National Organ Transplant Act (“NOTA”), a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for “valuable consideration.” NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. With the exception of removal and implantation, we provide services in all of these areas. We make payments to vendors in consideration for the services they provide in connection with the recovery and screening of donors. Failure to comply with the requirements of NOTA could result in enforcement action against us.

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. Failure to comply with state laws could also result in enforcement action against us.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, regardless of its classification or pre-market pathway, numerous regulatory requirements apply. These include, but are not limited to:

- establishing registration and device listings with the FDA;
- quality system regulation, which requires manufacturers to follow stringent design, testing, process control, documentation and other quality assurance procedures;
- labeling regulations, which prohibit the promotion of products for uncleared or unapproved, i.e. “off-label,” uses and impose other restrictions on labeling;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the U.S. Federal Food, Drug, and Cosmetic Act (“FDCA”) that may present a risk to health; and
- requirements to conduct post-market surveillance studies to establish continued safety data.

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

- untitled letters or warning letters;
- fines, injunctions and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;

Table of Contents

- refusing our request for 510(k) clearance or PMA of new products;
- withdrawing 510(k) clearance or PMAs that are already granted; and
- criminal prosecution.

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

International

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals and comply with extensive safety and quality regulations in other countries. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. The European Union/European Economic Area ("EU/EEA") requires CE conformity 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 although others, 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. 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 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. Except for low risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Device Directive, a conformity assessment procedure requires the intervention of a Notified Body, which is an organization accredited by a Member State of the EEA to conduct conformity assessments. The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements. Based on this certification we can draw up an EC Declaration of Conformity which allows us to affix the CE mark to our products. We have now successfully passed several Notified Body audits since our original certification in February 2006, granting us ISO registration and allowing the CE conformity marking to be applied to certain of our devices under the EU Medical Device Directive.

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.

Table of Contents

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. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions.

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.

To enforce compliance with the federal laws, the U.S. Department of Justice (“DOJ”) has increased its scrutiny of interactions between healthcare companies and healthcare providers which has led to an unprecedented level of investigations, prosecutions, convictions and settlements in the healthcare industry. Dealing with investigations can be time- and resource-consuming. Additionally, if a healthcare company settles an investigation with the DOJ or other law enforcement agencies, the company may be required to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement.

The United States and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased U.S. government oversight and enforcement of the U.S. Foreign Corrupt Practices Act (“FCPA”). Whenever a governmental authority concludes that we are not in compliance with applicable laws or regulations, that authority can impose fines, delay or suspend regulatory clearances, institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil penalties against us or our officers or employees and can recommend criminal prosecution. Moreover, governmental authorities can ban or request the recall, repair, replacement or refund of the cost of devices we distribute.

Additionally, the commercial compliance environment is continually evolving in the healthcare industry as some states, including California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively “PPACA”) also imposes new reporting and disclosure requirements on device manufacturers for any “transfer of value” made or distributed to prescribers and other healthcare providers, effective August 1, 2013. Such information will be made publicly available in a searchable format beginning September 30, 2014. Device manufacturers will also be required to report and disclose any investment interests held by physicians and their family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties of up to an

Table of Contents

aggregate of \$150,000 per year (and up to an aggregate of \$1 million per year for “knowing failures”), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. 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.

Third-Party Coverage and Reimbursement

We expect that, in the future, sales volumes and prices of our products may grow to be more dependent on the availability of coverage and reimbursement from third-party payors, such as governmental programs including Medicare and Medicaid, private insurance plans and managed care programs. Reimbursement is contingent on established coding for a given procedure, coverage of the codes by the third-party payors and adequate payment for the resources used.

Physician coding for procedures is established by the American Medical Association. For coding related to spine surgery, the North American Spine Society is the primary liaison to the American Medical Association. The Centers for Medicare and Medicaid Services (“CMS”), the agency responsible for administering Medicare and the National Center for Health Statistics, are jointly responsible for overseeing changes and modifications to billing codes used by hospitals for reporting inpatient procedures, and many private payors use coverage decisions and payment amounts determined by CMS for Medicare as guidelines in setting their coverage and reimbursement policies. All physician and hospital coding is subject to change which could impact coverage and reimbursement and physician practice behavior.

Independent of the coding status, third-party payors may deny coverage based on their own criteria, such as if they believe that the clinical efficacy of a device or procedure is not well established and is deemed experimental or investigational, is not the most cost-effective treatment available, or is used for an unapproved indication. We will continue to provide the appropriate resources to patients, physicians, hospitals and insurers in order to promote the best inpatient care and clarity regarding reimbursement and work to reverse any non-coverage policies. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, 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. As the portion of the U.S. population over the age of 65 and eligible for Medicaid continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. National and regional coverage policy decisions are subject to unforeseeable change and have the potential to impact physician behavior.

In international markets, reimbursement and healthcare payment systems vary significantly by country and many 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.

Particularly in the United States, third-party payors carefully review, and increasingly challenge, the prices charged for procedures and medical products as well as any technology that they, in their own judgment, consider experimental or investigational. In addition, an increasing percentage of insured individuals are receiving their medical care through managed care programs, which monitor and often require pre-approval or pre-authorization of the services that a member will receive. For example, certain insurers, such as Cigna, Blue Cross Blue Shield of North Carolina and First Coast (the administrator of Medicare in Florida), have changed their coverage policies such that they will no longer cover and reimburse for vertebral fusions in the lumbar spine to treat multilevel DDD or initial primary laminectomy/discectomy

Table of Contents

for nerve root decompression or spinal stenosis without documented spondylolisthesis. Many managed care programs are paying their providers on a capitated basis, which puts the providers at financial risk for the services provided to their patients by paying them a predetermined amount per member per month. The percentage of individuals covered by managed care programs is expected to grow in the United States over the next decade.

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, 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. The unavailability or inadequacy of third-party payor coverage or reimbursement could have a material adverse effect on our business, operating results and financial condition.

Healthcare Fraud and Abuse

Healthcare fraud and abuse laws apply to our business when a customer submits a claim for an item or service that is reimbursed under Medicare, Medicaid or most other federally-funded healthcare programs. The federal Anti-Kickback Law prohibits unlawful inducements for the referral of business reimbursable under federally-funded healthcare programs, such as remuneration provided to physicians to induce them to use certain tissue products or medical devices reimbursable by Medicare or Medicaid. The Anti-Kickback Law is subject to evolving interpretations. For example, the government has enforced the Anti-Kickback Law to reach large settlements with healthcare companies based on sham consultant arrangements with physicians. The majority of states also have anti-kickback laws which establish similar prohibitions that may apply to items or services reimbursed by any third-party payor, including commercial insurers. Further, the PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes.

If a governmental authority were to conclude that we are not in compliance with applicable laws and regulations, we, our officers and employees could be subject to severe criminal and civil penalties including, for example, exclusion from participation as a supplier of product to beneficiaries covered by Medicare or Medicaid.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigations of healthcare providers and suppliers throughout the country for a wide variety of Medicare billing practices, and has obtained multi-million and multi-billion dollar settlements in addition to individual criminal convictions. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and suppliers' compliance with the healthcare reimbursement rules and fraud and abuse laws.

Table of Contents

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, however, 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.

Employees

As of December 31, 2012, we had approximately 810 employees, including sales and marketing, product development, general administrative and accounting, both domestically and internationally. None of our employees is subject to a collective bargaining agreement and we consider our relationship with our employees to be good.

Facilities

Our headquarters are located in Audubon, Pennsylvania, which comprise approximately 245,000 square feet of owned space, of which 112,000 square feet was acquired in December 2012 for \$4.2 million. Our headquarters houses our research, product development, education, administration, warehouse and shipping functions, as well as our in-house manufacturing facility. Research, product development and education activities occupy approximately 50,000 square feet of our headquarters. We believe our facilities are adequate and suitable for our current needs.

Financial Information about Geographic Areas

For financial information about the geographic areas in which we derive revenues, see “Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 17. Segment and Geographic Information” below.

Corporate and Available Information

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

Table of Contents

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

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

Item 1A. Risk Factors

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

Risks Related to Our Business and Our Industry

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

Spine surgeons play a significant role in determining the course of treatment and, ultimately, the type of product that will be used to treat a patient, so we rely on effectively marketing to them. In order for us to sell our Innovative Fusion products, we must convince spine surgeons that they are attractive alternatives to competing products for use in spine fusion procedures. Acceptance of our Innovative Fusion products depends on educating spine surgeons as to the distinctive characteristics, perceived benefits, safety and cost-effectiveness of our Innovative Fusion products as compared to our competitors’ products and on training spine surgeons in the proper application of our Innovative Fusion products. If we are not successful in convincing spine surgeons of the merit of our Innovative Fusion 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 spine surgeons will not widely adopt our Disruptive Technology products unless they determine, based on experience, clinical data and published peer-reviewed journal articles, that MIS techniques and our motion preservation and advanced biomaterials technologies provide benefits or are an attractive alternative to conventional treatments of spine disorders and incorporate improved technologies that permit novel surgical procedures. Surgeons may be hesitant to change their medical treatment practices for the following reasons, among others:

Table of Contents

lack of experience with MIS or our motion preservation or advanced biomaterials 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.

We have also recently implemented plans to begin selling our existing and planned interventional pain management products, including our existing AFFIRM® kyphoplasty product. We have limited experience selling these types of products and selling to certain physician specialists who use them. If we are unable to market these products to physicians successfully, we will not achieve expected sales, and our financial condition and results of operation may be adversely affected.

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

Pricing pressure from our competitors and changes in third-party coverage and reimbursement may impact our ability to sell our products at prices necessary to support our current business strategies.

The spine market has attracted numerous new companies and technologies, and encouraged more established companies to intensify competitive pricing pressure. As a result of this increased competition, we believe there will be increased pricing pressure in the future. Because the hospital and other healthcare provider customers that purchase our products typically bill various third-party payors to cover all or a portion of the costs and fees associated with the procedures in which our products are used, including the cost of the purchase of our products, changes in the amount such payors are willing to reimburse our customers for procedures using our products could create pricing pressure for us. 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 invest in and grow our business.

Additionally, even if our customers are currently able to obtain coverage and reimbursement for procedures using our products, adverse changes in payors' coverage and reimbursement policies that affect our products could harm our ability to market and sell our products. For example, some payors, (e.g., Cigna, Blue Cross Blue Shield of North Carolina and First Coast (the administrator of Medicare in Florida)) 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 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, patients covered by these insurers, or other insurers who make similar coverage decisions in the future, may be unwilling or unable to afford to have lumbar fusion surgeries to treat these conditions, which could materially harm or limit our ability to sell our products designed for lumbar fusion procedures. Our business would be negatively impacted if the trend by third-party payors continues to reduce coverage of and/or reimbursement for procedures using our products.

Moreover, we are unable to predict what changes will be made to the reimbursement methodologies used by third-party payors in the future. We cannot be certain that under current and future payment systems, in which healthcare providers may be reimbursed a set amount based on the type of procedure performed on a prospective basis, such as those utilized by Medicare and in many privately managed care systems, the cost of our products will be justified and incorporated into the overall cost of the procedure.

Table of Contents

As we expand into international markets, we will face similar risks relating to adverse changes in coverage and reimbursement procedures and policies in those markets. Reimbursement and healthcare payment systems vary significantly among international markets. Our inability to obtain international coverage and reimbursement approval, or any adverse changes in coverage and the reimbursement policies of foreign third-party payors, could negatively affect our ability to sell our products.

If our hospital and other healthcare provider customers are unable to obtain adequate coverage and reimbursement for their purchases of our products, it is unlikely that our products will gain widespread acceptance.

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 medical devices, such as the ones that we manufacture for treatment of their patients, generally rely on third-party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices, including the cost to purchase the product. Our customers' access to adequate coverage and reimbursement for the procedures performed with our products by government and private insurance plans is central to the acceptance of our current and future products. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. Private payors may adopt coverage decisions and payment amounts determined by the CMS which administers the Medicare program, as guidelines in setting their coverage and reimbursement policies. Future action by CMS or other government agencies may diminish payments to physicians, outpatient surgery centers and/or hospitals. Private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for procedures performed with our products. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, 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. 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. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures performed with our products will be reimbursed at a cost-effective level.

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country, and include both government-sponsored healthcare and private insurance. We 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.

Because we were formed in 2003, we have limited experience marketing and selling our products. Our operating results are directly dependent upon the sales and marketing efforts of not only our employees, but also our independent distributors. We expect our direct sales representatives and independent distributors to develop long-lasting relationships with the surgeons they serve. If our direct sales representatives or independent distributors fail to adequately promote, market and sell our products, our sales could significantly decrease.

Table of Contents

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

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

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

We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow. Our currently marketed products are, and any future products we commercialize will be, subject to intense competition. Many of our current and potential competitors are major medical device companies that have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. In addition, many of these competitors have significantly longer operating history and more established reputations than we do. The spine industry is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. 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. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing competing products. We believe that our significant competitors are Medtronic, the DePuy Synthes Companies (a division of Johnson & Johnson), Stryker and NuVasive, which together represent a significant portion of the spine market. We also compete with smaller spine market participants such as Alphatec Spine, Orthofix International and Zimmer. At any time, these or other industry participants may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products. They may also develop and patent processes or products earlier than we can or obtain

Table of Contents

regulatory clearance or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. If alternative treatments are, or are perceived to be, superior to our spine surgery products, sales of our products could be negatively affected and our results of operations could suffer.

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

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

The spine industry is becoming increasingly crowded with new participants. Many of these new competitors specialize in a specific product or focus on a particular market segment, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are or claim to be superior to our products or that are alternatives to our existing or planned products may also create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the spine market generally.

As a result, without the timely introduction of new products and enhancements, our products may become obsolete over time. If we are unable to develop innovative new products, maintain competitive pricing and offer products that spine surgeons perceive to be as reliable as those of our competitors, our sales or margins could decrease, thereby harming our business.

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

We rely on third-party suppliers to supply substantially all of our products. For us to be successful, our suppliers must be able to provide us with products and components in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Our anticipated growth could strain the ability of our suppliers to deliver an increasingly large supply of products, materials and components. Suppliers often experience difficulties in scaling up production, including problems with production yields and quality control and assurance, especially with products such as allograft, which is processed human tissue. Our supplier agreements set forth terms, such as quality and delivery requirements, by which we would purchase products from the supplier if the supplier were to accept a purchase order from us. Under our supplier agreements, however, we generally have no obligation to buy any given quantity of products, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of products. As a result, we may face difficulties in obtaining acceptance for our purchase orders, which could impair our ability to purchase adequate quantities of our products. If we

Table of Contents

are unable to obtain sufficient quantities of high quality components to meet demand on a timely basis, we could lose customers, our reputation may be harmed and our business could suffer.

We generally use a small number of suppliers for each of our products. Our dependence on such a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our suppliers cease to provide us with sufficient quantities of manufactured products in a timely manner or on terms acceptable to us, or cease to manufacture components of acceptable quality, we would have to seek alternative sources of supply. Because of the nature of our internal quality control requirements, regulatory requirements and the custom and proprietary nature of the parts, we cannot quickly engage additional or replacement suppliers for many of our critical components. Failure of any of our third-party suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments to our customers and could have a material adverse effect on our business. We may also have difficulty obtaining similar components from other suppliers that are acceptable to the FDA, the competent authorities or notified bodies of the Member States of the EEA, which is composed of the 27 Member States of the EU, plus Norway, Iceland, and Liechtenstein, or other foreign regulatory authorities, and the failure of our suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters, product recalls, termination of distribution, product seizures or civil penalties. We could incur delays while we locate and engage qualified alternative suppliers, and we may be unable to engage alternative suppliers on favorable terms or at all. Any such disruption or increased expenses could harm our commercialization efforts and adversely affect our ability to generate sales.

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

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

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

Table of Contents

The proliferation of physician-owned distributorships 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.

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

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

We have a limited operating history and may face difficulties encountered by early stage companies in new and rapidly evolving markets.

We were formed in 2003. Accordingly, we have a limited operating history upon which to base an evaluation of our business and prospects. As an early stage company participating in new and rapidly evolving markets, and, particularly, as a company engaged in the development and sales of medical devices, we face risks that include our ability to:

- manage rapidly changing and expanding operations;
- establish and increase awareness of our brand and strengthen customer loyalty;
- grow our direct sales force and increase the number of our independent distributors to expand sales of our products in the United States and in targeted international markets;
- implement and successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments;
- continue to develop and enhance our products and product candidates;
- obtain regulatory clearance or approval to commercialize new products and enhance our existing products;
- expand our presence and commence operations in international markets;
- perform clinical research and trials on our existing products and current and future product candidates; and
- attract, retain and motivate qualified personnel.

We can also be negatively affected by general economic conditions. Because of our limited operating history, we may not have insight into trends that could emerge and negatively affect our business. As a result of these or other risks, our business strategy might not be successful.

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

We are dependent upon the continued services of key members of our senior management and a limited number of key advisors and personnel. In particular, we are highly dependent on the skills and leadership of our Chief Executive Officer (“CEO”), David C. Paul. The loss of any one of these individuals

Table of Contents

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

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

In order to increase our market share in the spine market, we must enhance and broaden our product offerings in response to changing customer demands and competitive pressures and technologies. We might not be able to successfully develop, obtain regulatory approval or clearance for or market new products, and our future products might not be accepted by the surgeons or the third-party payors who reimburse for many of the procedures performed with our products. 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.

Table of Contents

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

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

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

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

In addition, many of the countries in which we sell our products are, to some degree, subject to political, economic or social instability. 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;
- 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;

Table of Contents

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 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 have no current commitments with respect to any acquisition or investment. We do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses and to obtain any necessary financing. These efforts could be expensive and time-consuming, and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to integrate any acquired businesses, products or technologies effectively, our business, results of operations and financial condition will be materially adversely affected.

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

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

Table of Contents

have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory.

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

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

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

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

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

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

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

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

Our sales volumes and our operating results may fluctuate over the course of the year.

Our business is generally not seasonal in nature. However, our sales may be influenced by summer vacation and winter holiday periods, during which we have experienced fewer spine surgeries taking place. We have experienced and continue to experience meaningful variability in our sales and gross profit among quarters, as well as within each quarter, as a result of a number of factors, including, among other things:

Table of Contents

the number of products sold in the quarter;
the demand for, and pricing of, our products and the products of our competitors;
the timing of or failure to obtain regulatory clearances or approvals for products;
costs, benefits and timing of new product introductions;
increased competition;
the availability and cost of components and materials;
the number of selling days in the quarter;
fluctuation and foreign currency exchange rates; and
impairment and other special charges.

We may not be able to strengthen our brand.

We believe that establishing and strengthening our brand is critical to achieving widespread acceptance of our products, particularly because of the rapidly developing nature of the market for our products. Promoting and positioning our brand will depend largely on the success of our marketing efforts and our ability to provide surgeons with a reliable product for successful treatment of spine diseases and disorders. Historically, our efforts to build our brand have involved significant expense, and it is likely that our future marketing efforts will require us to incur significant additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand, our products may not be accepted by spine surgeons, which would cause our sales to decrease and would adversely affect our business, results of operations and financial condition.

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

Risks Related to our Legal and Regulatory Environment

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

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

design, development and manufacturing;
testing, labeling, content and language of instructions for use and storage;
clinical trials;
product safety;

Table of Contents

marketing, sales and distribution;
pre-market clearance and approval;
record keeping procedures;
advertising and promotion;
recalls and field safety corrective actions;
post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
post-market approval studies; and
product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

Before we can market or sell a new regulated product or a significant modification to an existing product in the United States, we must obtain either clearance under Section 510(k) of the FDCA or approval of a PMA application from the FDA, unless an exemption from pre-market review applies. In the 510(k) clearance process, the FDA must determine that a proposed device is “substantially equivalent” to a device legally on the market, known as a “predicate” device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) process may require a new 510(k) clearance. Both the 510(k) and PMA processes can be expensive and lengthy and require the payment of significant fees, unless exempt. The FDA’s 510(k) clearance process usually takes from three to 12 months, but may last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA until an approval is obtained. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all.

In the United States, our currently commercialized products have either received pre-market clearance under Section 510(k) of the FDCA or are exempt from pre-market review. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, lengthy and uncertain PMA process. Although we do not currently market any devices under PMA, the FDA may demand that we obtain a PMA prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product we currently market is subject to an exemption from pre-market review, the FDA may require us to submit a 510(k) or PMA in order to continue marketing the product. Further, even with respect to those future products where a PMA is not required, we cannot assure you that we will be able to obtain the 510(k) clearances with respect to those products.

Table of Contents

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

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

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, the FDA recently initiated changes to the pre-market clearance process in response to internal and external concerns regarding the 510(k) program. On October 1, 2012, the FDA implemented changes through the Medical Device User Fee Amendments of 2012, which are intended to make the process more rigorous and transparent, and to reduce the time to market, but which impose more restrictive review and acceptance criteria. These and possible future changes impose additional regulatory requirements upon us which could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances.

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

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

In the EEA, our medical devices must comply with the essential requirements of the EU Medical Device Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE conformity mark to our medical devices, without which they cannot be marketed or sold in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low risk medical devices (Class I), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the Medical Device Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments (the "Notified Body"). The Notified Body would typically audit and examine the quality system for the manufacture, design and final inspection of our devices before issuing a certification demonstrating compliance with the essential requirements.

Additionally, as part of the conformity assessment process, medical device manufacturers must carry out a clinical evaluation of their medical devices to verify that they comply with the relevant essential requirements of the Medical Device Directive covering safety and performance. This verification will generally comprise an assessment of whether a medical device's performance is in accordance with its intended use, that the known and foreseeable risks linked to the use of the device under normal conditions

Table of Contents

are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims are supported by suitable evidence. This assessment must be based on clinical data, which can be obtained from (i) clinical studies conducted on the devices being assessed; (ii) scientific literature from similar devices whose equivalence with the assessed device can be demonstrated; or (iii) both clinical studies and scientific literature. With respect to implantable devices or devices classified as Class III in the EU, the manufacturer must conduct clinical studies to obtain the required clinical data, unless relying on existing clinical data from similar devices can be justified. As part of the conformity assessment process, depending on the type of devices, the Notified Body will review the manufacturer's clinical evaluation process, assess the clinical evaluation data of a representative sample of the devices' subcategory or generic group (for Class IIa and IIb devices), or assess all the clinical evaluation data, verify the manufacturer's assessment of that data, and assess the validity of the clinical evaluation report and the conclusions drawn by the manufacturer (for implantable and Class III devices). The conduct of clinical studies to obtain clinical data that might be required as part of the described clinical evaluation process can be expensive and time-consuming.

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

- warning letters;
- fines;
- injunctions;
- civil penalties;
- termination of distribution;
- recalls or seizures of products;
- delays in the introduction of products into the market;
- total or partial suspension of production;
- refusal of the FDA or other regulator to grant future clearances or approvals;
- withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and/or
- in the most serious cases, criminal penalties.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition. For example, in February 2012 we executed a settlement agreement with the FDA in which we and our CEO, David C. Paul, agreed to pay a total of \$1.0 million in exchange for the FDA's release of claims related solely to the FDA's determination that we failed to obtain the 510(k) clearance required for the sale of our NUBONE® product, which we ceased selling in the United States in December 2010.

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

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

Table of Contents

required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

Furthermore, the FDA's ongoing review of the 510(k) program may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a new 510(k) for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. In July and December 2011, respectively, the FDA issued draft guidance documents addressing when to submit a new 510(k) due to modifications to 510(k)-cleared products and the criteria for evaluating substantial equivalence. The practical import of these new guidance documents on 510(k)s for new and modified products remains unclear, and we cannot assure you that they will not result in a more rigorous pre-market clearance process. In the EEA, we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned substantial changes to our quality system or changes to our devices which could affect compliance with the essential requirements or the devices' intended use. The Notified Body will then assess the changes and verify whether they affect the products' conformity. If the assessment is favorable, the Notified Body will issue a new certificate or an addendum to the existing certificates attesting compliance with the essential requirements.

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

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

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

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

The FCPA and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employees or agents. Violations of these laws, or allegations of such violations, could disrupt our operations, involve significant

Table of Contents

management distraction and result in a material adverse effect on our business, results of operations and financial condition. We also could suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures, including further changes or enhancements to our procedures, policies and controls, as well as potential personnel changes and disciplinary actions.

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

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

We and our third-party suppliers are required to comply with QSRs, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. In addition, suppliers and processors of allograft must comply with the CGTPs, which govern the methods used in and the facilities and controls used for the manufacture of human cell tissue and cellular and tissue-based products, record-keeping and the establishment of a quality program.

The FDA audits compliance with the QSR and GTPs through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may impose inspections or audits at any time. If we or our suppliers have significant non-compliance issues or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action, including any of the following sanctions:

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

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

Outside the United States, our products and operations are also often required to comply with standards set by industrial standards bodies, such as the ISO. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. We intend to comply with the standards enforced

Table of Contents

by such foreign regulatory bodies as needed to commercialize our products. If we fail to adequately comply with any of these standards, a foreign regulatory body may take adverse actions similar to those within the power of the FDA. Any such action may harm our reputation and business, and could have an adverse effect on our business, results of operations and financial condition.

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

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

Further, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, results of operations and financial condition.

In the EEA, we must comply with the EU Medical Device Vigilance System. Under this system, incidents must be reported to the relevant authorities of the Member States of the EEA, and manufacturers are required to take Field Safety Corrective Actions ("FSCAs") to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An incident is defined as any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or of other persons or to a serious deterioration in their state of health. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

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

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

Our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of off-label use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of

Table of Contents

medicine. However, if the FDA determines that our promotional efforts constitutes promotion of an off-label use, it could request that we modify our training or promotional efforts or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us and harm our reputation.

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

In the United States, the procurement and transplantation of allograft bone tissue is subject to federal law pursuant to the NOTA, a criminal statute which prohibits the purchase and sale of human organs used in human transplantation, including bone and related tissue, for "valuable consideration." NOTA permits reasonable payments associated with the removal, transportation, processing, preservation, quality control, implantation and storage of human bone tissue. We provide services in all of these areas in the United States, with the exception of removal and implantation, and receive payments for all such services. We make payments to certain of our clients and tissue banks for their services related to recovering allograft bone tissue on our behalf. If NOTA is interpreted or enforced in a manner that prevents us from receiving payment for services we render or that prevents us from paying tissue banks or certain of our clients for the services they render for us, our business could be materially adversely affected.

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

Table of Contents

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

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

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

The manufacture of certain of our products, including our allograft implants and products, and the handling of materials used in the product testing process, including in our cadaveric laboratory, involve the controlled use of biological, hazardous and/or radioactive materials and wastes. Our business and facilities and those of our suppliers are subject to foreign, federal, state and local laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling and disposal of, and exposure to, such materials and wastes. In addition, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third-party waste disposal sites even if such contamination was not caused by us. A failure to comply with current or future environmental laws and regulations could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations and financial condition.

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

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

We and our distributor sales representatives must comply with U.S. federal and state fraud and abuse laws, including anti-kickback laws and other U.S. federal and state anti-referral laws.

There are numerous U.S. federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Our relationships with surgeons, hospitals and our independent distributors are subject to scrutiny under these laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration

Table of Contents

health programs. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our business practices to be in compliance with these laws.

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

- the Federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections;
- the FCPA, which prohibits corrupt payments, gifts or transfers of value to foreign officials; and
- foreign and U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Further, under the PPACA, a person or entity can now be found guilty without actual knowledge of the statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare and Medicaid programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

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

Table of Contents

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

In certain cases, federal and state authorities pursue actions for false claims on the basis that manufacturers and distributors are promoting unapproved, or "off-label" uses of their products. 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, we are prohibited from promoting products for "off-label" uses. We market our products and provide promotional materials and training programs to surgeons regarding the use of our products. If it is determined that our marketing, promotional materials or training programs constitute promotion of unapproved uses, we could be subject to significant fines in addition to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure and criminal penalty.

Beginning in 2013, the PPACA also imposes new reporting and disclosure requirements on device manufacturers for payments to healthcare providers and ownership of their stock by healthcare providers. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. On February 1, 2013, CMS released its final rule implementing these provisions, providing further details to statutory language and providing instructions for manufacturers to comply with such requirements. In addition, CMS estimates that approximately 1,000 device and medical supply companies will be required to comply with the disclosure requirements and that the average cost per entity will be approximately \$170,000 in the first year.

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

The scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

Table of Contents

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory clearance or approval of our products and to produce, market and distribute our products after clearance or approval is obtained.

Recent political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. The sales of our products depend in part on the availability of coverage and reimbursement from third-party payors such as government health administration authorities, private health insurers, health maintenance organizations and other healthcare-related organizations. Both the federal and state governments in the United States and foreign governments continue to propose and pass new legislation and regulations designed to contain or reduce the cost of healthcare. Such legislation and regulations may result in decreased reimbursement for medical devices, which may further exacerbate industry-wide pressure to reduce the prices charged for medical devices. This could harm our ability to market our products and generate sales.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of or failure to receive regulatory clearances or approvals for our new products would have a material adverse effect on our business, results of operations and financial condition. In addition, the FDA is currently evaluating the 510(k) process and may make substantial changes to industry requirements, including which devices are eligible for 510(k) clearance, the ability to rescind previously granted 510(k) clearances and additional requirements that may significantly impact the process.

Federal and state governments in the United States have recently enacted legislation to overhaul the nation's healthcare system. While the goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The PPACA substantially changes the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industries. Among other things, the PPACA:

- establishes a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models, beginning on or before January 1, 2013; and
- creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

A number of state governors have strenuously opposed certain of the PPACA's provisions, and initiated lawsuits challenging its constitutionality. In June 2012, the United States Supreme Court upheld most of the provisions of the PPACA. However, it remains unclear whether there will be changes made to certain provisions of the PPACA through acts of Congress in the future, including possible repeal of the PPACA.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. Most recently, on August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to

Table of Contents

several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. The uncertainties regarding the ultimate features of the PPACA and other healthcare reform initiatives and their enactment and implementation may have an adverse effect on our customers' purchasing decisions regarding our products. In the coming years, additional changes could be made to governmental healthcare programs that could significantly impact the success of our products. Cost control initiatives could decrease the price that we receive for our products. At this time, we cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they, or the PPACA, may have on our business and operations, and any such impact may be adverse on our operating results and financial condition.

Our financial performance may be adversely affected by medical device tax provisions in the healthcare reform laws. The PPACA imposes an annual medical device excise tax ("MDET") of 2.3% on any entity that manufactures or imports certain medical devices offered for sale in the United States beginning in 2013. Under these provisions, the Congressional Research Service predicts that the total cost to the medical device industry may be up to \$20 billion over the next decade. We expect to be subject to this MDET in the future on our sales of certain medical devices we manufacture, produce or import. We anticipate that our sales of certain medical devices in the United States will be subject to this 2.3% MDET. The financial impact of this tax on our business is unclear and there can be no assurance that our business will not be materially adversely affected by it.

Compliance with government regulations regarding the use of "conflict minerals" may result in additional expense and affect our operations.

The SEC recently adopted a final rule to implement Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, which imposes new disclosure requirements regarding the use of "conflict minerals" mined from the Democratic Republic of Congo and adjoining countries. These minerals include tantalum, tin, gold and tungsten. The new requirements will require due diligence efforts on our part in fiscal 2013 and thereafter, and we will also be required to comply with the initial disclosure requirements that become effective in May 2014. We may incur significant costs associated with complying with the new disclosure requirements, including but not limited to costs related to determining which of our products may be subject to the new rules and the source of any "conflict minerals" used in those products. Additionally, implementing the new requirements could adversely affect the sourcing, supply and pricing of materials used in the manufacture of our products. We may also face reputational challenges if we are unable to verify through our compliance procedures the origins for all metals used in our products.

Risks Related to our Financial Results and Need for Financing

We will need to generate significant sales to remain profitable.

We intend to increase our operating expenses substantially as we add sales representatives and distributors to increase our geographic sales coverage, submit additional IDE applications to the FDA, increase our marketing capabilities, conduct clinical trials and increase our general and administrative functions to support our growing operations. We will need to generate significant sales to maintain profitability and we might not be able to do so. Even if we do generate significant sales, we might not be able to sustain or increase profitability on a quarterly or annual basis in the future. If our sales grow more slowly than we anticipate or if our operating expenses exceed our expectations, our financial performance will likely be adversely affected.

Table of Contents

Our quarterly operating results may fluctuate significantly.

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

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

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

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

We believe that our current cash and cash equivalents, together with cash to be generated from expected product sales, will be sufficient to meet our projected operating requirements for the next twelve months. However, continued expansion of our business will be expensive and we may seek funds from public and private stock offerings, borrowings under our existing or future credit facilities or other sources. Our capital requirements will depend on many factors, including:

- the revenues generated by sales of our products;
- the costs associated with expanding our sales and marketing efforts;
- the expenses we incur in manufacturing and selling our products;
- the costs of developing and commercializing new products or technologies;
- the cost of obtaining and maintaining regulatory approval or clearance of our products and products in development;

Table of Contents

- the number and timing of acquisitions and other strategic transactions;
- the costs associated with our planned international expansion;
- the costs associated with increased capital expenditures, including fixed asset purchases of instrument sets which we loan to hospitals to support surgeries; and
- unanticipated general and administrative expenses.

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

Prolonged negative economic conditions in domestic and global markets may adversely affect us, our suppliers, counterparties and consumers, which could harm our financial position.

As has been widely reported, global credit and financial markets have been experiencing extreme disruptions over the past several years, including severely diminished liquidity and availability of credit, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Credit and financial markets and confidence in economic conditions might deteriorate further. Our general business strategy may be adversely affected by the recent economic downturn and volatile business environment and continued unpredictable and unstable market conditions. In addition, there is a risk that one or more of our current service providers, suppliers and other partners may not continue to operate, which could directly affect our ability to attain our operating goals on schedule and on budget. Any lender that is obligated to provide funding to us under any now existing or future credit agreement with us may not be able to provide funding in a timely manner, or at all, when we require it. The cost of, or lack of, available credit or equity financing could impact our ability to develop sufficient liquidity to maintain or grow our company, which in turn may adversely affect our business, results of operations or financial condition. We also manage cash and cash equivalents and short-term investments through various institutions. There may be a risk of loss on investments based on the volatility of the underlying instruments that will prevent us from recovering the full principal of our investments. These negative changes in domestic and global economic conditions or additional disruptions of either or both of the financial and credit markets may also affect third-party payors and may have a material adverse effect on our stock price, business, results of operations, financial condition and liquidity.

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

Our existing revolving credit facility contains certain restrictive covenants that limit our ability to transfer or dispose of assets, merge with other companies or consummate certain changes of control, acquire other companies, pay dividends, incur additional indebtedness and liens, experience changes in management and enter into new businesses. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lender or terminate the revolving credit facility. There is no guarantee that we will be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest on any such debt. Furthermore, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance any such debt.

Table of Contents

Risks Related to our Intellectual Property and Potential Litigation

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

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

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

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

We are subject to various litigation claims and legal proceedings, including litigation initiated by NuVasive, Synthes, N-Spine, L5, Sabatino Bianco and Altus Partners LLC.

We, as well as certain of our officers and independent distributors, are subject to a number of legal proceedings, including those initiated by NuVasive, Synthes, N-Spine (subsequently acquired by Synthes),

Table of Contents

L5, Sabatino Bianco, and Altus Partners LLC, which are described in more detail under “Item 3. Legal Proceedings,” below. These lawsuits may result in significant legal fees and expenses and could divert management’s time and other resources. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices or product lines. Any of these outcomes could cause our business, financial performance and cash position to be negatively impacted. There is no guarantee of a successful result in any of these lawsuits, either in defending these claims or in pursuing counterclaims.

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

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

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

Any litigation or claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, and harm our reputation. Further, as the number of participants in the spine industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (including treble, or triple, damages if an infringement is found to be willful) and/or royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement.

Table of Contents

Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations and financial condition.

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

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

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

Because allograft implants used in our advanced biomaterials program may entail a risk of communicable diseases to human recipients, we may be the subject of product liability claims regarding our allograft implants.

The development of allograft implants and technologies for human tissue repair and treatment may entail particular risk of transmitting diseases to human recipients. Any such transmission could result in the assertion of substantial product liability claims against us. In addition, successful product liability claims made against one of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. Claims against us arising out of our advanced biomaterials program, regardless of their merit or potential outcome, may also hurt our reputation and ability to sell our products.

Table of Contents

We may incur product liability losses, and insurance coverage may be inadequate or unavailable to cover these losses. Our business exposes us to potential product liability claims that are inherent in the testing, design, manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. In addition, if longer-term patient results and experience indicates that our products or any component of a product cause tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. Furthermore, if spine surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients. Product liability lawsuits and claims, safety alerts or product recalls, regardless of their ultimate outcome, could have a material adverse effect on our business and reputation, our ability to attract and retain customers and our results of operations or financial condition.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies or cause us to record a self-insured loss. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial retentions or deductibles that we are responsible for. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, results of operations and financial condition.

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

Risks Related to the Ownership of our Class A Common Stock

Because of their significant stock ownership, our chief executive officer, our other executive officers, and our directors and principal stockholders will be able to exert control over us and our significant corporate decisions. Based on an aggregate of 91,270,064 shares of our Class A and Class B common stock outstanding as of December 31, 2012, our executive officers and directors and their affiliates beneficially owned, in the aggregate, approximately 84% of the voting power of our outstanding capital stock. In particular, as of December 31, 2012, David C. Paul, our CEO, controlled approximately 30% of our Class A and Class B common stock, representing approximately 81% of the voting power of our outstanding capital stock as of that date.

As a result, David C. Paul has, and these persons acting together have, the ability to significantly influence or determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. Furthermore, as of December 31, 2012, we had 192,547,170 shares of Class B common stock available for issuance. This amount exceeds 5% of our outstanding common stock, meaning our Board of Directors ("Board") could issue Class B common stock without necessarily triggering the automatic conversion of that Class B common stock to Class A common stock that, pursuant to our charter, will occur when any holder's shares of Class B common stock represents less than 5% of the aggregate number of all outstanding shares of our common stock, thereby further concentrating the voting power of our capital stock in a limited number of stockholders.

Table of Contents

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

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

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

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

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

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

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

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

In addition, we are subject to the provisions of Section 203 of the Delaware General Corporation Law regulating corporate takeovers and which has an anti-takeover effect with respect to transactions not

Table of Contents

approved in advance by our Board, including discouraging takeover attempts that might result in a premium over the market price for shares of our Class A common stock. In general, those provisions prohibit a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder, unless:

- the transaction is approved by the Board before the date the interested stockholder attained that status;
- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced; or
- on or after such date, the business combination is approved by the Board and authorized at a meeting of stockholders, and not by written consent, by at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by any such entity or person.

A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of, and do not currently intend to opt out of, this provision.

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

We do not intend to pay cash dividends.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, we have a revolving credit facility that, if we borrow under it, may preclude us from paying any dividends. Accordingly, you may have to sell some or all of your shares of our Class A common stock in order to generate cash flow from your investment.

Table of Contents

You may not receive a gain on your investment when you sell shares and you may lose the entire amount of the investment.

Our management team may invest or spend our capital in ways with which you may not agree or in ways which may not yield a return.

Our management has considerable discretion in the application of our cash and liquid assets. We do not have any specific uses of our cash or liquid assets planned. Such cash and liquid assets may be used for corporate purposes that do not favorably affect our operating results. In addition, until we use our cash and liquid assets, they may be placed in investments that do not produce income or that lose value.

We do not know if a market for our Class A common stock will develop to provide you with adequate liquidity. We completed an initial public offering (the “IPO”) of our Class A common stock in August 2012, and the shares of our common stock outstanding as of the IPO were only recently released from the restrictions on sale of those shares. We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the New York Stock Exchange or otherwise or how liquid that market might become. If an active trading market does not develop, you may have difficulty selling any shares of our Class A common stock that you purchase, and the value of such shares might be materially impaired. Consequently, you may not be able to sell shares of our Class A common stock at prices equal to or greater than the price you paid for them or at all.

If securities or industry analysts do not publish research or publish unfavorable or inaccurate research about our business, our stock price and trading volume could decline.

The trading market for our Class A common stock will be influenced by the research and reports that industry or securities analysts publish about us, our business or our industry. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause the price or trading volume of our Class A common stock to decline. Moreover, if one or more of the analysts who cover our company downgrade our Class A common stock or release a negative report, or if our operating results do not meet analyst expectations, the price of our Class A common stock could decline.

We are an “emerging growth company” and we cannot be certain if the reduced disclosure requirements and relief from certain other significant obligations that are applicable to emerging growth companies will make our Class A common stock less attractive to investors.

We are an “emerging growth company,” as defined in the Jumpstart our Business Startups Act of 2012 (the “JOBS Act”), and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, less extensive disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved and an extended transition period for complying with new or revised accounting standards. We cannot predict if investors will find our Class A common stock less attractive because we will rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

Table of Contents

The requirements of being a public company will increase our costs and may strain our resources and distract our management.

As a public company, we face, and will continue to face, increased legal, accounting, administrative and other costs and expenses that we did not incur as a private company, particularly, after we are no longer an “emerging growth company.” For example, we are subject to the reporting requirements of the Exchange Act, as amended, which requires that we file annual, quarterly and current reports with respect to our business and financial condition, and the rules and regulations implemented by the SEC, the Sarbanes-Oxley Act of 2002, the Dodd-Frank Act, the Public Company Accounting Oversight Board and the New York Stock Exchange, each of which imposes additional reporting and other obligations on public companies. As a public company, we are required to:

- prepare and distribute periodic public reports and other stockholder communications in compliance with federal securities laws and the New York Stock Exchange Rules;
- expand the roles and duties of our Board and committees thereof;
- institute more comprehensive financial reporting and disclosure compliance functions;
- involve and retain to a greater degree outside counsel and accountants in the activities listed above;
- enhance our investor relations function;
- establish new internal policies, including those relating to trading in our securities and disclosure controls and procedures; and
- comply with the Sarbanes-Oxley Act of 2002, in particular Section 404 and Section 302.

We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. A number of these requirements will require us to carry out activities we have not done previously and complying with such requirements may divert management’s attention from other business concerns, which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

However, for as long as we remain an “emerging growth company” as defined in the JOBS Act, we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, less extensive disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements to hold a nonbinding advisory vote on executive compensation and

Table of Contents

stockholder approval of any golden parachute payments not previously approved and an extended transition period for complying with new or revised accounting standards. We may take advantage of these reporting exemptions until we are no longer an “emerging growth company.” We may remain an “emerging growth company” for up to five years. These increased costs will require us to divert a significant amount of money that we could otherwise use to expand our business and achieve our strategic objectives. We also expect that it will be difficult and expensive to maintain directors’ and officers’ liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board or as executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our Class A common stock, fines, sanctions and other regulatory action and potentially civil litigation.

Pursuant to the recently enacted JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 for so long as we are an “emerging growth company” and we may take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards.

We are required to disclose changes made in our internal control over financial reporting on a quarterly basis and management will be required to assess the effectiveness of our controls annually. Under the recently enacted JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 until we are no longer an “emerging growth company.” We could be an “emerging growth company” for up to five years.

In addition, Section 107 of the JOBS Act also provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to delay such adoption of new or revised accounting standards, and as a result, we may not comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public companies that are not emerging growth companies. As a result of our election, our financial statements may not be comparable to the financial statements of other public companies. We may take advantage of these reporting exemptions until we are no longer an “emerging growth company.”

Our internal control over financial reporting does not currently meet the standards required by Section 404 of the Sarbanes-Oxley Act of 2002, and failure to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and stock price.

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). As a privately held company prior to our IPO in August 2012, and as a newly public company since that date, we have not been required to maintain internal control over financial reporting in a manner that meets the standards of publicly traded companies required by Section 404(a) of the Sarbanes-Oxley Act of 2002 (“Section 404(a)"). We anticipate being required to meet these standards in the course of preparing our consolidated financial statements as of and for the year ended December 31, 2013, and our management will be required to report

Table of Contents

on the effectiveness of our internal control over financial reporting for such year. Additionally, once we are no longer an “emerging growth company,” our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting on an annual basis. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation.

We are currently in the process of reviewing, documenting and testing our internal control over financial reporting, but we are not currently in compliance with, and we cannot be certain when we will be able to implement the requirements of Section 404(a). We may encounter problems or delays in implementing any changes necessary to make a favorable assessment of our internal control over financial reporting. In addition, we may encounter problems or delays in completing the implementation of any requested improvements and receiving a favorable attestation in connection with the attestation provided by our independent registered public accounting firm. If we cannot favorably assess the effectiveness of our internal control over financial reporting, or if our independent registered public accounting firm is unable to provide an unqualified attestation report on our internal controls, investors could lose confidence in our financial information and the price of our Class A common stock could decline.

The price of our Class A common stock might fluctuate significantly, and you could lose all or part of your investment.

The trading price of our Class A common stock may be volatile and subject to wide price fluctuations in response to various factors, including:

- actual or anticipated fluctuations in our quarterly financial and operating results;
- the overall performance of the equity markets;
- introduction of new services or announcements of significant contracts, acquisitions or capital commitments by us or our competitors;
- legislative, political or regulatory developments;
- issuance of new or changed securities analysts’ reports or recommendations;
- additions or departures of key personnel;
- threatened or actual litigation and government investigations;
- investor perceptions of us and the medical device industry, changes in accounting standards, policies, guidance, interpretations or principles;
- sale of shares of our Class A common stock by us or members of our management;
- general economic conditions;
- changes in interest rates; and
- availability of capital.

These and other factors might cause the market price of our Class A common stock to fluctuate substantially, which might limit or prevent investors from readily selling their shares of our Class A common stock and may otherwise negatively affect the liquidity of our Class A common stock. In addition, in recent years, the stock market has experienced significant price and volume fluctuations. This volatility has had a significant impact on the market price of securities issued by many companies across many industries. The changes frequently appear to occur without regard to the operating performance of the affected companies. Accordingly, the price of our Class A common stock could fluctuate based upon factors that have little or nothing to do with our company, and these fluctuations could materially reduce our share price. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company’s securities. This litigation, if instituted against us, could result

Table of Contents

in substantial costs, divert our management's attention and resources, and harm our business, operating results and financial condition.

Future sales, or the perception of future sales, of shares of our Class A common stock could depress the market price of our Class A common stock.

Future sales, or the perception of future sales, of a substantial number of shares of our Class A common stock in the public market could have a material adverse effect on the prevailing market price of our Class A common stock.

Based on the number of shares of our Class A and Class B common stock outstanding as of December 31, 2012, our outstanding capital stock consisted of 63,892,508 shares of our Class A common stock and 27,377,556 shares of our Class B common stock. All shares of our Class A common stock sold in our IPO are freely tradable without restriction under the Securities Act, except for any shares that are held or acquired by our affiliates, as that term is defined in the Securities Act.

As of January 31, 2013, stockholders holding approximately 15,949,761 shares of our common stock have the right, subject to various conditions and limitations, to include their shares in registration statements relating to our securities. In addition, these holders are entitled to piggyback registration rights with respect to the registration under the Securities Act of shares of our common stock. Shares of Class A common stock sold under such registration statements can be freely sold in the public market. In the event such registration rights are exercised and a large number of shares of Class A common stock are sold in the public market, such sales could reduce the trading price of our Class A common stock.

In the future, we may also issue our securities if we need to raise capital. The number of new shares of our Class A common stock issued in connection with raising capital could constitute a material portion of the then-outstanding shares of our Class A common stock.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

As of December 31, 2012, our owned corporate headquarters in Audubon, PA comprised approximately 245,000 square feet, of which 112,000 was acquired in December 2012 for \$4.2 million. Our headquarters houses our research, product development, education, administration, warehouse and shipping functions, as well as our in-house manufacturing facility. Research, product development and education activities occupy approximately 50,000 square feet of our headquarters.

Item 3. Legal Proceedings

We are involved in a number of legal proceedings, suits and claims. These matters are subject to many uncertainties, and the outcomes of these matters are not within our control and may not be known for prolonged periods of time. In some actions, the claimants seek damages, as well as other relief, including injunctions prohibiting us from engaging in certain activities, which, if granted, could require significant expenditures and/or result in lost revenues. The material legal proceedings to which we are currently a party are described below.

Table of Contents

N-Spine and Synthes Litigation

In April 2010, N-Spine, Inc. and Synthes USA Sales, LLC filed suit against us in the U.S. District Court for the District of Delaware for patent infringement. N-Spine, the patent owner, and Synthes USA, a licensee of the subject patent, allege that we infringe one or more claims of the patent by making, using, offering for sale or selling our TRANSITION® stabilization system product. N-Spine and Synthes USA seek injunctive relief and an unspecified amount in damages. We intend to defend our rights vigorously. This matter was stayed on July 14, 2011 pending the resolution of an inter partes reexamination on the asserted patent granted by the U.S. Patent and Trademark Office in February 2011. In December 2011, the examiner withdrew the original grounds of rejection of the asserted patent and we have appealed the examiner's decision. The probable outcome of this litigation cannot be determined, nor can we estimate a range of potential loss. Therefore, in accordance with authoritative guidance on the evaluation of loss contingencies, we have not recorded an accrual related to this litigation.

Synthes USA, LLC, Synthes USA Products, LLC and Synthes USA Sales, LLC Litigation

In July 2011, Synthes USA, LLC, Synthes USA Products, LLC and Synthes USA Sales, LLC filed suit against us in the U.S. District Court for the District of Delaware for patent infringement. Synthes USA LLC, the patent owner, Synthes USA Products, LLC, a licensee to manufacture products of the subject patents, and Synthes USA Sales LLC, a licensee to sell products of the subject patents, allege that we infringe one or more claims of three patents by making, using, offering for sale or selling our COALITION®, INDEPENDENCE® and INTERCONTINENTAL® products. Synthes seeks injunctive relief and an unspecified amount in damages. We intend to defend our rights vigorously. The probable outcome of this litigation cannot be determined, nor can we estimate a range of potential loss. Therefore, in accordance with authoritative guidance on the evaluation of loss contingencies, we have not recorded an accrual related to this litigation.

L5 Litigation

In December 2009, we filed suit in the Court of Common Pleas of Montgomery County, Pennsylvania against our former exclusive independent distributor L5 Surgical, LLC and its principals, seeking an injunction and declaratory judgment concerning certain restrictive covenants made to L5 by its sales representatives. L5 brought counterclaims against us alleging tortious interference, unfair competition and conspiracy. The injunction phase was resolved in September 2010, and the parties' underlying damages claims are pending. We intend to defend our rights vigorously. The probable outcome of this litigation cannot be determined, nor can we estimate a range of potential loss. Therefore, in accordance with authoritative guidance on the evaluation of loss contingencies, we have not recorded an accrual related to this litigation.

NuVasive Infringement Litigation

In October 2010, NuVasive, Inc. filed suit against us in the U.S. District Court for the District of Delaware for patent infringement. NuVasive, the patent owner, alleges that we infringe one or more claims of three patents by making, using, offering for sale or selling our MARSTM3V, TRANSCONTINENTAL®, INTERCONTINENTAL®, and CALIBER®-L products. NuVasive seeks injunctive relief and an unspecified amount in damages. We intend to defend our rights vigorously. This matter is currently near the end of the discovery stage. Additionally, we sought inter partes reexaminations of the three patents asserted by NuVasive in the U.S. Patent and Trademark Office, which were granted in April 2012. In August 2012, the examiner withdrew the original grounds of rejection of the patents asserted by NuVasive, and we are in the process of appealing the examiner's decision. The probable outcome of this litigation cannot be determined, nor can

Table of Contents

we estimate a range of potential loss. Therefore, in accordance with authoritative guidance on the evaluation of loss contingencies, we have not recorded an accrual related to this litigation.

NuVasive Employee Litigation

We have hired several employees who were formerly employed by NuVasive, Inc. In July 2011, NuVasive filed suit against us in the District Court of Travis County Texas alleging that our hiring of one named former employee and other unnamed former employees constitutes tortious interference with their contract with employees, and with prospective business relationships, as well as aiding and abetting the breach of fiduciary duty. NuVasive is seeking compensatory damages, permanent injunction, punitive damages and attorneys' fees. We intend to defend our rights vigorously. The probable outcome of this litigation cannot be determined, nor can we estimate a range of potential loss. Therefore, in accordance with authoritative guidance on the evaluation of loss contingencies, we have not recorded an accrual related to this litigation.

Bianco Litigation

On March 21, 2012, Sabatino Bianco filed suit against us in the Federal District Court for the Eastern District of Texas claiming that we misappropriated his trade secret and confidential information and improperly utilized it in developing our CALIBER® product. Bianco alleges that we engaged in misappropriation of trade secrets, breach of contract, unfair competition, fraud and theft and seeks correction of inventorship, injunctive relief and exemplary damages. On April 20, 2012, Bianco filed a motion for a preliminary injunction, seeking to enjoin us from making, using, selling, importing or offering for sale our CALIBER® product. On November 15, 2012, the court denied Bianco's motion for preliminary injunction. The matter is now in the discovery phase of litigation on the underlying damages claims. We intend to defend our rights vigorously. The probable outcome of this litigation cannot be determined, nor can we estimate a range of potential loss. Therefore, in accordance with authoritative guidance on the evaluation of loss contingencies, we have not recorded an accrual related to this litigation.

Altus Partners, LLC Litigation

On February 20, 2013, Altus Partners, LLC filed suit against us in the U.S. District Court for the Eastern District of Pennsylvania for patent infringement. Altus Partners, LLC alleges that we infringe one or more claims of U.S. Patent No. 8,162,989, which issued on April 24, 2012, by making, using, offering for sale or selling our REVERE® products. Altus Partners seeks injunctive relief and an unspecified amount in damages. We intend to defend our rights vigorously. The probable outcome of this litigation cannot be determined, nor can we estimate a range of potential loss. Therefore, in accordance with authoritative guidance on the evaluation of loss contingencies, we have not recorded an accrual related to this litigation.

In addition, we are subject to legal proceedings arising in the ordinary course of business.

Item 4. Mine Safety Disclosures

Not applicable.

Table of Contents

PART II

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

Class A Common Stock Market Price

Our Class A common stock began trading on The New York Stock Exchange on August 3, 2012 under the symbol "GMED." Prior to that time, there was no public trading market for our Class A common stock. The following table sets forth the high and low sales prices per share for our Class A common stock for the periods indicated, as reported by New York Stock Exchange:

Year Ended December 31, 2012:	High	Low
3rd Quarter (beginning August 3, 2012)	18.17	13.06
4th Quarter	19.93	10.26

We had approximately 368 stockholders of record as of February 28, 2013. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our Class A common stock is held of record through brokerage firms in "street name."

Recent Sales of Unregistered Securities

During the third quarter of 2012 and subsequent to our IPO, we issued to our directors, officers, employees, consultants, and other service providers an aggregate of 578,106 shares of our Class A common stock pursuant to exercises of options granted under our Amended and Restated 2003 Stock Plan and our 2008 Stock Plan at per-share exercise prices ranging from \$0.11 to \$11.86.

The sales of the above securities were exempt from registration under the Securities Act in reliance upon Section 4(2) of the Securities Act, or Rule 701 promulgated under Section 3(b) of the Securities Act as transactions by an issuer not involving any public offering or pursuant to benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions.

Use of Proceeds

On August 2, 2012, our registration statement on Form S-1 (File No. 333-180426) was declared effective for our IPO, pursuant to which we registered the sale of 9,583,333 shares of Class A common stock at \$12.00 per share, of which 2,083,333 shares were sold by us and 6,250,000 shares were sold by selling stockholders, plus 1,250,000 additional shares to cover the underwriters' overallotment option, all of which were sold by selling stockholders. On August 8, 2012, we closed the IPO and the exercise of the underwriters' overallotment. These sales were at the IPO price of \$12.00 per share, for an aggregate gross offering price of \$25.0 million for the shares sold by our company, and \$90.0 million for the shares sold by selling stockholders. We did not receive any proceeds from the sale of securities by selling stockholders.

There has been no material change in the planned use of proceeds from our IPO as described in our final prospectus filed with the SEC on August 3, 2012 pursuant to Rule 424(b).

Table of Contents

Dividend Policy

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

Equity Compensation Plan Information

The following table sets forth certain information relating to the Company's equity compensation plans as of December 31, 2012. Each number of securities reflected in the table is a reference to shares of our Class A common stock.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	6,253,393 (1)	6.99	5,952,479 (2)
Equity compensation plans not approved by security holders	—	—	—
Total	6,253,393		5,952,479

(1) Consists of shares subject to outstanding options under our Amended and Restated 2003 Stock Plan, our 2008 Stock Plan and our 2012 Equity Incentive Plan.

(2) Consists of 679,724 shares available for future issuance under our Amended and Restated 2003 Stock Plan, which plan expires on September 25, 2013, and 5,272,755 shares available for future issuance under our 2012 Equity Incentive Plan. Under the terms of the 2012 Equity Incentive Plan, the aggregate number of shares of Class A common stock that may be subject to options and other awards is equal to the sum of (1) 3,076,923 shares of Class A common stock, (2) any shares available for issuance under the 2008 Stock Plan as of March 13, 2012, (3) any shares underlying any award outstanding under the 2008 Stock Plan as of March 13, 2012 that, on or after that date, is forfeited, terminates, expires, or lapses for any reason, or is settled for cash without the delivery of shares and (4) starting January 1, 2013, an annual increase in the number of shares available under the 2012 Equity Incentive Plan equal to up to 3% of the number of shares of our common and preferred stock outstanding at the end of the previous year, as determined by the Board of Directors.

Comparative Stock Performance Graph

The following graph illustrates a comparison of the total cumulative stockholder return on our Class A common stock since August 3, 2012, which is the date our common stock first began trading on The New York Stock Exchange, to two indices: the S&P 500 Index and the S&P 500 Health Care Equipment Index. The graph assumes an initial investment of \$100 on August 3, 2012, in each of our Class A common stock, the stocks comprising the S&P 500 Index, and the stocks comprising the S&P 500 Health Care Equipment Index, including reinvestment of dividends, if any. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.

Table of Contents

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

Company/Index	August 3, 2012	December 31, 2012
Globus Medical, Inc.	\$ 100	\$ 87
S&P 500 Index	\$ 100	\$ 106
S&P 500 Health Care Equipment	\$ 100	\$ 108

Item 6. Selected Financial Data

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

Table of Contents

Statement of Operations Data: (In thousands, except per share amounts)	Year Ended December 31,				
	2012	2011	2010	2009	2008
Sales	\$385,994	\$331,478	\$288,195	\$254,344	\$176,778
Cost of goods sold	75,199	68,796	53,825	41,607	33,794
Gross profit	310,795	262,682	234,370	212,737	142,984
Operating expenses:					
Research and development	27,926	23,464	21,309	20,521	15,340
Selling, general and administrative	168,862	140,386	122,589	108,422	85,477
Provision for litigation settlements	(786)	) 1,470	2,787	1,889	6,000
Total operating expenses	196,002	165,320	146,685	130,832	106,817
Operating income	114,793	97,362	87,685	81,905	36,167
Other income/(expense), net	(140)	) (413)	) 54	(127)	) 274
Income before income taxes	114,653	96,949	87,739	81,778	36,441
Income tax provision	40,822	36,165	33,281	29,745	15,289
Net income	73,831	60,784	54,458	52,033	21,152
Less: Net income attributable to noncontrolling interest ⁽¹⁾	—	—	—	3,300	2,157
Net income attributable to Globus Medical, Inc.	\$73,831	\$60,784	\$54,458	\$48,733	\$18,995
Net income per common share:					
Basic	\$0.82	\$0.69	\$0.61	\$0.55	\$0.22
Diluted	\$0.80	\$0.67	\$0.60	\$0.54	\$0.21
Weighted average number of common shares:					
Basic	89,608	88,112	88,925	88,197	87,632
Diluted	92,208	90,420	91,352	91,045	90,693
Balance Sheet Data: (In thousands)	As of December 31,				
	2012	2011	2010	2009	2008
Cash and cash equivalents	\$212,400	\$142,668	\$111,701	\$50,950	\$46,652
Working capital	320,602	229,504	187,245	122,127	82,688
Total assets	447,133	329,390	266,575	196,772	152,311
Debt, net of current portion	—	—	—	5,234	6,398
Business acquisition liabilities, including current portion ⁽²⁾	11,344	10,289	—	—	—
Stockholders' equity	\$386,502	\$282,476	\$228,195	\$167,745	\$120,331

Through December 29, 2009, we consolidated a VIE that manufactures certain products for us. This resulted in net income attributable to noncontrolling interest or a reduction of net income attributable to us of \$3.3 million, \$2.2

⁽¹⁾ million in 2009 and 2008, respectively. Effective December 29, 2009, a third-party investor contributed capital to the VIE, which resulted in us being no longer considered the primary beneficiary. As a result, we deconsolidated the entity as of December 29, 2009.

In connection with acquisitions completed in 2012 and 2011, we have certain contingent consideration obligations payable to the sellers in these transactions upon the achievement of certain regulatory and sales milestones. The aggregate undiscounted amounts potentially payable not included in the table above were \$9.9 million and \$7.2 million as of December 31, 2012 and 2011, respectively.

Table of Contents

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

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

Overview

We are a medical device company focused exclusively on the design, development and commercialization of products that promote healing in patients with spine disorders. We are an engineering-driven company with a history of rapidly developing and commercializing products that assist surgeons in effectively treating their patients, respond to evolving surgeon needs and address new treatment options. Since our inception in 2003, we have launched over 110 products and offer a comprehensive product portfolio of innovative and differentiated products addressing a broad array of spinal pathologies, anatomies and surgical approaches.

We sell implants and related disposables to our customers, primarily hospitals, for use by surgeons to treat spine disorders. All of our products fall into one of two categories: Innovative Fusion or Disruptive Technologies. Spinal fusion is a surgical procedure to correct problems with the individual vertebrae, the interlocking bones making up the spine, by preventing movement of the affected bones. Our Innovative Fusion products are used in cervical, thoracolumbar, sacral, and interbody/corpectomy fusion procedures to treat degenerative, deformity, tumor, and trauma conditions.

We define Disruptive Technologies as those that represent a significant shift in the treatment of spine disorders by allowing for novel surgical procedures, improvements to existing surgical procedures, the treatment of spine disorders by new physician specialties, and surgical intervention earlier in the continuum of care. Our current portfolio of approved and pipeline products includes a variety of Disruptive Technology products, which we believe offer material improvements to fusion procedures, such as minimally invasive surgical techniques, as well as new treatment alternatives including motion preservation technologies, such as dynamic stabilization, total disc replacement and interspinous process spacer products, and advanced biomaterials technologies, as well as interventional pain management solutions, including treatments for vertebral compression fractures.

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 by the end of 2013. As of December 31, 2012, we had also hired additional sales representatives to market and sell our current and planned interventional pain management products, including our existing AFFIRM® kyphoplasty product, which we market under the trade name Algea Therapies®. Furthermore, we believe there is a significant opportunity to strengthen our position by increasing the size of this separate sales force and intend to recruit additional sales representatives strategically to grow that business.

Table of Contents

During the year ended December 31, 2012, our international sales accounted for approximately 8% of our total sales. We sell our products through a combination of direct sales representatives employed by us and international distributors. We believe there are significant opportunities for us to increase our presence in both existing and new international markets through the expansion of our direct and distributor sales forces and the commercialization of additional products.

Recent Developments

During the year ended December 31, 2012, we launched 14 new products, achieved a new milestone and completed an acquisition, all in furtherance of our strategic initiatives. In September 2012, we received our first U.S. Food and Drug Administration (“FDA”) pre-market approval (“PMA”), for our SECURE[®] Cervical Artificial Disc. Clinical data from a 380 patient investigational device exemption (“IDE”) study demonstrated that SECURE[®] is statistically superior to anterior cervical discectomy and fusion in terms of overall success, subsequent surgery at the index level, device-related adverse events, and patient satisfaction at 24 months.

In July 2012, we acquired the assets of a small company with operations in the United States and Germany, including a new product designed to treat vertebral compression fractures (“VCFs”). For more information about this acquisition, see “Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 3.

Business Acquisitions.”

Components of our Results of Operations

We manage our business globally within one reportable segment, which is consistent with how our management reviews our business, makes investment and resource allocation decisions and assesses operating performance. Geographic segmentation of operating income and identifiable assets is not applicable because our sales outside the United States are predominantly export sales and substantially all of our long-lived operating assets reside within the United States.

Sales

We sell implants and related disposables, primarily to hospitals, for use by spine surgeons to treat spine disorders. We generally consign our surgical sets, which contain our implants, disposables, surgical instruments and cases to our sales representatives, and the sets are maintained with the sales representatives or at our hospital customers that purchase the implants and related disposables used in the surgeries. We recognize revenue when we are notified that consigned implants and related disposables have been implanted or used or, for sets that are sold directly and not consigned, when title to the goods and risk of loss are transferred to customers with no remaining performance obligations which affect the customer’s final acceptance of the sale. We expect to expand our U.S. and international sales forces, which will provide us with significant opportunity to continue to increase our penetration in existing markets and to enter new international markets. We also expect to increase sales by commercializing new products, but expect the increase of sales from new products to be partially offset by decreased sales of earlier-generation products.

We classify our products into two categories: Innovative Fusion and Disruptive Technologies. Disruptive Technologies are those that represent a significant shift in the treatment of spine disorders, by allowing for novel surgical procedures, improvements to existing surgical procedures, the treatment of spine disorders by new physician specialties, and surgical intervention earlier in the continuum of care. As a result, we anticipate Disruptive Technology products to continue to drive our sales growth in the future.

Table of Contents

Cost of Goods Sold

Our products are generally manufactured by third-party suppliers. Substantially all of our suppliers manufacture our products in the United States. Our cost of goods sold consists primarily of costs of products purchased from our third-party suppliers, excess and obsolete inventory charges, depreciation of surgical instruments and cases, royalties, shipping, inspection and related costs incurred in making our products available for sale or use. In 2013, we expect our cost of goods sold to increase in absolute terms due primarily to increased sales volume and as a result of a medical device excise tax (“MDET”) of up to 2.3% on the sale of certain medical devices in the United States.

Research and Development Expenses

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

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

Selling, General and Administrative Expenses

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

Provision for Litigation Settlements

We record a provision for litigation settlements when a loss is known or considered probable and the amount can be reasonably estimated.

Income Tax Provision

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

Deferred tax assets and liabilities are determined using the enacted tax rates in effect for the years in which those tax assets are expected to be realized. A valuation allowance is established when it is more likely than not that the future realization of all or some of the deferred tax assets will not be achieved.

Net Income Attributable to Noncontrolling Interest

Through December 29, 2009, we consolidated a variable interest entity (“VIE”) that manufactures certain products for us. We and the VIE have common ownership, but we never had an equity interest in

Table of Contents

this entity. As a result, we allocated the full amount of net income attributable to our interest in the VIE to a noncontrolling interest in our consolidated statements of operations. Effective December 29, 2009, a third-party investor contributed capital to the VIE, which resulted in us being no longer considered the primary beneficiary of the VIE. As a result, we deconsolidated the entity as of December 29, 2009. The operating results of the entity through December 29, 2009 are consolidated in our consolidated statement of operations. We recognized no gain or loss upon deconsolidation because we owned no equity interest in the VIE. The VIE continues to manufacture products for us and is considered a related party due to, among other things, common ownership. For more information, see “Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 16. Related-Party Transactions” below.

Critical Accounting Policies and Estimates

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

Revenue Recognition. We recognize revenue when persuasive evidence of an arrangement exists, product delivery has occurred, pricing is fixed or determinable, and collection is reasonably assured. We generate a significant portion of our revenue from consigned inventory maintained at hospitals or with sales representatives. For these products, we recognize revenue at the time we are notified the product has been used or implanted. For all other transactions, we recognize revenue when title to the goods and risk of loss transfer to customers, provided there are no remaining performance obligations that will affect the customer’s final acceptance of the sale. Our policy is to classify shipping and handling costs billed to customers as sales and the related expenses as cost of goods sold. In general, our customers do not have any rights of return or exchange.

Accounts Receivable and Allowance for Doubtful Accounts. The majority of our accounts receivable is composed of amounts due from hospitals. Accounts receivable is carried at cost less an allowance for doubtful accounts. On a regular basis, we evaluate accounts receivable and estimate an allowance for doubtful accounts, as needed, based on various factors such as customers’ current credit conditions, length of time past due, and the general economy as a whole. Receivables are written off against the allowance when they are deemed uncollectible.

Table of Contents

Excess and Obsolete Inventory. We state inventories at the lower of cost or market. We determine cost on a first-in, first-out basis. The majority of our inventory is finished goods, because we primarily utilize third-party suppliers to source our products. We periodically evaluate the carrying value of our inventories in relation to the estimated forecast of product demand, which takes into consideration the estimated life cycle of product releases. When quantities on hand exceed estimated sales forecasts, we record a reserve for excess inventories, which results in a corresponding charge to cost of goods sold. Charges incurred for excess and obsolete inventory were \$6.1 million, \$10.5 million and \$6.1 million for the years ended December 31, 2012, 2011 and 2010, respectively.

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

Goodwill and Intangible Assets. Goodwill represents the excess purchase price over the fair value of the net tangible and identifiable intangible assets acquired by us. We acquired goodwill in connection with the acquisitions completed in 2012 and 2011. Goodwill is tested for impairment at a minimum on an annual basis. Goodwill is tested for impairment at the reporting unit level by comparing the reporting unit's carrying amount, to the fair value of the reporting unit. The fair values are estimated using an income and discounted cash flow approach. We completed our annual goodwill and intangible assets impairment test in the fourth quarter of 2012 and determined that there was no impairment.

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

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

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

Table of Contents

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

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

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

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

As we have only recently become a public entity, historic volatility is not available for our common stock. As a result, we estimate volatility based on a peer group of public companies that we believe collectively provides a reasonable basis for estimating volatility. We intend to continue to consistently use the same group of publicly traded peer companies to determine volatility in the future until sufficient information regarding volatility of the price of our shares of Class A common stock becomes available or the selected companies are no longer suitable for this purpose.

Table of Contents

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

We estimate the weighted-average fair value of the options granted using a Black-Scholes option-pricing model, which requires the input of subjective assumptions, including the expected stock price volatility, the calculation of expected term and fair value of the underlying common stock on the date of grant, among other inputs.

To the extent that further evidence regarding these variables is available and provides estimates that we believe are more indicative of actual trends, we may refine or change our approach to deriving these input estimates. Any such changes could materially affect the stock-based compensation expense we record in the future.

We expect to continue to grant stock options in the future, and to the extent that we do, our actual stock-based compensation expense recognized may increase.

Significant Factors Used in Determining Fair Value of Our Common Stock. Prior to our IPO, our Board, with the assistance of management, used the market approach and the income approach in order to estimate the fair value of common stock underlying our option grants during those periods. Prior to our IPO, there had been no public market for our common stock. Our Board had determined the fair value of our common stock by utilizing, among other things, independent third-party valuation studies conducted following our equity financing in 2007 and biannually as of April 30 and October 31 until October of 2011. The findings of these valuations were based on our business and general economic, market and other conditions that could be reasonably evaluated at that time. The analyses of the valuation studies included a review of our company, including our financial results and capital structure, as well as an independent third-party review of the conditions of the industry in which we operate and the markets that we serve. The methodologies and assumptions used were consistent with those set forth in the American Institute of Certified Public Accountants (the “AICPA”), in the AICPA Technical Practice Guide, Valuations of Privately-Held Company Equity Securities Issued as Compensation.

In the valuation studies, industry standard valuation methodologies were used to value our common stock, as described below. In estimating our equity value, a probability weighting of the market approach and the income approach was used to first arrive at a total equity value.

For the market approach, we utilized the guideline company method by analyzing a population of comparable companies and selected those companies that we considered to be the most comparable to us in terms of product offerings, sales, margins and growth. We then used these guideline companies to develop relevant market multiples and ratios, which are then applied to our corresponding financial metrics to estimate our equity value. Under the market approach, we also utilized the comparable transaction methodology using multiples of earnings and cash flow determined through an analysis of transactions involving controlling interests in companies with operations similar to our principal business operations. For the income approach, we performed discounted cash flow analyses which utilized projected cash flows which were then discounted to the present using a range of 14% to 15% in order to arrive at our current equity value.

Prior to our IPO, our Board, with the assistance of management, used the market approach and income approach to estimate the fair value per share of common stock underlying our option grants during those

Table of Contents

periods. In allocating the total equity value between preferred and common stock, we considered the liquidation preferences of the preferred stockholders. The preferred stock had a liquidation value of \$110.0 million as of March 31, 2012. Additionally, each valuation during this period utilizes the option pricing method for allocating the total equity value between preferred and common stock. The significant input assumptions used in our valuation models were based on subjective future expectations combined with management's judgment, including:

Assumptions utilized in the income approach were:

- our expected revenue, operating performance and cash flows for the current and future years, determined as of the valuation date based on our estimates;

- a discount rate, which is applied to discretely forecasted future cash flows in order to calculate the present value of those cash flows;

- a terminal value multiple, which is applied to our last year of discretely forecasted cash flows to calculate the residual value of our future cash flows; and

- lack of marketability factor of 10% to 20%.

Assumptions utilized in the market approach using guideline companies were:

- our expected sales, operating performance and cash flows for the current and future years, determined as of the valuation date based on our estimates;

- multiples of market value to trailing and expected future revenues and earnings before interest, taxes, depreciation and amortization ("EBITDA"), determined as of the valuation date, based on a group of comparable public companies we identified; and

- a lack of marketability factor of 10% to 20%.

Assumptions utilized in the market approach using comparable transactions:

- selection of guideline transactions involving target companies with similar operations, characteristics, and business risks.

Results of Operations

Year Ended December 31, 2012 Compared to the Year Ended December 31, 2011

Sales

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

(In thousands, except percentages)	Year Ended		Change		
	December 31, 2012	December 31, 2011	\$	%	
Innovative Fusion	\$238,723	\$224,356	\$14,367	6.4	%
Disruptive Technology	147,271	107,122	40,149	37.5	%
Total sales	\$385,994	\$331,478	\$54,516	16.4	%

In 2012, we launched 14 new products, in addition to several other product line extensions, improvements, and enhancements. The increase in total sales was attributable primarily to an increase in sales of our Disruptive Technology products, led by recent product launches. Innovative Fusion sales increased due to strong sales of pedicle screw and interbody systems. Each of these systems increased in international markets.

Table of Contents

(In thousands, except percentages)	Year Ended		Change		
	December 31, 2012	December 31, 2011	\$	%	
United States	\$355,609	\$311,024	\$44,585	14.3	%
International	30,385	20,454	9,931	48.6	%
Total sales	\$385,994	\$331,478	\$54,516	16.4	%

Sales growth in the United States was due primarily to increased sales of our Disruptive Technology products and increased market penetration in new and existing sales territories. We believe there is significant opportunity to strengthen our position in existing markets and in new sales territories by increasing the size of our U.S. sales force. The increase in international sales was attributable to increased market penetration in both new and existing sales territories. We increased our international presence by selling in countries in the year ended December 31, 2012 in which we had no sales in the year ended December 31, 2011. We believe there is significant opportunity for us to expand our international presence through increased market penetration in existing territories, expansion into new territories, expansion of our direct and distributor sales force and the commercialization of additional products.

Cost of Goods Sold

(In thousands, except percentages)	Year Ended		Change		
	December 31, 2012	December 31, 2011	\$	%	
Cost of goods sold	\$75,199	\$68,796	\$6,403	9.3	%
Percentage of sales	19.5	% 20.8	%		

The increase in cost of goods sold was due to the \$7.7 million impact from increased sales volume and a \$3.6 million increase in depreciation of surgical instruments and cases, distribution and other costs, partially offset by a \$4.8 million reduction in inventory write-off expense.

Research and Development Expenses

(In thousands, except percentages)	Year Ended		Change		
	December 31, 2012	December 31, 2011	\$	%	
Research and development	\$27,926	\$23,464	\$4,462	19.0	%
Percentage of sales	7.2	% 7.1	%		

The increase in research and development expenses was due to an increase of \$2.0 million in employee compensation including taxes, benefits and stock compensation primarily due to increased headcount and an increase of \$2.8 million in supplies, outside services and other costs, offset by a decrease of \$0.4 million in clinical trial and other costs.

Selling, General and Administrative Expenses

(In thousands, except percentages)	Year Ended		Change		
	December 31, 2012	December 31, 2011	\$	%	
Selling, general and administrative	\$168,862	\$140,386	\$28,476	20.3	%
Percentage of sales	43.7	% 42.4	%		

The increase in selling, general and administrative expenses was due primarily to an increase of \$13.1 million in compensation costs in the United States. This was to support increased sales volume and

Table of Contents

company growth, including hiring of additional sales representatives, exclusive of our Algea Therapies® sales representatives, and general administrative personnel. Additionally, the costs associated with building our Algea Therapies® sales force increased by \$8.4 million over the prior year; the costs to support international sales growth and expansion into new international territories increased by \$4.5 million; and there was an increase of \$2.5 million of other selling, general and administrative costs.

Provision for Litigation Settlements

(In thousands, except percentages)	Year Ended		Change	
	December 31, 2012	December 31, 2011	\$	%
Provision for litigation settlements	\$(786)	\$1,470	\$(2,256)	(153.5)%
Percentage of sales	(0.2)%	0.4 %		

The decrease in provision for litigation settlements was due primarily to the favorable settlement of a lawsuit during the year ended December 31, 2012 and the \$1.0 million FDA settlement that was accrued during the fourth quarter of 2011 (see “Item 8. Financial Statements and Supplementary Data; Notes to Consolidated Financial Statements; Note 14. Commitments and Contingencies” below for more information).

Other Expense

Other expense of \$0.1 million for the year ended December 31, 2012 was attributable primarily to a loss due to the effect of changes in foreign exchange rates on payables and receivables held in currencies other than their functional (local) currency.

Income Tax Provision

(In thousands, except percentages)	Year Ended		Change	
	December 31, 2012	December 31, 2011	\$	%
Income tax provision	\$40,822	\$36,165	\$4,657	12.9 %
Effective income tax rate	35.6 %	37.3 %		

The increase was primarily due to a \$17.7 million increase in taxable income as a result of increased operating profits. The effective rate for the year ended December 31, 2012 was favorably affected by the impact of the corporate manufacturing deduction and the reversal of valuation allowances associated with certain international jurisdictions, offset by the unfavorable impacts of a research and experimentation credit that was in effect in the prior year that Congress did not extend during 2012. Additionally, the effective tax rate for the year ended December 31, 2011 was favorably affected by the reversal of a \$0.9 million tax provision related to a FIN 48 reserve resulting from the completion of U.S. Internal Revenue Service examinations with respect to the 2005 through 2008 tax years.

On January 2, 2013, the American Taxpayer Relief Act of 2012 (the “ATRA”) was signed into law. One of the provisions of the ATRA was a reinstatement and extension of the research and experimentation tax credit from January 1, 2012 through December 31, 2013. However, as of December 31, 2012 no benefit could be recognized for this tax credit due to the passage of the ATRA in 2013. We estimate that the impact on fiscal 2012 would have been a tax benefit of approximately \$0.7 million, which we will record as a discrete tax benefit in the first quarter of 2013, the period in which the legislation, including the reinstatement, was enacted.

Table of Contents

Year Ended December 31, 2011 Compared to the Year Ended December 31, 2010

Sales

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

(In thousands, except percentages)	Year Ended		Change		
	December 31, 2011	December 31, 2010	\$	%	
Innovative Fusion	\$224,356	\$215,565	\$8,791	4.1	%
Disruptive Technology	107,122	72,630	34,492	47.5	%
Total sales	\$331,478	\$288,195	\$43,283	15.0	%

The increase in total sales was attributable primarily to an increase in sales of our Disruptive Technology products, led by new products launched in 2011. Innovative Fusion sales increased due to strong sales of integrated plate and spacer systems. Both Disruptive Technology and Innovative Fusion products saw sales growth in international markets.

(In thousands, except percentages)	Year Ended		Change		
	December 31, 2011	December 31, 2010	\$	%	
United States	\$311,024	\$277,974	\$33,050	11.9	%
International	20,454	10,221	10,233	100.1	%
Total sales	\$331,478	\$288,195	\$43,283	15.0	%

Sales growth in the United States was due primarily to increased sales of our Disruptive Technology products, increased market penetration in existing territories, and an increase in the size of our U.S. sales force. We believe there is significant opportunity to strengthen our position in new and existing markets and in new sales territories by increasing the size of our U.S. sales force.

The increase in international sales was attributable to increased market penetration in existing territories and the addition of new sales territories, as we increased our international presence by selling in countries in the year ended December 31, 2011 in which we had no sales in the year ended December 31, 2010. We believe there is significant opportunity for us to expand our international presence through increased market penetration in existing territories, expansion into new territories, expansion of our direct and distributor sales force and the commercialization of additional products.

Cost of Goods Sold

(In thousands, except percentages)	Year Ended		Change		
	December 31, 2011	December 31, 2010	\$	%	
Cost of goods sold	\$68,796	\$53,825	\$14,971	27.8	%
Percentage of sales	20.8	% 18.7	%		

The increase in cost of goods sold was due primarily to \$6.5 million impact from increased sales volume, while the remaining \$8.5 million increase was primarily attributable to an increase in inventory reserves and write-offs of \$5.7 million as inventory balances grew to support product launches and increased sales volume. Of this amount, \$4.4 million was related to the change in provision for excess and obsolete inventories and \$1.3 million was due to the change in inventory write-offs. Additionally, increases in depreciation of surgical instruments and cases, shipping expenses and other operating costs were partially

Table of Contents

offset by a decrease in biomanufacturing production costs due to the discontinuance of a former product, NUBONE®, in the fourth quarter of 2010.

Research and Development Expenses

(In thousands, except percentages)	Year Ended		Change	
	December 31, 2011	December 31, 2010	\$	%
Research and development	\$23,464	\$21,309		