Alphatec Holdings, Inc.
Form 10-K
March 04, 2011
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

Form 10-K

(Mark One)

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2010

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number: 000-52024

ALPHATEC HOLDINGS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	20-2463898
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
5818 El Camino Real, Carlsbad, California	92008
(Address of Principal Executive Offices)	(Zip Code)

(760) 431-9286

(Registrant s Telephone Number, Including Area Code)

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

Title of Each Class	Name of Each Exchange on Which Registered
Common Stock, par value $0.0001 per share	The NASDAQ Global Select Market

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

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ¨ No ¨

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

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

Large accelerated filer ¨ Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company) Smaller reporting company ¨
Indicate by a check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ¨ No x

The aggregate market value of the registrant s common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) based on the last reported sale price of the common stock on June 30, 2010 was approximately $236.8 million.

The number of outstanding shares of the registrant s common stock, par value $0.0001 per share, as of March 1, 2011 was 89,041,663.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant s Proxy Statement for the 2011 Annual Meeting of Stockholders.

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ALPHATEC HOLDINGS, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2010

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PART I

Item 1. Business

We are a Delaware corporation. We were incorporated in March 2005. Our principal executive office is located at 5818 El Camino Real, Carlsbad, California 92008. In this Annual Report on Form 10-K, the terms we, us, our, Alphatec Holdings and Alphatec mean Alphatec Holdings, Inc. and our subsidiaries. Alphatec Spine refers to our wholly-owned operating subsidiary Alphatec Spine, Inc. and Scient x refers to our wholly-owned operating subsidiary, Scient x S.A.S., and its subsidiaries.

Our Internet address is www.alphatecspine.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on Form 10-K. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the Investor Relations section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission.

Overview

We are a medical technology company focused on the design, development, manufacturing and marketing of products for the surgical treatment of spine disorders, with a focus on products that treat conditions that affect the aging spine. We have a comprehensive product portfolio and pipeline that addresses the cervical, thoracolumbar and intervertebral regions of the spine and covers a variety of major spinal disorders and procedures such as vertebral compression fractures, disorders related to poor bone quality, and spinal stenosis. Our principal product offerings are focused on the global market for orthopedic spinal disorder solutions, which is estimated to be more than $9.0 billion in revenue in 2010 and is expected to grow between 6%-8% over the next year. Our surgeons culture emphasizes collaboration with spinal surgeons to conceptualize, design and co-develop a broad range of products. We have a state-of-the-art, in-house manufacturing facility that provides us with a unique competitive advantage, and enables us to rapidly deliver solutions to meet surgeons and patients critical needs. Our products and systems are made of titanium, titanium alloy, stainless steel, cobalt chrome, ceramic, and a strong, heat resistant, radiolucent, biocompatible plastic called polyetheretherketone, or PEEK. In addition, we sell products made of allograft, which is human tissue that surgeons can use in place of metal and PEEK. We also sell bone-grafting products and products to promote bone fusion that are comprised of both human tissue and synthetic materials. We believe that our products and systems have enhanced features and benefits that make them attractive to surgeons and that our broad portfolio of products and systems provide a comprehensive solution for the safe and successful surgical treatment of spine disorders. All of our implants that are sold in the U.S. that require U.S. Food and Drug Administration, or FDA, clearance have been cleared by the FDA.

Strategy

Our strategy is to be the world s leading independent full-line spine company, with a focus on solutions for the aging spine. The aging spine has unique characteristics and our aging spine solutions are targeted at providing superior efficacy in treating patients who suffer from poor bone density, vertebral compression fractures, adult deformity or scoliosis, degenerative disc disease, and spinal stenosis. To further differentiate our solutions, we have incorporated minimally invasive access techniques and biologics-based solutions into our portfolio to improve patient outcomes. We believe that we have developed a strong product platform for consistent and measured growth and intend to leverage this platform by, among other things, providing unmatched service to, and taking scientific direction from, surgeons. In addition to bringing innovative products to market, we understand that surgeons are a critical component of the product development process. Accordingly, we view our relationship with the surgeon community as an integral component of our strategy.

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The key elements of our strategy are:

Provide a Full Range of Spine Disorder Products and Continually Expand our Product Offerings. We offer a full range of spinal devices and surgical instruments used to treat spine disorders. We believe that this comprehensive approach enables us to maximize our revenue for each procedure by fulfilling a greater portion of a surgeon s spine product needs. We intend to continue to enhance our product offerings by developing technologies that we can market through our sales organization to our established surgeon base and surgeons not yet using our products.

Focus on Underserved and Rapidly Growing Segments of the Market. We are focused on creating solutions to address the rapidly growing elderly demographic and the unique issues facing such patients. We will focus on less invasive implants and techniques, and solutions for adult onset deformities, vertebral compression fractures, stenosis and issues related to patients with poor bone quality, each of which represents a large underserved market segment. We believe that our strategic focus in underserved and rapidly growing areas will offer us increased revenue and deeper market penetration.

Enhance U.S. Sales and Marketing Efforts. Our products are sold in the U.S. through a network of over 110 independent distributors, which we believe employ approximately 270 sales representatives. We also employ 31 direct sales representatives and sales management employees and executives. We continually seek to increase the number and quality of our independent distributors, direct sales representatives and sales management employees and executives. We train, educate and support our independent distributors, often our first point of contact with surgeons, as if they were part of our organization.

Develop Innovative Products and Solutions in Conjunction with Surgeons. One of our core competencies is our ability to develop and commercialize creative spinal implants and instruments that incorporate concepts and feedback from surgeons. We collaborate with surgeons to help us to enhance our current products and develop innovative new technologies. We believe that our short-term and long-term product pipeline will offer us increased revenue opportunities by addressing a wider range of spine disorders, and improving patient outcomes.

Grow our International Business. As the result of our acquisition of Scient x, which transaction closed in March 2010, we now have an established global platform from which we can grow internationally. In addition to our previously existing subsidiaries in Japan and Hong Kong, as a result of the Scient x acquisition we added a direct sales force in each of France, Italy and the U.K., and independent distributors in Europe, South America, the Middle East, China and Latin America. We plan to continue expanding our distribution network and product offerings throughout the world. In addition, we also plan to continue to obtain regulatory clearances and distribution networks in other areas of the world where we can benefit from selling our unique products and technologies.

Spine Anatomy

The human spine is the core of the human skeleton and provides important structural support while remaining flexible to allow movement. The human spine is a column of 33 bones that protects the spinal cord and enables people to stand upright. Each bony segment of the spine is referred to as a vertebra (two or more are called vertebrae). The spine has five regions containing groups of similar bones, listed from top to bottom: seven cervical vertebrae in the neck, 12 thoracic vertebrae in the mid-back (each attached to a rib), five lumbar vertebrae in the lower back, five sacral vertebrae fused together to form one bone in the hip region, and four coccygeal bones fused together that form the tailbone. At the front of each vertebra is a block of bone called the vertebral body. The vertebral body consists of an inner core of soft cancellous bone, surrounded by a thin outer layer of hard cortical bone. Vertebrae are stacked on top of each other and enable people to sit and stand upright. Vertebrae in the cervical, thoracic and lumbar regions are separated from each other and cushioned by a rubbery soft tissue called the intervertebral disc. Segments of bone that extend outward at the back of each cervical, thoracic and lumbar vertebral body surround and protect the spinal cord and its nerve roots. These bones, known as the posterior spinous processes, can be felt along the middle of a person s back.

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Disorders Affecting the Spine

There are four major categories of spine disorders: degenerative conditions, deformities, trauma-based disorders and tumors. While our product offering addresses all four categories of spine disorders, the majority of our business is concentrated on products used in the treatment of degenerative and deformity conditions. These conditions can result in instability and pressure on the nerve roots as they exit the spinal column, causing back pain and potentially pain in the arms or legs.

Some of the most common medical conditions affecting the spine are as follows:

Degenerative disc disease is a common medical condition affecting the cervical, thoracic and lumbar regions of the spine and refers to the degeneration of the disc from aging and repetitive stresses, resulting in a loss of flexibility, elasticity and shock-absorbing properties. As degenerative disc disease progresses, the space between the vertebrae narrows, or the disc can bulge or rupture, which can pinch the nerves exiting the spine and result in back pain, leg pain, numbness and loss of motor function. This back pain can be overwhelming for patients as the resulting pain can have significant physical, psychological and financial implications.

A *Vertebral compression fracture,* or VCF, occurs when a vertebra in the spinal column fractures or collapses. Vertebral compression fractures have multiple acute and chronic consequences, including back pain, loss of back function and diminished quality of life. Chronic consequences of a VCF can also result in pulmonary and gastric dysfunction, as well as depression. Deformity resulting from a VCF worsens these problems and can increase the risk of another fracture, which can further exacerbate complications from the initial VCF, including an increase in the loss of mobility and ultimately increased mortality.

Spinal stenosis is a narrowing of the spinal canal, which places pressure on the spinal cord. If the stenosis is located on the lower part of the spinal cord it is called lumbar spinal stenosis. Stenosis in the upper part of the spinal cord is called cervical spinal stenosis. While spinal stenosis can be found in any part of the spine, the lumbar and cervical areas are the most commonly affected. Some patients are born with this narrowing, but most often spinal stenosis is seen in patients over the age of 50. In these patients, stenosis is the gradual result of aging and wear and tear on the spine during everyday activities.

Spondylolisthesis occurs when one vertebra slips forward in relation to an adjacent vertebra, usually in the lumbar spine. The symptoms that accompany spondylolisthesis include pain in the lower back and legs, and muscle spasms and weakness. Spondylolisthesis can be congenital or develop later in life. The disorder may result from physical stresses to the spine, intense physical activity, and general wear and tear.

The Alphatec Solution

Our principal product offering includes a wide variety of spinal implant products and systems comprised of components such as spine screws and rods, spinal spacers, plates, and various biologics offerings. In addition, outside of the U.S. we sell solutions for treating vertebral compression fractures and spinal stenosis. Certain of our biologics offerings are used as an alternative to PEEK or metal products while others complement our PEEK and metal products by promoting fusion.

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The chart below illustrates our broad portfolio of currently marketed spine systems and our systems under development by market segment. Certain systems and products are described in greater detail below the chart. Items marked with an asterisk are not available for sale in the U.S.

Current Products:

Market Segment	Key Products
Cervical and Cervico-thoracic	Trestle Anterior Cervical Plate Solanas Posterior Cervico/Thoracic Fixation System DiscoCerv Artificial Disc* PCB Evolution*
Thoracolumbar	Zodiac Degenerative Fixation System Zodiac Smart Set Deformity Fixation System TTL IN/Xenon Fixation System Isobar Evolution Dynamic Rod* ASPIDA ALIF Plate
Spinal Spacers	Novel Spinal Spacers Solus Locking ALIF Spacer* Samarys*/Samarys RF* TeCorp*
Minimally Invasive Surgery (MIS)	Illico MIS System GLIF/Arc Portal Access System OsseoScrew MIS System* Epicage TLIF System
Aging Spine	OsseoFix Spinal Fracture Reduction System* OsseoFix+ Vertebroplasty System OsseoScrew Spinal Fixation System* HeliFix Interspinous Spacer System*
Biologics	AlphaGraft Structural Allograft Spacers AlphaGraft Demineralized Bone Matrix PureGen Osteoprogenitor Cell Allograft AlphaGraft ProFuse Demineralized Bone Scaffolds

	AmnioShield Amniotic Membrane
	AlphaGUARD Anterior Vessel Guard

Products in Development (None of the following products are currently available for sale):

Market Segment	**Key Products**
Cervical and Cervico-thoracic	Avalon Occipital Plate
	Preview Anterior Cervical Plate
Thoracolumbar	Next-Generation Degenerative and Deformity Screw Systems
MIS	Raptor Facet Fixation System
Aging Spine	OsseoFix Next-Generation Implant

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Cervical and Cervico-Thoracic Products

Trestle Anterior Cervical Plate System

Our Trestle Anterior Cervical Plate System has a large window that enables the surgeon to have improved graft site and end plate visualization; which is designed to allow for better placement of the plate. The Trestle Anterior Cervical Plate System also has a low-profile design, which we believe is among the lowest in the spine market. Low-profile cervical plates are intended to reduce the disruption of the tissue adjacent to the plate following surgery. Other key features of the Trestle Anterior Cervical Plate system include a self-retaining screw-locking mechanism that is designed to ensure quick and easy locking of the plate and a flush profile after the screws are inserted.

Posterior Cervico/Thoracic Fixation Products

Solanas Posterior Cervico/Thoracic Fixation System

Our Solanas Posterior Cervico/Thoracic Fixation System consists of rods, polyaxial screws and connectors that provide a solution for posterior cervico/thoracic fusion procedures. Our Solanas Cervico/Thoracic System includes many of the benefits of our Zodiac Degenerative Fixation System, including a polyaxial pedicle screw that contains a unique set screw. We also designed the Solanas Cervico/Thoracic System to be used in combination with our existing Zodiac Degenrative Fixation System, thereby providing additional options for surgeons.

Thoracolumbar Fixation Products

Zodiac Degenerative Fixation System

Our Zodiac Degenerative Fixation System is a comprehensive spinal system that offers a wide variety of polyaxial pedicle screws, and advanced instruments. We believe our Zodiac Degenerative Fixation System offers surgeons one of the lowest profiles, or the height that the screw sits above the plane of the rod after insertion, among polyaxial screws currently on the market. This low profile reduces the amount of internal disruption of tissue adjacent to the pedicle and is intended to speed the healing cycle. Our Zodiac Degenerative Fixation System has a unique set-screw closure mechanism that helps to ensure that the assembly is easily constructed during surgery. It also has pre-cut and pre-contoured rods that are available in several sizes, which allow surgeons to customize each construct depending on the patient s needs. Our Zodiac Degenerative Fixation System is designed to be used in connection with our Novel Spacers and our AlphaGraft Allograft spacers.

Zodiac Smart Set Deformity Fixation System

Our Zodiac Smart Set Deformity Fixation System is designed to be used in conjunction with many of our other products, including our Zodiac Degenerative Fixation System, our Novel Spacers and our AlphaGraft Allograft Spacers. Our Zodiac Smart Set Deformity Fixation System has components such as polyaxial screws, and is complemented by fixed and uniplanar screws, rods in multiple alloys, connectors and instrumentation that are designed to enable the surgeon to address patient-specific spinal deformities.

ASPIDA Anterior Lumbar Interbody Fusion, or ALIF, Plate System

Our ASPIDA ALIF Plate System is designed to be used in conjunction with a spacer, and is intended to offer comparable stabilization to pedicle screw and rod systems. Our ALIF Plate System is designed to provide surgeons with the option of performing a single anterior procedure without having the need for a complementary posterior procedure. The ALIF Plate System is designed to be anatomically shaped and have a low profile, which should minimize the risk of irritation or damage to the adjacent tissue.

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Spinal Spacers

Novel PEEK and Titanium Spacers

Our family of Novel PEEK and titanium spacers addresses the surgical need to accommodate varying patient anatomies, surgical approaches and composite material options. We offer multiple unique implant designs, each of which is available in numerous shapes and heights. Our Novel PEEK spinal spacers have been approved for use in both the lumbar and cervical regions of the spine. Novel spacers and their accompanying instrumentation are designed to be inserted from several planes of the body to accommodate surgeons needs. Novel spacers feature sizable central openings that help accommodate the placement of bone grafting material inside and around the spacer, which we believe promotes fusion. A ridge pattern on the top and bottom of our Novel spacers helps prevent movement after placement and enhances the stability of the overall construct. Our Novel PEEK spacers are not visible during a magnetic resonance imaging, which allows the surgeon to better assess the progress of the healing process following surgery.

Solus Locking ALIF Spacer

Our Solus locking spinal spacer is a zero-profile device offering four points of fixation for improved stability. Solus features a one-step insertion and deployment feature and is used in ALIF procedures. This product has been submitted to the FDA for 510(k) clearance. Solus is available for sale in the European Union.

Minimally Invasive Surgery, or MIS Products

Illico Minimally Invasive System

The Illico Minimally Invasive System is a cannulated pedicle screw and rod system that is designed to be inserted via a minimally invasive surgical procedure. Access to the spine is gained through a small incision. The surgeon is then able to see the surgical site by using a small canal through which implants are inserted into the patient with a minimum amount of disruption to the surrounding tissue. We believe that the Illico System will significantly reduce the length of posterior surgeries that use pedicle screws. We also believe that the Illico System limits trauma to the tissue surrounding the location of the surgery, which is designed to enable patients to recover faster.

Guided Lumbar Interbody Fusion, or GLIF, Technique and ARC Portal Access System

Our GLIF technique, used in conjunction with our ARC Portal Access System, is a unique access system that is designed to allow surgeons to perform a minimally invasive procedure from multiple surgical planes without the need for a second incision or repositioning of the patient. The GLIF technique is intended to reduce the length of the procedure, reduce trauma to the patient and reduce the post-surgery recovery period.

Aging Spine

OsseoFix Spinal Fracture Reduction System

Our OsseoFix system provides a solution for VCF indications. The OsseoFix implant is an expandable titanium cage that is designed to be implanted in a minimally invasive manner into a vertebral body to treat a VCF. The OsseoFix system is designed to provide the surgeon with control over the placement and expansion of the device as the fracture is treated. In addition, the OsseoFix system is designed to use less bone cement than current standards of care and may overcome one of the primary complications of kyphoplasty and vertebroplasty, which is the potential risk of extravasation of PMMA bone cement into the spinal canal or venous system, which we believe carries a benefit to the patient. The OsseoFix System is undergoing a clinical trial in the U.S. in connection with its 510(k) application. OsseoFix is available for sale in the European Union.

OsseoFix+ Vertebroplasty System

Our OsseoFix+ product consists of our bone cement and a mixing and delivery system that can be used in a stand-alone vertebroplasty procedure.

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OsseoScrew Spinal Fixation System

The OsseoScrew Spinal Fixation is an innovative pedicle screw system that is designed to provide a solution for patients who have poor bone density. The OsseoScrew is designed to be implanted into the pedicle and then expanded after implementation to achieve increased screw fixation in bone with poor density. We believe that the OsseoScrew Spinal Fixation System will help us reach our goal of providing solutions targeted at serving the needs of the spine surgeon and the aging spinal segment of the marketplace. This product has been submitted to the FDA for 510(k) clearance. The OsseoScrew Spinal Fixation System is available for sale in the European Union.

Helifix Interspinous Spacer System

Our Helifix Interspinous Spacer System is designed to be inserted in a minimally invasive manner into a patient s spinous process to treat lumbar spinal stenosis. Helifix is a non-fusion interspinous device designed to provide relief from lumbar spinal stenosis by widing the spinal canal and decompressing the level of the compressed nerve, providing flexion in the posterior elements. The Helifix Interspinous Spacer System is not available for sale in the U.S. The Helifix Interspinous Spacer System is available for sale in the European Union.

Biologics

AlphaGraft Structural Allograft Spacers

We offer a broad portfolio of allograft spacers available in a wide range of shapes and sizes, each with corresponding instrumentation, which are intended for use in the cervical, thoracic, and lumbar regions of the spine. We have multiple distinct cervical allograft spacer designs. Additionally, we offer a posterior lumbar allograft spacer. This gives the surgeon several variations of size and shape to choose from during a surgical procedure. Our allograft spacers also come in a variety of densities, permitting surgeons to decide whether to place an emphasis on rigidity, by using a dense allograft, or porosity, by using a less-dense allograft. In addition, many of our allograft spacers are packaged in our VIP packaging system. The VIP system is a packaging and fluid delivery system that allows for fast and efficient infusion of the surgeon s choice of hydration fluid. With the use of a vacuum, the VIP system allows for enhanced infusion of fluids into either our ProFuse or structural allograft products. This rapid hydration system is designed to reduce the length of a surgical procedure by allowing the surgeon to significantly reduce the amount of time required for hydration.

Alphagraft Demineralized Bone Matrix

Our Alphagraft Demineralized Bone Matrix consists of demineralized human tissue that is mixed with a bioabsorbable carrier and used in surgery for bone grafting.

PureGen Osteoprogenitor Cell Allograft

Pursuant to our agreement with Parcell Spine, LLC, or Parcell Spine, an affiliate of Parcell Laboratories, Alphatec Spine has the exclusive right to market and sell our PureGen Osteoprogenitor Cell Allograft, an unique adult stem cell that possesses self-renewal and bone regenerative capabilities.

AlphaGraft ProFuse Demineralized Bone Scaffold

Our AlphaGraft ProFuse Bone Scaffold consists of a sponge-like demineralized bone matrix that has been cut into precise sizes to fit within our spinal spacers. The AlphaGraft ProFuse product provides a natural scaffold derived entirely of bone that can be placed into a void within a spinal spacer or on top of a spinal spacer. The sponge-like qualities of the scaffold allow a surgeon to compress the scaffold and place it into a small space. Following placement, the scaffold expands for maximum contact between the spinal spacer and the endplate of the vertebral body and is designed to promote fusion. The AlphaGraft ProFuse scaffold comes pre-packaged in our proprietary VIP vacuum infusion packaging system.

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AmnioShield Amniotic Membrane

Pursuant to an agreement with a third-party supplier, we have the right to market and sell our privately labeled AmnioShield Amniotic Membrane product, an in-vivo reabsorbable wound covering derived from the amniotic membrane that delivers a defensive barrier at the site where it is placed.

AlphaGUARD Anterior Vessel Guard

Pursuant to an agreement with a third-party supplier, we have the right to market and sell our privately labeled AlphaGUARD Anterior Vessel Guard product, a non-reabsorbable synthetic membrane used for vessel protection in connection with anterior spine surgery.

Sales and Marketing

Our U.S. sales force consists of over 110 independent distributors, which we believe employ approximately 270 agents dedicated to selling our products in the U.S., and 31 direct sales representatives and sales management employees and executives. In general, in the U.S., although surgeons in the U.S. make the ultimate decision to use our products, we bill hospitals for the products that are used and pay commissions to our independent distributors and direct sales agents based on payments received from hospitals. In general, outside of the U.S. we sell products directly to distributors, and the distributors resell the products to hospitals. We compensate our sales management employees and sales executives through salaries and incentive bonuses based on performance measures. We select our sales force based on their expertise in selling spinal devices, reputation within the surgeon community, geographical coverage and established sales network. Increasingly, we contractually require our distributors to exclusively sell our products both within and outside of their allocated sales territory. We offer each of our independent distributors and direct sales representatives sales and product training programs. We market our products at various industry conferences, organized surgical training courses, and in industry trade journals and periodicals. We plan on expanding our global sales coverage through the use of additional distributors and direct sales representatives in order to support continued adoption of our products by new surgeons and increased use of our products by surgeons who currently use our products.

In France, Italy and the U.K. we have a direct sales force consisting of an aggregate of 26 direct sales representatives, and in Europe and the Middle East/Africa we have an aggregate of 33 independent distributors. In Japan, our sales and marketing activities are conducted through our subsidiary Alphatec Pacific, Inc., or Alphatec Pacific. Alphatec Pacific has 20 sales and marketing employees. We intend to continue to increase our direct sales force at Alphatec Pacific and also increase the emphasis that Alphatec Pacific places on selling our spinal disorder solutions to the large and growing Asian market. In the remainder of Asia (excluding Japan), our sales and marketing activities are conducted through our subsidiaries Milverton Ltd., or Milverton and Scient x Asia Pacific. Through these two entities we have 6 direct sales representatives and sales managers and 10 independent distributors selling our products. In Latin America we plan to conduct our sales and marketing activities through a newly acquired subsidiary, Cibramed Products Medicos Ltda., which we plan to rename Alphatec Spine do Brasil. Currently, we have five sales and marketing employees in Latin America, and eight independent distributors selling our products in Latin America.

In the markets in which we have a direct sales force, we bill the hospitals for the products that are used. In markets that use independent distributors, we sell our products to the distributor, and the distributor resells the products to the hospital. We plan to continue expanding our distribution network and product offerings throughout the world. Similar to our sales and marketing activities in the U.S., we market our products at various international industry conferences, organized surgical training courses, and in industry trade journals and periodicals. In addition, we host several international educational conferences, including the International Spine Research and Innovation and Argos and Sisyphean Spinal Society meetings, in the United States, Europe, Asia and Latin America.

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Surgeon Training and Education

We devote significant resources to train and educate surgeons in the proper use of our implants, instrumentation, and surgical access technologies. We believe that one of the most effective ways to introduce and build market demand for our products is by training and educating spine surgeons, independent distributors, and direct sales representatives in the use of our products. We believe that surgeons, independent distributors, and direct sales representatives will become exposed to the merits and distinguishing features of our products through our training and education programs, and in doing so, will increase the use and promotion of our products. In addition, we believe surgeons using our products that were trained by us will be instrumental in generating valuable clinical data, providing feedback and demonstrating the benefits of our products to the medical community.

Research and Development

Our research and development department has extensive experience in developing products to treat spine pathologies. Our research and development department works closely with our Scientific Advisory Board and surgeon collaborators to design products that are intended to improve patient care, simplify surgical techniques and reduce overall costs. We are focusing our research and development efforts in two major strategic areas. First, we focus on continually enhancing and upgrading our current product portfolio and supplementing it with new products where appropriate. Second, we devote significant resources to developing complementary products and unique technologies to create new solutions to address spinal pathologies that affect the aging spine. Our goal is to become the market leader in providing solutions for the aging spine by developing products that have superior efficacy for patients who suffer from conditions that disproportionally affect the aging spine, such as poor bone density, a VCF, adult deformity or scoliosis, degenerative disc disease and spinal stenosis. We also plan to continue development programs initiated by Scient x for developing and commercializing semi-rigid technologies for dynamic fusion, cervical disc arthroplasty and minimally invasive access techniques. In order to further promote this strategy, we are focused on converting these research and development programs into commercially viable products that incorporate minimally invasive access techniques and biologics solutions to improve patient outcomes across all of our product lines.

Manufacture and Supply

We conduct most of our manufacturing operations at our facilities in Carlsbad, California, although we also manufacture products at our facility in Beaurains, France. We manufacture the majority of our implants in-house. Certain of our implants and a significant amount of our instrumentation are purchased from third parties. We believe that the in-house production of our implants maximizes efficiency, reduces product development time, simplifies production scheduling, reduces inventory backlogs and is more responsive to the changing needs of surgeons. Our facilities include distinct areas dedicated to the machinery, tooling, quality control, cleaning and labeling of our products. Additionally, we have an advanced manufacturing group that includes design engineering and manufacturing personnel. The advanced manufacturing group is dedicated to providing rapid prototyping and innovative custom instrumentation for our research and development programs and our surgeon customers. Occasionally we enter into distribution agreements, pursuant to which we distribute products manufactured by a third party either under our own private label or under third-party trademarks. Following the receipt of products or product components that we receive from third parties, we conduct inspection, quality control, packaging and labeling, as needed, at our manufacturing facilities.

We devote significant time and attention to ensure that all of our products are safe, effective, adhere to all applicable regulations and are of the highest quality. An established and comprehensive quality system drives our focus from the initial translation of surgeon needs into design specifications through an exhaustive series of quality control checks that are performed through the purchasing, production, and packaging of our products. We record the complete production history for every product, ensuring full traceability from the raw material stage through the delivery of the product into the marketplace. The raw materials used in the manufacture of our products are principally titanium, titanium alloys, stainless steel, cobalt chrome, ceramic, allograft and PEEK. Invibio is one of a limited number of companies that is currently approved in the U.S. to distribute PEEK for use

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in implantable devices. In October 2004, we entered into an exclusive supply agreement with Invibio, pursuant to which we agreed to purchase our entire supply of medical quality PEEK in the U.S. for use in our Novel implants from Invibio. As consideration for the PEEK materials, we pay Invibio an amount that depends on the weight or the length of either the raw material or stock product that Invibio processes for us. The cost of the PEEK may increase over time, but the price increase is capped at a certain percentage annually. Under the terms of the agreement, we are restricted from selling PEEK to third parties, except when it is incorporated into our products, and we are not authorized to alter the chemical structure of the PEEK. The term of the supply agreement is through October 2014. Either we or Invibio may terminate the supply agreement for an uncured material breach of the agreement.

With the exception of PEEK and allograft-based products, none of our raw material requirements is limited to any significant extent by critical supply. We are subject to the risk that Invibio will fail to supply PEEK in adequate amounts for our needs on a timely basis. In addition, because our biologics products are processed from human tissue, maintaining a steady supply can sometimes be challenging.

Our manufacturing operations and those of the third-party manufacturers we use on a limited basis are subject to extensive regulation by the FDA under its quality systems regulations, or QSRs, and other device-related or tissue-related good manufacturing practice, or GMP, regulations, state regulations, such as the regulations promulgated by the California Department of Health Services, and under similar requirements of regulatory authorities in different states and foreign countries. For biologics products, we are FDA-registered and licensed in the states of California, New York and Florida, the only states that currently require licenses. For our implants and instruments, we are FDA-registered, California-licensed and International Organization for Standardization, or ISO, certified. Our facility and the facilities of the third-party manufacturers we use on a limited basis are subject to periodic unannounced inspections by regulatory authorities, and may undergo compliance inspections conducted by the FDA and corresponding state and foreign agencies. The FDA inspected our Carlsbad, California facilities in January 2010 and non-compliance items were cited on an FDA Form 483 that we received following the inspection. On June 24, 2010 we received a Warning Letter from the Irvine District office of the FDA. The Warning Letter related specifically to non-conformances in quality systems previously identified in the Form 483 that was issued following the January inspection. We have has responded to the Warning Letter and completed corrective actions that we believe fully address the observations. The FDA conducted a planned re-inspection of our Carlsbad, California facility in December 2010, and we are awaiting the results of such inspection.

Competition

Although we believe that our current broad product portfolio and development pipeline is differentiated and has numerous competitive advantages, the spinal implant industry is highly competitive, subject to rapid technological change, and significantly affected by new product introductions. We believe that the principal competitive factors in our market include:

- improved outcomes for spine pathology procedures;
- ease of use and reliability;
- effective sales, marketing and distribution;
- technical leadership and superiority;
- surgeon services, such as training and education;
- responsiveness and ability to develop unique products that addresses the needs of surgeons;
- manufacturing capabilities;

acceptance by spine surgeons;

product price and qualification for reimbursement; and

speed to market.

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Our currently marketed products are, and any future products we commercialize will be, subject to intense competition and we are aware of several companies that compete in our current and future product areas. We believe that our most significant competitors are Medtronic Sofamor Danek, DePuy Spine, Stryker, Biomet, NuVasive, Zimmer, Synthes, Orthofix, Globus, and others, many of which have substantially greater financial resources than we do. In addition, these companies may have more established distribution networks, entrenched relationships with physicians, and greater experience in developing, launching, marketing, distributing and selling products.

Our competitors include providers of non-operative therapies for spine disorder conditions. While these non-operative treatments are considered to be an alternative to surgery, surgery is used in the event that non-operative treatments are unsuccessful. We do not believe that, to date, these non-operative treatments have caused a material reduction in the demand for surgical treatment of spinal disorders.

Intellectual Property

We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure agreements, proprietary information ownership agreements and other measures to protect our intellectual property rights. We believe that in order to have a competitive advantage, we must develop, maintain and enforce the proprietary aspects of our technologies. We require our employees, consultants, co-developers, distributors and advisors to execute agreements governing the ownership of proprietary information and use and disclosure of confidential information in connection with their employment, consulting, co-development, distribution or advisory relationships with us. These agreements require these people and entities to agree to disclose and assign to us all inventions that were conceived on our behalf or which relate to our property or business and to keep our confidential information confidential and only use such confidential information in connection with our business.

Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary. In addition, our competitors may independently develop similar technologies. Further, as described in Item 3 Legal Proceedings, others may attempt to obtain royalties based on the net sales of our products, which may impact our revenues. We may lose market share to our competitors if we fail to protect our intellectual property rights.

Patents

As of December 31, 2010, we owned 48 issued U.S. patents, 41 pending U.S. patent applications and 309 issued or pending foreign patents. In addition, as of December 31, 2010 we have licensed or otherwise acquired rights to 97 U.S. patents, and patent pending applications. We own multiple patents relating to unique aspects and improvements for several of our products. We do not believe that the expiration of any single patent is likely to significantly affect our intellectual property position.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Any claim relating to infringement of patents that is successfully asserted against us may require us to pay substantial damages (including treble damages if our infringement is found to be willful) or may require us to remove our infringing product from the market. Even if we were to prevail, any litigation could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. Our success will also depend in part on our not infringing patents issued to others, including our competitors and potential competitors. If our products are found to infringe the patents of others, our development, manufacture and sale of such potential products could be severely restricted or prohibited. In addition, our competitors may independently develop similar technologies. We may lose market share to our competitors if we fail to protect our intellectual property rights.

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As the number of entrants into our market increases, the possibility of a patent infringement claim against us grows. While we make an effort to ensure that our products do not infringe other parties patents and proprietary rights, our products and methods may be covered by U.S. or foreign patents held by our competitors. In addition, our competitors may assert that future products we may market infringe their patents.

A patent infringement suit brought against us or any strategic partners, co-developers or licensors may force us or strategic partners, co-developers or licensors to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party s intellectual property, unless that party grants us or strategic partners, co-developers or licensors rights to use its intellectual property. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all. Even if strategic partners, co-developers, licensors or we were able to obtain rights to the third party s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Ultimately, we may be unable to commercialize some of our potential products or may have to cease some of our business operations as a result of patent infringement claims, which could severely harm our business financial condition and results of operations.

License and Supply Agreements

In 2007, as part of our product development strategy, we began entering into agreements with third parties that enable us to develop, commercialize and/or distribute products for the treatment of spinal disorders that are based upon technology owned by such third parties.

Agreements Executed in 2010

Distribution Agreement with Parcell Spine, LLC

In January 2010, we entered into an exclusive distribution agreement with Parcell Spine, or the Parcell Agreement, that provides Alphatec with an exclusive right to distribute Parcell Spine s proprietary adult stem cells for the treatment of spinal disorders. The financial terms of the Parcell Agreement include: (i) a cash payment of $0.5 million payable following the execution of the Parcell Agreement; (ii) a milestone payment consisting of $1.0 million in cash and the issuance of $1.0 million shares of our common stock following the successful completion of the pre-clinical study; and (iii) sales milestone payments in cash and our common stock.

Asset Purchase Agreement with AlpineSpine, LLC

In April 2010, we entered into an Asset Purchase Agreement with AlpineSpine, LLC, or the AlpineSpine Agreement, to purchase an anterior cervical plate system, including all of the related intellectual property and inventory. The financial terms of the AlpineSpine Agreement include: (i) a payment of $0.5 million in exchange for the assets received in April 2010 related to the anterior cervical plate system; (ii) a milestone payment after full market launch; and (iii) a royalty payment based on net sales of licensed products with minimum annual royalties beginning in the year after the first commercial sale of a licensed product.

License Agreement with R Tree Innovations LLC

In September 2010, we entered into a License Agreement, or the R Tree License Agreement, with R Tree Innovations LLC, or R Tree, that provides us with a worldwide license to develop and commercialize R Tree s proprietary intellectual property related to its Epicage interbody fusion device and related instrumentation. The financial terms of the R Tree License Agreement include: (i) a cash payment of $0.8 million and the issuance of $0.5 million of our common stock following the execution of the R Tree License Agreement; (ii) development and sales milestone payments in cash that could begin to be achieved and paid in 2011; and (iii) a royalty payment based on net sales of licensed products with minimum annual royalties beginning in the year after the first commercial sale of a licensed product.

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License Agreement with Merlot Orthopedix, Inc.

In July 2010, we entered into a License Agreement, or the Merlot Ortho Agreement, with Merlot Orthopedix, Inc., or Merlot Ortho, which provides us with a worldwide license to develop and commercialize Merlot Ortho s proprietary intellectual property related to its bone anchorage, interbody stabilizer, locking mechanism and certain other technologies. The financial terms of the Merlot Ortho License Agreement include: (i) a cash payment of $0.3 million following the execution of the Merlot Ortho License Agreement; (ii) a cash payment of $150,000 for materials transferred to us; (iii) development and sales milestone payments in cash that could begin to be achieved and paid in 2011; and (iv) a royalty payment based on net sales of licensed products with minimum annual royalties beginning in the year after the first commercial sale of a licensed product.

License Agreement with International Spinal Innovations, LLC

In July 2010, we entered into a License Agreement, or the ISI Agreement, with International Spinal Innovations, LLC, or ISI, which provides us with a worldwide license to develop and commercialize ISI s proprietary intellectual property related to a retractor system. The financial terms of the ISI License Agreement include royalty payments based on net sales of licensed products or a splitting of gross margin with minimum annual payments beginning in the fifth year after the effective date of the agreement.

Other Material License Agreements Executed Since 2007

OsseoFix License Agreement

In September 2007, Alphatec Spine entered into an exclusive license agreement with Stout Medical Group LP, or Stout, that provides Alphatec Spine with an exclusive worldwide license to develop and commercialize a vertebral compression fracture fixation system called the OsseoFix system. The OsseoFix implant is an expandable titanium cage that is designed to be implanted minimally invasively into a vertebral body to treat compression fractures of the vertebral body. The financial terms of the agreement include an up-front license fee payment to be made by Alphatec Spine to Stout upon Stout s delivery of certain deliverables related to the prototype of the OsseoFix; design, regulatory and sales milestone payments that began to be achieved and paid by Alphatec Spine to Stout in 2008; and a royalty payment based on net sales of the OsseoFix product. The term of the license agreement is 20 years after the first commercial sale of a product containing the licensed technology which occurred in 2008. Alphatec Spine has the right to terminate the license agreement for convenience upon 90 days prior written notice. Each party has the right to terminate the license agreement for material uncured breach by the other party.

On April 16, 2009, Alphatec Spine and Stout entered into an amendment to the license agreement. Under the original license agreement, our minimum royalty obligation began in 2009. Pursuant to the amended license agreement, the minimum royalty obligation is suspended until a licensed product obtains regulatory approval from the FDA. In addition, under the terms of the amended license agreement, Stout has the ability to terminate the license agreement if we are not using commercially reasonably efforts to obtain regulatory approval to market and sell a licensed product; provided that we have the right to delay such termination in exchange for making certain payments to Stout. If, during the time period when such payments are made, we were to make a regulatory filing for the marketing and sale of a licensed product, such termination will be null and void. Pursuant to the amended license agreement, Stout is entitled to retain all up-front payments that had been previously paid to it. The other material terms to the license agreement were not changed.

GLIF License Agreement

In September 2007, Alphatec Spine entered into an exclusive license agreement with JGMG Bengochea, LLC, or JGMG, which provided Alphatec Spine with an exclusive worldwide license to develop and commercialize JGMG s guided lumbar interbody fusion system, or the GLIF system. The GLIF system is designed to allow surgeons to perform a 360-degree minimally invasive procedure without the need for a second incision or repositioning of the patient, which is intended to reduce the length of the procedure, reduce the trauma

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to the patient and reduce the post-surgery recovery period. The financial terms of the agreement include an issuance of our common stock to JGMG, a portion of which common stock is subject to a five-year lockup period, with automatic waivers of such lockup to occur upon the achievement of certain milestone events; design, regulatory and sales milestone payments that could begin to be achieved and paid by Alphatec Spine to JGMG in 2009; and a royalty payment based on net sales of licensed products. The term of the license agreement on a country-by-country basis and on a product-by-product basis with respect to each licensed patent is the longer of (i) the last patent to expire that is contained in a licensed product, or (ii) 20 years. Alphatec Spine has the right to terminate the license agreement for convenience upon 30 days prior written notice. Each party has the right to terminate the license agreement for material uncured breach by the other party.

OsseoScrew License Agreement

In December 2007, Alphatec Spine entered into an exclusive license agreement with Progressive Spinal Technologies LLC, or PST, that provides Alphatec Spine with an exclusive worldwide license to develop and commercialize PST s proprietary intellectual property related to a pedicle screw designed to be used for patients with osteopenic bone or poor bone density. The technology consists of an expandable titanium pedicle screw that is designed to be implanted into the pedicle and then expanded in order to achieve increased purchase within the pedicle. This solution is designed for patients with osteopenic bone or poor bone density who are not viable candidates for procedures that use the current standard pedicle screw. The parties amended certain financial terms of this agreement in January 2009. The financial terms of the agreement include a cash payment payable following the execution of the agreement; development and sales milestone payments in cash and our common stock that could begin to be achieved and paid in 2009; and a royalty payment based on net sales of licensed products. The license agreement contains a provision that limits the number of shares that may be issued pursuant to the license agreement to less than 19.99% of our issued and outstanding common stock. The term of the license agreement is 20 years after the first commercial sale of a product containing the licensed technology. Alphatec Spine has the right to terminate the license agreement for convenience upon 90 days prior written notice. Each party has the right to terminate the license agreement for material uncured breach by the other party.

In January 2008, we entered into the first amendment to the OsseoScrew License Agreement, which amended and restated in its entirety Section 1.10 of the OsseoScrew License Agreement which contains the definition of the term Licensed Field, and added a new section 4.4.4 to the Agreement which limits the number of shares that may be issued pursuant to the license agreement to less than 19.99% of our issued and outstanding common stock.

In January 2009, we entered into the second amendment to the OsseoScrew License Agreement, which amended and restated Section 4.1.2 of the OsseoScrew License Agreement related to the milestone payments due under the license agreement.

In June 2009, we entered into the third amendment of the OsseoScrew License Agreement, pursuant to which PST assigned certain of the payment rights to a third party.

In December 2009, we entered into a fourth amendment to the OsseoScrew License Agreement. Under the fourth amendment, the timing and payment of a $0.5 million development and sales milestone payment and royalty payment have been adjusted. The timing of the royalty payments based on net sales of licensed products has been amended and minimum annual royalties begin in 2010 instead of 2009.

In November 2010, we entered into a fifth amendment to the OsseoScrew License Agreement. Pursuant to the fifth amendment, the minimum royalty obligation is suspended until a licensed product obtains regulatory approval from the FDA. In addition, under the terms of the amended license agreement, PST has the ability to terminate the license agreement if we are not using commercially reasonably efforts to obtain regulatory approval to market and sell a licensed product; provided that we have the right to delay such termination in exchange for making certain payments to PST. If, during the time period when such payments are made, we were to make a

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regulatory filing for the marketing and sale of a licensed product, such termination will be null and void. In addition, pursuant to the fifth amendment, one of the milestone payments is deleted and replaced with a new milestone.

Self-Locking Spacer Assignment Agreement

In January 2009, Alphatec Spine entered into an assignment agreement, the Patent and Technology Assignment Agreement, with Spine Vision, S.A, or Spine Vision, that provides Alphatec Spine with the rights, title and interest in and to certain patents and technology of Spine Vision that relate to a self-locking spacer. The financial terms of the Patent and Technology Assignment Agreement include: (i) an up-front fee of $500,000; and (ii) a royalty payment.

Self-Locking Anterior Lumbar Interbody Fusion Device License Agreement

In June 2009, we entered into a Cross License Agreement, or the ISI License Agreement, with International Spinal Innovations, LLC, or ISI, that provides us with a worldwide license to develop and commercialize ISI s proprietary intellectual property related to a self-locking anterior lumbar interbody fusion device. The financial terms of the ISI License Agreement include: (i) the issuance of 260,000 shares of the Company s common stock following the execution of the ISI License Agreement; (ii) sales milestone payments in cash that could begin to be achieved and paid in 2011; and (iii) a royalty payment based on net sales of licensed products.

Trademarks

As of December 31, 2010, we owned these registered US marks: Adonys, Aging Spine Center design/logo, Aladyn, Alis, Alpha symbol design/logo, Alphagraft, Alphagraft Profuse, Alphatec, Alphatec Spine, Inc. logo, Alphatec Spine design/logo, Antelys GX, Antelys, Aurys, Biofill, Bone x, Calisto, Cerviplaque, Chorus, Claris, Corelys, Corlok, Cortek, C design, Cortek design/logo, Deltaloc, D.O.S., Discocerv, Dovetome, Dynoss, Dynamic-TTL Rod, Easys, Electra, Elfix, Ellys, Heliumx, Illico, Inspiration, Iridiumx, Isobar, Isobar Duo, Isobar Evolution, Isobar Hemispherical Screw, Isobar LP, Isobar SL, Isobar TTC, Isobar TTL, Isobar U-Screw, Isolock, Majorys, Modulock, MX System, Novel, Openview, Oria, OsseoFix, OsseoFix+, Pach, Pantheon, Paris, Perigene, Perpetua, Preview, Samarys, Scientx, SCS, Solanas, Solo, Solutions for the Aging Spine, Spine Network, Spine Team, Spinegen, Spinenet, Spineview, Stella, Surgiview, Tamarack, Trestle, Tribeca, Twinflex, X, Zenith and Zodiac. In addition, as of December 31, 2010, we owned these pending US trademark applications: Alphagraft Nanoblast, Alphagraft Duofuse, Amnioshield, Anchormax, ARC and design/logo, Argonox, Aspida, Avalon, Bridgepoint, Diamond Driver, Epicage, Hēlifix, Hēlifuse, Heliumx, Iridiumx, Isoform, Lithiumx, OsseoScrew, Precision Pack, Puregen, Scientx Dynamic Solutions for the Spine, Solus, Sparta, Trestle Luxe, Xenon, Xenonx and Xenon x.

Government Regulation

Our products are medical devices subject to extensive regulation by the FDA and other U.S. federal and state regulatory bodies and comparable authorities in other countries. To ensure that medical products distributed domestically and internationally are safe and effective for their intended use, FDA and comparable authorities in other countries have imposed regulations that 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 labeling;

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product storage;

premarket clearance or approval;

advertising and promotion;

product marketing, sales and distribution; and

post-market surveillance, including reporting deaths or serious injuries related to products and certain product malfunctions.

FDA s Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device we wish to commercially distribute in the U.S. will require either prior 510(k) clearance or approval of a premarket approval application (PMA). The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the intended use of the device, the indications for use and on controls deemed by the FDA to be necessary to reasonably ensure their safety and effectiveness. Class I devices, which are those that have the lowest level or risk associated with them, are subject to general controls, Class II devices are subject to general controls and special controls, including performance standards, and Class III devices, which have the highest level of risk associated with them, are subject to general controls and premarket approval. Most Class I devices and many Class II devices are exempt from the 510(k) requirement, although the manufacturers will still be subject to registration, listing, labeling and GMP requirements. Class III devices are subject to those requirements, too, but also require and PMA approval. A new medical device for which there is no substantially equivalent device is automatically designated a Class III device. Depending on the nature of the new device, the manufacturer may ask the FDA to make a risk-based determination of the new device and reclassify it in Class I or Class II. This process is referred to as the *de novo* process. If the FDA agrees, the new device will be reassigned to the appropriate other class. If it does not agree, the manufacturer will have to submit a PMA. Our current commercial products are Class II devices marketed under FDA 510(k) premarket clearance. Both premarket clearance and premarket approval applications are subject to the payment of user fees, paid at the time of submission for FDA review.

510(k) Clearance Pathway

To obtain 510(k) clearance, we must submit a premarket notification demonstrating that the proposed device is substantially equivalent to a device legally marketed in the U.S. for which a PMA was not required. The FDA s goal is to review and act on each 510(k) within 90 days of submission, but it may take longer based on requests for additional information by the FDA. Most 510(k)s do not require supporting data from clinical trials, but the FDA may request such data.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, require premarket approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), or a premarket approval, 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, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket approval is obtained. If the FDA requires us to seek 510(k) clearance or premarket approval 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. We have made and plan to continue to make additional product enhancements to our products, and we will consider on a case-by-case basis whether a new 510(k) or PMA is necessary.

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Premarket Approval Pathway

A premarket approval application must be submitted if the device cannot be cleared through the 510(k) process. The premarket approval application process is generally more complex, costly and time consuming than the 510(k) process. A premarket approval application must be supported by extensive data including, but not limited to, technical, preclinical, clinical trials, manufacturing and labeling to demonstrate to the FDA s satisfaction the safety and effectiveness of the device for its intended use.

After a premarket approval application is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the accepted application, although, generally, review of the application can take between one and three years. 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. New premarket approval applications or premarket approval application supplements are required prior to marketing for product modifications that affect the safety and efficacy of the device. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and may not require clinical data or the convening of an advisory panel. We were not required to submit a PMA for any of our currently marketed products, but devices in development may require a PMA.

Clinical Trials

Clinical trials are usually required to support a PMA and are sometimes required for a 510(k). In the U.S., if the device is determined to present a significant risk, the manufacturer may not begin a clinical trial until it submits an investigational device exemption, or IDE, and obtains approval of the IDE from the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. These clinical trials are also subject to the review, approval and oversight of an institutional review board, or IRB, at each clinical trial site. The clinical trials must be conducted in accordance with FDA s IDE regulations and international regulations concerning human subject protection. A clinical trial may be suspended by FDA, the sponsor or the IRB at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, the results of a clinical trial may not demonstrate the safety and efficacy of a device, or may be equivocal or otherwise not be sufficient to obtain approval of a device.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include:

- quality system regulations, which require manufacturers, including third-party contract manufacturers, to follow stringent design, testing, control, documentation, record maintenance and other quality assurance controls, during all aspects of the manufacturing process and to maintain and investigate complaints;
- labeling regulations, and FDA prohibitions against the promotion of products for uncleared or unapproved off-label uses;
- medical device reporting obligations, which require that manufacturers submit reports to the FDA of adverse events; and
- other post-market surveillance requirements, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

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Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions:

- warning letters;
- fines, injunctions, and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal to grant 510(k) clearance or PMA approvals of new products; and
- criminal prosecution.

To ensure compliance with regulatory requirements, medical device manufacturers are subject to market surveillance and manufacturers and their third-party manufacturers are subject to periodic announced and unannounced inspection by the FDA. In January 2011, we received a Warning Letter from the FDA relating to post-market surveillance study protocol for certain of our dynamic fusion rods. We have responded to this Warning Letter and we are awaiting the FDA s reply to our response.

International Device Regulation

International sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA approval, and the requirements may differ.

Japan

In Japan, certain medical devices classified as highly controlled must be approved prior to importation and commercial sale by the Ministry of Health, Labour and Welfare, or MHLW, pursuant to the Japanese Pharmaceutical Affairs Law. Manufacturers of medical devices outside of Japan which do not operate through a Japanese entity are required to appoint a contractually bound authorized representative to directly submit an application for device approval to the MHLW. The MHLW evaluates each device for safety and efficacy and may require that the product be tested in Japanese laboratories. After a device is approved for importation and commercial sale in Japan, the MHLW continues to monitor sales of approved products for compliance. Failure to comply with applicable regulatory requirements can result in enforcement action by the MHLW, including administrative inspections and recommendations; recall or seizure of products; operating restrictions, including partial suspension or total shut down of marketing activity in Japan; withdrawal of product approvals; and criminal prosecution by a public prosecutor, including criminal fines and/or imprisonment.

Our devices fall into the highly controlled medical device category. Currently, MHLW review times for our device applications range from one year if clinical data is not required, to up to two years if clinical data is required. The review times for our products are expected to be reduced to six months and one year, respectively, and we expect application fees to be reduced as new approval screening standards are established by the MHLW, which has delegated responsibility for these review functions to the Japanese Pharmaceuticals and Medical Devices Agency, for various medical device categories. Currently, the MHLW is working with trade organizations such as AdvaMed, and MHLW may adopt similar standards.

European Union

The European Union, which consists of 27 of the major countries in Europe, has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling, and adverse event reporting for medical devices. Other countries, such as Switzerland, have

voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear CE conformity marking and, accordingly, can be commercially

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distributed throughout the member states of the European Union, and other countries that comply with or mirror these directives. The method of assessing conformity varies depending on the type and class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a Notified Body, an independent and neutral institution appointed to conduct conformity assessment. This third-party assessment consists of an audit of the manufacturer s quality system and technical review and testing of the manufacturer s product. An assessment by a Notified Body in one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. In addition, compliance with voluntary harmonized standards including ISO 13845 issued by the International Organization for Standards establishes the presumption of conformity with the essential requirements for a CE mark. In October 2007, we were certified by Intertek Semko, a Notified Body, under the European Union Medical Device Directive allowing the CE conformity marking to be applied.

Environmental Matters

Our facilities and operations are subject to extensive federal, state, and local environmental and occupational health and safety laws and regulations. These laws and regulations govern, among other things, air emissions; wastewater discharges; the generation, storage, handling, use and transportation of hazardous materials; the handling and disposal of hazardous wastes; the cleanup of contamination; and the health and safety of our employees. Under such laws and regulations, we are required to obtain permits from governmental authorities for some of our operations. If we violate or fail to comply with these laws, regulations or permits, we could be fined or otherwise sanctioned by regulators. We could also be held responsible for costs and damages arising from any contamination at our past or present facilities or at third-party waste disposal sites. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur material liability as a result of any contamination or injury.

Compliance with Fraud and Abuse Laws and Other Applicable Statutes

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws, physician self-referral laws, false claims laws, criminal health care fraud laws, and foreign corrupt practice laws. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, fines, imprisonment and, within the United States, exclusion from participation in government healthcare programs, including Medicare, Medicaid and Veterans Administration health programs. These laws are administered by, among others, the U.S. Department of Justice, the Office of Inspector General of the Department of Health and Human Services and state attorneys general. Many of these agencies have increased their enforcement activities with respect to medical device manufacturers in recent years.

The Medicare and Medicaid Patient Protection Act of 1987, as amended, or Anti-Kickback statute, prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service, for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. For example, the definition of remuneration has been broadly interpreted to include anything of value, including, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, in March 2010, the U.S. Congress adopted and President Obama signed into law the Patient Protection and Affordable Health Care Act, which, as amended by the Health Care and Education Reconciliation Act, is referred to as PPACA. PPACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

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In implementing the Anti-Kickback Statute, the Office of Inspector General, or OIG, has issued a series of regulations, known as the safe harbors, which began in July 1991. These safe harbors set forth provisions that, in circumstances where all the applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy all requirements of an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Penalties for violations of the Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have anti-kickback laws that are similar to the federal law, including penalties, fines, sanctions for violations, and exclusions from state or commercial programs.

The federal ban on physician self-referrals, commonly known as the Stark Law, prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain designated health services if the physician or an immediate family member of the physician has any financial relationship with the entity. Penalties for violating the Stark Law include fines, civil monetary penalties and possible exclusion from federal healthcare programs. In addition to the Stark Law, many states have their own self-referral laws. Often, these laws closely follow the language of the federal law, although they do not always have the same scope, exceptions or safe harbors.

We have entered into various agreements with certain surgeons that perform services for us, including some who make clinical decisions to use our products. Some of our referring surgeons own our stock, which they either purchased in an arms length transaction on terms identical to those offered to non-surgeons or received from us as fair market value consideration for services performed. In addition, physician-owned distribution companies have increasingly become involved in the sale and distribution of medical devices, including the products for the surgical treatment of spine disorders. In many cases, these distribution companies enter into arrangements with hospitals that bill Medicare or Medicaid for the furnishing of medical services, and the physician-owners are among the physicians who refer patients to the hospitals for surgery. While we believe that our current operations comply with applicable fraud and abuse laws and do not believe that we are subject to any arrangements that violate any such laws, we are not aware of all of the financial arrangements of the physician-owned distribution companies with which we contract. All arrangements we have that involve surgeons, sales agents or distributors have all been structured with the intention of complying with all applicable fraud and abuse laws, including the anti-kickback statute, Stark Law and similar state anti-referral laws.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false or fraudulent claim to, or the knowing use of false statements to obtain payment from, the federal government. Private suits filed under the False Claims Act, known as *qui tam* actions, can be brought by individuals on behalf of the government. These individuals, sometimes known as relators or, more commonly, as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. The number of filings of *qui tam* actions has increased significantly in recent years, causing more healthcare companies to have to defend a False Claim Act action. If an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between $5,500 to $11,000 for each separate false claim and may be subject to exclusion from Medicare, Medicaid and other federal healthcare programs. Various states have also enacted similar laws modeled after the federal False Claims Act which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The Health Insurance Portability and Accountability Act, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. Under recent changes in PPACA, the intent requirement of the healthcare fraud statute is lowered such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. A

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violation of this statute is a felony and may result in fines, imprisonment or possible exclusion from Medicare, Medicaid and other federal healthcare programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute is a felony and in similar sanctions.

PPACA also includes various provisions designed to strengthen significantly fraud and abuse enforcement in addition to those changes discussed above. Among these additional provisions include increased funding for enforcement efforts and new sunshine provisions to require reporting and disclosures of any transfer of value made or distributed to prescribers and other health care providers, effective March 30, 2013. There are various state laws and initiatives that require device manufacturers to disclose to the appropriate regulatory agency certain payments or other transfers of value made to physicians, with the risk of fines for any violation of such requirements. Massachusetts has one of the most stringent of these laws, and the District of Columbia and Vermont passed such laws in 2008 and 2009, respectively.

We may also be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, which generally prohibits companies and their intermediaries from making corrupt payments to foreign officials for the purpose of obtaining or keeping business or otherwise obtaining favorable treatment, and requires companies to maintain adequate record-keeping and internal accounting practices to accurately reflect the transactions of the company. We are also subject to a number of other laws and regulations relating to money laundering, international money transfers and electronic fund transfers. These laws apply to companies, individual directors, officers, employees and agents.

If any of our operations are found to have violated or be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, among them being civil and criminal penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of our operations.

Third-Party Reimbursement

In the U.S., healthcare providers generally rely on third-party payors, principally private insurers and governmental payors such as Medicare and Medicaid, to cover and pay for all or part of the cost of a spine surgery in which our medical devices are used. We expect that sales volumes and prices of our products will depend in large part on the continued availability of reimbursement from such third-party payors. These third-party payors may deny reimbursement if they determine that a device used in a procedure was not medically necessary in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved indication. Particularly in the U.S., third-party payors continue to carefully review, and increasingly challenge, the prices charged for procedures and medical products.

Medicare reimbursement policies are developed by the Centers for Medicare and Medicaid Services, or CMS, the federal agency responsible for administering the Medicare program, and its contractors. CMS establishes Medicare reimbursement policies for medical products and procedures and such policies are periodically reviewed and updated. While private payors vary in their coverage and payment policies, the Medicare program is viewed as a benchmark. Medicare payment rates for the same or similar procedures vary due to geographic location, nature of the facility in which the procedure is performed (i.e., teaching or community hospital) and other factors. We cannot assure you that government or private third-party payors will cover and provide adequate payment for the procedures in which our products are used.

PPACA and other reform proposals contain significant changes regarding Medicare, Medicaid and other third party payors. Among these changes is the imposition of a 2.3% excise tax on domestic sales of medical devices following December 31, 2012. These taxes will result in a significant increase in the tax burden on our industry. Other elements of this legislation include numerous provisions to limit Medicare spending through reductions in various fee schedule payments and by instituting more sweeping payment reforms, such as bundled

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payments for episodes of care, the establishment of accountable care organizations under which hospitals and physicians will be able to share savings that result from cost control efforts, comparative effectiveness research, value-based purchasing, and the establishment of an independent payment advisory board. Many of these provisions will be implemented through the regulatory process, and policy details have not yet been finalized. In addition, PPACA has been subject to various legal and legislative challenges. For example, the U.S. House of Representatives recently voted to repeal PPACA, two courts have ruled that one provision, the minimum coverage rule, or so-called personal mandate, which is not scheduled to go into effect until 2014, is unconstitutional. Other proposals have been introduced in Congress to repeal the device tax. Various healthcare reform proposals have also emerged at the state level. We cannot predict with certainty whether PPACA will be fully implemented as enacted or what other healthcare initiatives at the federal or state level, if any, will be implemented. However, an expansion in government s role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes, and adversely affect our business and results of operations, possibly materially.

Internationally, healthcare payment systems vary substantially from country to country and include single-payor, government-managed systems as well as systems in which private payors and government-managed systems exist side-by-side. Our ability to achieve market acceptance or significant sales volume in international markets we enter will be dependent in large part on the availability of reimbursement for procedures performed using our products under the healthcare payment systems in such markets. A small number of countries may require us to gather additional clinical data before covering our products. It is our intent to complete the requisite clinical studies and obtain coverage in countries where it makes economic sense to do so.

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. We cannot assure you that government or private third-party payors will cover and provide adequate payment for the procedures using our products. In addition, it is possible that future legislation, regulation, or reimbursement policies of third-party payors will adversely affect the demand for procedures using our products or our ability to sell our products on a profitable basis. The unavailability or inadequacy of third-party payor coverage or reimbursement could have a significant adverse effect on our business, operating results and financial condition.

Employees

As of December 31, 2010, we had approximately 460 employees worldwide in the following areas: sales, physician services, marketing, clinical education, manufacturing, advanced manufacturing, quality assurance, regulatory affairs, research and development, human resources, finance, legal, information technology and administration. We have never experienced a work stoppage due to labor difficulties and believe that our relations with our employees are good. Certain employees in Europe have labor committees and collective bargaining agreements in place.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained in this Annual Report on Form 10-K. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of such risks or the risks described below occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

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Risks Related to Our Business and Industry

Our business plan relies on certain assumptions pertaining to the market for our products that, if incorrect, may adversely affect our growth and profitability.

We allocate our design, development, manufacturing, marketing, management and financial resources based on our business plan, which includes assumptions about various demographic trends and trends in the treatment of spine disorders and the resulting demand for our products. However, these trends are uncertain. There can be no assurance that our assumptions with respect to an aging population with broad medical coverage and longer life expectancy, which we expect to lead to increased spinal injuries and degeneration, are accurate. In addition, an increasing awareness and use of non-invasive means for the prevention and treatment of back pain and rehabilitation purposes may reduce demand for, or slow the growth of sales of, spine fusion products. A significant shift in technologies or methods used in the treatment of back pain or damaged or diseased bone and tissue could adversely affect demand for some or all of our products. For example, pharmaceutical advances could result in non-surgical treatments gaining more widespread acceptance as a viable alternative to spine fusion. The emergence of new biological or synthetic materials to facilitate regeneration of damaged or diseased bone and to repair damaged tissue could increasingly minimize or delay the need for spine fusion surgery and provide other biological alternatives to spine fusion. New surgical procedures could diminish demand for some of our products. The increased acceptance of emerging technologies that do not require spine fusion, such as artificial discs and nucleus replacement, for the surgical treatment of spine disorders would reduce demand for, or slow the growth of sales of, spine fusion products. If our assumptions regarding these factors prove to be incorrect or if alternative treatments to those offered by our products gain further acceptance, then actual demand for our products could be significantly less than the demand we anticipate for our products and we may not be able to achieve or sustain growth or profitability.

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

We continue to experience rapid growth in, and we will continue to pursue rapid growth in, the number of surgeons using our products, the types of products we offer and the number of states in which our products are sold. Such growth has placed and will continue to place significant demands on our managerial, operational and financial resources and systems. We are currently focused on increasing the size and effectiveness of our sales force and distribution network, marketing activities, research and development efforts, inventory management systems, management team and corporate infrastructure. If we do not manage our growth effectively, the quality of our products, our relationships with physicians, distributors and hospitals, and our reputation could suffer, which would have a significant adverse effect on our business, financial condition and results of operations. We must attract and retain qualified personnel and third-party distributors and manage and train them effectively. Personnel qualified in the design, development, production and marketing of our products are difficult to find and hire, and enhancements of information technology systems to support our growth are difficult to implement. We will also need to carefully monitor and manage our surgeon services, our manufacturing capabilities, quality assurance and efficiency, and the quality assurance and efficiency of our suppliers and distributors. This managing, training and monitoring will require allocation of valuable management resources and significant expense. The efficient operation of our business is dependent on our management information systems. We rely on our management information systems to effectively manage accounting and financial functions; manage order entry, order fulfillment and inventory replenishment processes; and maintain our research and development data. Any failure of our management information systems to perform as we anticipate could disrupt our business and product development and could result in decreased sales, increased overhead costs, excess inventory and product shortages, causing our business and results of operations to suffer.

Global economic and credit market conditions could affect a portion of our client base, subcontractors and suppliers, which could materially affect our backlog and profits.

Volatility and disruption in the global capital and credit markets has reduced the availability of liquidity and credit to fund or support the continuation and expansion of industrial business operations worldwide. Recent financial market conditions have resulted in significant write-downs of asset values by financial institutions, and

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have caused many financial institutions to seek additional capital, to merge with larger and stronger institutions and, in some cases, to fail. Many lenders and institutional investors have reduced and, in some cases, ceased to provide funding to borrowers. Continued disruption of the credit markets could adversely affect the borrowing capacity of us or our suppliers and customers, which support the continuation and expansion of our sales worldwide, and could result in suppliers not being able to supply us with raw materials or finished goods or payment delays or defaults by our customers. In addition, in response to current market conditions, vendors or customers may choose to seek contract terms more favorable to them. Finally, our ability to expand our business could be limited if, in the future, we are unable to raise capital, on favorable terms or at all.

We may not be successful in manufacturing products at the levels required to meet future market demand.

We are seeking to rapidly grow sales of our products and if we are successful, such growth may strain our ability to manufacture an increasingly large supply of our products. We have never produced products in quantities significantly in excess of our current production levels. Manufacturers regularly experience difficulties in scaling up production and we may face such difficulties in increasing our production levels. Moreover, we may not be able to manufacture our products with consistent and satisfactory quality or in sufficient quantities to meet demand. Our failure to produce products of satisfactory quality or in sufficient quantities could hurt our reputation, cause hospitals, surgeons or distributors to cancel orders or refrain from placing new orders for our products and reduce or slow growth of sales of our products. Increases in our production volume also could make it harder for us to maintain control over expenses, manage our relationships with our suppliers, maintain good relations with our employees or otherwise manage our business. In addition, should we not be able to achieve our revenue forecast and cash consumption starts to exceed forecasted consumption, management will need to adjust our production of surgical instruments and manage our inventory to the decreased sales volumes. If we do not make these adjustments in a timely manner, there could be an adverse impact on our financial resources.

We are in a highly competitive market segment, face competition from large, well-established medical device companies with significant resources, and may not be able to compete effectively.

The market for spine fusion products and procedures is intensely competitive, subject to rapid technological change and significantly affected by new product introductions and other market activities of industry participants. In 2010, a large portion of U.S. spine fusion product revenues were generated by Medtronic Sofamor Danek, a subsidiary of Medtronic, Inc., Depuy Spine, a subsidiary of Johnson & Johnson, Stryker Spine, and Synthes Spine. Our competitors also include numerous other publicly traded companies and privately held companies.

Several of our competitors enjoy competitive advantages over us, including:

- more established relationships with spine surgeons;
- more established distribution networks;
- broader spine surgery product offerings;
- stronger intellectual property portfolios;
- greater financial and other resources for product research and development, sales and marketing, and patent litigation;
- greater experience in, and resources for, launching, marketing, distributing and selling products;
- significantly greater name recognition as well as more recognizable trademarks for products similar to the products that we sell;

more established relationships with healthcare providers and payors;

products supported by more extensive clinical data; and

greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements.

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In addition, at any time our current competitors or other companies may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products, including ones that prove to be superior to our spine surgery products. For these reasons, we may not be able to compete successfully against our existing or potential competitors. Any such failure could lead us to modify our strategy, lower our prices, increase the commissions we pay on sales of our products and have a significant adverse effect on our business, financial condition and results of operations.

A significant percentage of our revenues are derived from the sale of our systems that include polyaxial pedicle screws.

Net sales of our systems that include polyaxial pedicle screws represented approximately 34.0% and 37.2% of our net sales for 2010 and 2009, respectively. A decline in sales of these systems, due to market demand, the introduction by a third party of a competitive product, an intellectual property dispute involving these systems, or otherwise, would have a significant adverse impact on our business, financial condition and results of operations. Some of the technology related to our polyaxial pedicle screw systems is licensed to us. Any action that would prevent us from manufacturing, marketing and selling our polyaxial pedicle screw systems would have a significant adverse effect on our business, financial condition and results of operations. In February 2010, a complaint was filed in the U.S. District Court for the Central District of California, by Cross Medical Products, LLC, or Cross, alleging that we breached a patent license agreement with Cross by failing to make certain royalty payments allegedly due under the agreement. Cross is seeking payment of prior royalties allegedly due from our sales of polyaxial pedicle screws and an order from the court regarding payment of future royalties by us. While we denied the allegations in our answer to the complaint and believe that Cross allegations are without merit, the outcome of the litigation cannot be predicted at this time. In February 2011, the court issued an order granting Cross s motion for partial summary judgment on issues of contract interpretation. While this ruling interpreted the license agreement as asserted by Cross, it was not dispositive of any claims and we continue to assert defenses and counterclaims the court preserved until a later phase of the case. Any outcome in favor of Cross could result in the payment of significant costs and damages by us, which could have a material adverse effect on our results of operations, financial condition and cash flows.

To be commercially successful, we must convince the spine surgeon community that our products are an attractive alternative to our competitors products. If the spine surgeon community does not use our products, our sales will decline and we will be unable to increase our sales and profits.

In order for us to sell our products, surgeons must be convinced that they are superior to competing products for use in spine fusion procedures. Acceptance of our products depends on educating the spine surgeon community as to the distinctive characteristics, perceived benefits, safety and cost-effectiveness of our products compared to our competitors products and on training surgeons in the proper application of our products. If we are not successful in convincing the spine surgeon community of the merit of our products, our sales will decline and we will be unable to increase our sales and will be unable to achieve and sustain growth or profitability.

There is a learning process involved for spine surgeons to become proficient in the use of our products. Although most spine surgeons may have adequate knowledge on how to use most of our products based on their clinical training and experience, we believe that the most effective way to introduce and build market demand for our products is by directly training spine surgeons in the use of the products. If surgeons are not properly trained, they may misuse or ineffectively use our products. This may also result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have a significant adverse effect on our business, financial condition and results of operations.

Our sales and marketing efforts in the U.S. are largely dependent upon third parties, some of which are free to market products that compete with our products.

As of December 31, 2010, approximately 30% of our independent distributors in the U.S also market and sell the products of our competitors, and those competitors may have the ability to influence the products that our

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independent distributors choose to market and sell. Our competitors may be able, by offering higher commission payments or otherwise, to convince our independent distributors to terminate their relationships with us, carry fewer of our products or reduce their sales and marketing efforts for our products.

We may be unable to accurately predict future sales through distributors that purchase products directly from us, which could harm our ability to forecast sales performance.

A portion of our sales are made through domestic and international third-party distributors that purchase our products directly though us and then resell such products to hospitals. As a result, our financial results, quarterly product sales, trends and comparisons are affected by fluctuations in the buying patterns and inventory levels of these distributors. While we attempt to assist such distributors in forecasting its future sales and maintaining adequate inventory levels, we may not consistently be accurate or successful. In addition, our distributors decision-making process regarding orders is complex and involves several factors, including surgeon demand levels, which can make it difficult to accurately predict our sales until late in a quarter. Our failure to accurately forecast sales through distributors that purchase products directly from us could lead to a decline in sales and adversely affect our results of operations.

Scient x conducts a significant amount of its sales activity outside of the United States, which subjects it to additional business risks and may adversely affect the combined business s results of operations and financial condition due to increased costs.

During the year ended December 31, 2010, Scient x derived approximately $23.8 million, or 82% of its net sales from sales of its products outside of the United States. The combined business intends to continue to pursue growth opportunities in sales internationally, which could expose it to additional risks associated with international sales and operations that we do not currently face. Scient x s international operations are, and the combined business s international operations will continue to be, subject to a number of risks and potential costs, including:

- changes in foreign medical reimbursement policies and programs;
- unexpected changes in foreign regulatory requirements;
- differing local product preferences and product requirements;
- diminished protection of intellectual property in some countries outside of the United States;
- differing payment cycles;
- trade protection measures and import or export licensing requirements;
- difficulty in staffing, training and managing foreign operations;
- differing legal regulations and labor relations;
- potentially negative consequences from changes in tax laws (including potentially taxes payable on earnings of foreign subsidiaries upon repatriation); and

political and economic instability.

In addition, Scient x is subject to risks arising from currency exchange rate fluctuations, which could increase the combined business s costs and may adversely affect its results of operations. The U.S. dollar value of Scient x s foreign-generated revenues varies with currency exchange rate fluctuations. Measured in local currency, the majority of Scient x s foreign-generated revenues were generated in Europe. Significant increases in the value of the U.S. dollar relative to foreign currencies could have a material adverse effect on the combined business s results of operations. Scient x s consolidated net sales were negatively affected by approximately 7.9% during the year ended December 31, 2010 as a result of the impact of foreign currency translation.

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We must retain the current distributors of our products and attract new distributors of our products.

As we launch new products and increase our marketing efforts with respect to existing products, we will need to expand our sales and marketing organization. We plan to accomplish this by increasing our network of independent distributors and hiring additional direct sales representatives. The establishment and development of a broader sales network and dedicated sales force may be expensive and time consuming. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified independent distributors and to hire additional direct sales representatives to work with us. Often, our competitors enter into distribution agreements with independent distributors that require such distributors to exclusively sell the products of our competitors. Further, we may not be able to enter into agreements with independent distributors on commercially reasonable terms, if at all. Even if we do enter into agreements with additional independent distributors, it often takes 90 to 120 days for new distributors to reach full operational effectiveness and such distributors may not generate revenue as quickly as we expect them to, commit the necessary resources to effectively market and sell our products or ultimately be successful in selling our products. Our business, financial condition and results of operations will be materially adversely affected if we do not retain our existing independent distributors and attract new, additional independent distributors or if the marketing and sales efforts of our independent distributors and our own direct sales representatives are unsuccessful.

We depend on various third-party suppliers, and in one case a single third-party supplier, for key raw materials used in our manufacturing processes and the loss of these third-party suppliers, or their inability to supply us with adequate raw materials, could harm our business.

We use a number of raw materials, including titanium, titanium alloys, stainless steel, PEEK, and human tissue. We rely from time to time on a number of suppliers and in one case on a single source vendor, Invibio, Inc. We have a supply agreement with Invibio, pursuant to which it supplies us with PEEK, a biocompatible plastic that we use in some of our spacers. Invibio is one of a limited number of companies approved to distribute PEEK in the U.S. for use in implantable devices. During 2010 and 2009, approximately 16% and 20%, respectively, of our revenues each year were derived from products manufactured using PEEK.

We depend on a limited number of sources of human tissue for use in our biologics products, and any failure to obtain tissue from these sources or to have the tissue processed by these entities for us in a timely manner will interfere with our ability to effectively meet demand for our biologics products. The processing of human tissue into biologics products is 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 for our biologics products are at times in particularly short supply. We cannot be certain that our supply of human tissue from our current suppliers and our current inventory of biologics products will be available at current levels or will be sufficient to meet our needs.

Our dependence on a single third-party PEEK supplier and the challenges we may face in obtaining adequate supplies of biologics products involve several risks, including limited control over pricing, availability, quality and delivery schedules. In addition, any supply interruption in a limited or sole sourced component or raw material, such as PEEK or human tissue, could materially harm our ability to manufacture our 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 significant adverse effect on our business, financial condition and results of operations.

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

Media reports or other negative publicity concerning both alleged improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of biologics products. Unfavorable reports of improper or illegal tissue recovery practices, both in the U.S. 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 biologics product. 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, which could have a negative effect on our biologics products business.

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Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse effect on us.

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators and third-party payors to control these costs and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products, limit the acceptance and availability of our products, and have a material adverse effect on our financial position and results of operations.

In March 2010, the U.S. Congress adopted and President Obama signed into law the the PPACA. The legislation imposes a 2.3% excise tax on domestic sales of medical devices following December 31, 2012. These taxes will result in a significant increase in the tax burden on our industry. Other elements of this legislation include numerous provisions to limit Medicare spending through reductions in various fee schedule payments and by instituting more sweeping payment reforms, such as bundled payments for episodes of care, the establishment of accountable care organizations under which hospitals and physicians will be able to share savings that result from cost control efforts, comparative effectiveness research, value-based purchasing, and the establishment of an independent payment advisory board. Many of these provisions will be implemented through the regulatory process, and policy details have not yet been finalized. In addition, PPACA has been subject to various legal and legislative challenges. For example, the U.S. House of Representatives recently voted to repeal PPACA, two courts have ruled that one provision, the minimum coverage rule, or so-called personal mandate, which is not scheduled to go into effect until 2014, is it unconstitutional. Other proposals have been introduced in Congress to repeal the device tax. We cannot predict with certainty whether PPACA will be fully implemented as enacted or what other healthcare initiatives at the federal or state level, if any, will be implemented. However, an expansion in government s role in the U.S. healthcare industry may lower reimbursements for our products, reduce medical procedure volumes and adversely affect our business and results of operations, possibly materially.

The demand for our products and the prices at which customers and patients are willing to pay for our products depend upon the ability of our customers to obtain adequate third-party coverage and reimbursement for their purchases of our products.

Sales of our products depend in part on the availability of adequate coverage and reimbursement from governmental and private payors. In the U.S., healthcare providers that purchase our products generally rely on third-party payors, principally Medicare, Medicaid and private health insurance plans, to pay for all or a portion of the costs and fees associated with the use of our products. While our currently marketed products are eligible for reimbursement in the U.S., if surgical procedures utilizing our products are performed on an outpatient basis, it is possible that private payors may no longer provide reimbursement for our products without further supporting data on our procedure. Any delays in obtaining, or an inability to obtain, adequate coverage or reimbursement for procedures using our products could significantly affect the acceptance of our products and have a significant adverse effect on our business. Additionally, third-party payors continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. Our business would be negatively impacted to the extent any such changes reduce reimbursement for our products.

With respect to coverage and reimbursement outside of the U.S., reimbursement systems in international markets vary significantly by country, and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis and can take up to 18 months, or longer. Many international markets have government-managed healthcare systems that govern reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. Reimbursement in international markets may require us to undertake country-specific reimbursement activities, including additional clinical studies, which could be time consuming, expensive and may not yield acceptable reimbursement rates.

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Furthermore, healthcare costs have risen significantly over the past decade. There have been and may continue to be proposals by legislators, regulators and third-party payors to contain these costs. Several such proposals were enacted as part of PPACA, and include numerous provisions to limit Medicare spending through reductions in various fee schedule payments and sweeping payment reforms. Other federal and state cost-control measures include prospective payment systems, capitated rates, group purchasing, redesign of benefits, requiring pre-authorizations or second opinions prior to major surgery, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare. Some healthcare providers in the U.S. have adopted or are considering a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may also attempt to control costs by authorizing fewer elective surgical procedures or by requiring the use of the least expensive devices possible. These cost-control methods also potentially limit the amount which healthcare providers may be willing to pay for medical devices. In addition, in the U.S., no uniform policy of coverage and reimbursement for medical technology exists among all these payors. Therefore, coverage of and reimbursement for medical technology can differ significantly from payor to payor. The continuing efforts of third-party payors, whether governmental or commercial, whether inside the U.S. or outside, to contain or reduce these costs, combined with closer scrutiny of such costs, could restrict our customers ability to obtain adequate coverage and reimbursement from these third-party payors. The cost containment measures contained in PPACA and other measures being considered at the federal and state level, as well as internationally, could harm our business by adversely affecting the demand for our products or the price at which we can sell our products.

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, financial condition or results of operations.

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 create new companies with greater market power, including hospitals. 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 some of our customers. We expect that market demand, government regulation, third-party 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, financial condition or results of operations.

We may be subject to or otherwise affected by federal and state healthcare laws, including fraud and abuse, health information privacy and security, and disclosure laws, and could face substantial penalties if we are unable to fully comply with such laws.

Although we do not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from Medicare, Medicaid, or other third-party payors for our products or the procedures in which our products are used, healthcare regulation by federal and state governments significantly impacts our business. Healthcare fraud and abuse, health information privacy and security, and disclosure laws potentially applicable to our operations include:

- the federal Anti-Kickback Law, as well as state analogs, which constrains our marketing practices and those of our independent sales agents and distributors, educational programs, pricing policies, and relationships with healthcare providers by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing remuneration, intended to induce the purchase or recommendation of an item or service reimbursable under a federal (or state or commercial) healthcare program (such as the Medicare or Medicaid programs);

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the federal ban, as well as state analogs, on physician self-referrals, which prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain designated health services if the physician or an immediate family member of the physician has any financial relationship with the entity;

federal false claims laws which prohibit, among other things, 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, or HIPAA, and its implementing regulations, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information;

the state and federal laws sunshine provisions that require the reporting and disclosures of any transfer of value made or distributed to prescribers and other health care providers, require the adoption of marketing codes of conduct, and constrain their relationships with physicians and other referral sources; and

state laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

PPACA includes various provisions designed to strengthen significantly fraud and abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal anti-kickback statute and criminal healthcare fraud statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it.

If our past or present operations, or those of our independent sales agents and distributors are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal healthcare programs and/or the curtailment or restructuring of our operations. Similarly, if the healthcare providers, sales agents, distributors or other entities with whom we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the Courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business.

In January 2004, the Advanced Medical Technology Association or AdvaMed, the principal U.S. trade association for the medical device industry, put in place a model code of conduct that sets forth standards by which its members should abide in the promotion of their products. We have in place policies and procedures for compliance that we believe are at least as stringent as those set forth in the AdvaMed Code, and we provide routine training to our sales and marketing personnel on our policies regarding sales and marketing practices. The AdvaMed Code was revised in 2009 to make it more stringent with respect to interactions with healthcare professionals. We have adopted the new aspects of the revised AdvaMed Code.

The sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies, and we believe that this trend will continue. Prosecutorial scrutiny and governmental oversight over some major device companies regarding the retention of healthcare professionals as consultants has affected and may continue to affect the manner in which medical device companies may retain

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healthcare professionals as consultants. We have in place policies to govern how we may retain healthcare professionals as consultants that reflect the current climate on this issue and are providing training on these policies. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business.

If we or our suppliers fail to comply with the FDA s quality system and good tissue practice regulations, the manufacture of our products could be delayed.

We and our suppliers are required to comply with the FDA s QSRs, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, record keeping, storage and shipping of our products. In addition, suppliers and processors of allograft must comply with the FDA s current good tissue practice regulations, or CGTPs, which govern the methods used in and the facilities and controls used for the manufacture of human cell tissue and cellular and biologics products, record keeping and the establishment of a quality program. The FDA audits compliance with the QSRs and CGTPs through inspections of manufacturing and other facilities. If we or our suppliers have significant non-compliance issues or if any corrective action plan is not sufficient, we or our suppliers could be forced to delay the manufacture of our products until such problems are corrected to the FDA s satisfaction, which could have a material adverse effect on our business, financial condition and results of operations. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement demanding that we seek additional approvals or clearances could result in delays, costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA, all of which could have a material adverse effect on our business, financial condition and results of operations.

The FDA inspected our Carlsbad, California facilities in January 2010 and non-compliance items were cited on an FDA Form 483 that we received following the inspection. In June 2010, we received a Warning Letter from the Irvine District office of the FDA. The Warning Letter related specifically to non-conformances in quality systems previously identified in the Form 483 that was related to the January inspection. We have has responded to the Warning Letter and completed corrective actions to address the observations. The FDA conducted a planned re-inspection of our Carlsbad, California facility in December 2010, and we are awaiting the results of such inspection. Following the receipt of the Warning Letter we developed a comprehensive plan to review and augment the quality systems at our Carlsbad, California facility, and we have implemented nearly all of the measures outlined in that plan. At this time, we do not currently believe that the Warning Letter has had or will have a material effect on our business. Nonetheless, if the FDA were to raise additional concerns regarding the adequacy of our corrective actions taken in response to the Warning Letter, the FDA could take further action that could have a material adverse effect on our business and operations.

If we fail to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or modifications to our products, our ability to commercially distribute and market our products could suffer.

Our medical devices are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of most new medical devices only after the devices have received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or 510(k), or are the subject of an approved premarket approval application, or a PMA. The 510(k) process generally takes three to nine months, but can take significantly longer, especially if the FDA requires a clinical study to support the 510(k) application. In connection with the 510(k) we submitted for the OsseoFix system, the FDA required clinical data to support the 510(k). Currently, we are not certain as to whether the FDA will require clinical data in support of any other

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510(k)s that we intend to submit for other products in our pipeline. In addition, the FDA is currently re-examining its 510(k) clearance process for medical devices and any changes that make the process more restrictive could increase the time it takes for us to obtain clearances or could make the 510(k) process unavailable for certain of our products. A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process or is not exempt from premarket review by the FDA. A PMA must be supported by extensive data, including results of preclinical studies and clinical trials, manufacturing and control data and proposed labeling, to demonstrate to the FDA s satisfaction the safety and effectiveness of the device for its intended use. The PMA process is more costly and uncertain than the 510(k) clearance process, and generally takes between one and three years, if not longer. In addition, 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, a PMA.

Our commercial distribution and marketing of any products or product modifications that we develop may be delayed since regulatory clearance or approval is required. In addition, because we cannot assure you that any new products or any product modifications we develop will be subject to the shorter 510(k) clearance process, the regulatory approval process for our new products or product modifications may take significantly longer than anticipated. There is no assurance that the FDA will not require a new product or product modification to go through the lengthy and expensive PMA approval process. Delays in obtaining regulatory clearances and approvals may:

- delay or prevent commercialization of products we develop;
- require us to perform costly procedures;
- diminish any competitive advantages that we might otherwise have obtained; and
- reduce our ability to collect revenues.

To date, all of our medical device products that have required FDA review that are being sold in the U.S. have been cleared through the 510(k) process without any required clinical trials. We have no experience in obtaining approval for a device through the 510(k) clinical trial process or the PMA process.

Our biologics products and related technologies could become subject to significantly greater regulation by the FDA, which could disrupt our business.

The FDA may regulate certain biologics products as medical devices, drugs or biologics if the product is deemed to have been more than minimally manipulated or indicated for nonhomologous use. Homologous use is generally interpreted as the use of tissue for the same basic function in the recipient as it fulfilled in the donor. If the FDA decides that any of our current or future biologics products are more than minimally manipulated or indicated for nonhomologous use, it would require us to either obtain 510(k) clearance or a PMA approval if the biologics product is viewed as a medical device or obtain approval as a drug or biologics if it is viewed as a drug or biologics. Depending on the nature and extent of any FDA decision applicable to our biologics products, further distribution of the affected products could be interrupted for a substantial period of time, which would reduce our revenues and hurt our profitability.

The safety of our products is not yet supported by long-term clinical data and may therefore prove to be less safe and effective than initially thought.

We obtained clearance to offer all of our current medical device products through the FDA s 510(k) clearance process. The 510(k) clearance process is generally based on the FDA s agreement that a new product is substantially equivalent to already marketed products. Thus, the FDA s 510(k) review process is less rigorous than the PMA process and requires little, if any, supporting clinical data. For these reasons, surgeons may be slow to adopt our 510(k)-cleared products, we may not have the comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. With the passage of the American Recovery and Reinvestment Act of 2009, funds have been appropriated for the U.S. Department of

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Health and Human Services Healthcare Research and Quality to conduct comparative effectiveness research to determine the effectiveness of different drugs, medical devices, and procedures in treating certain conditions and diseases. Some of our products or procedures performed with our products could become the subject of such research. It is unknown what effect, if any, this research may have on our business. Further, future research or experience may indicate that treatment with our products does not improve patient outcomes. Such results would reduce demand for our products and this could cause us to withdraw our products from the market. Moreover, if future research or experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability, significant negative publicity, damage to our reputation and a dramatic reduction in sales of our products, all of which would have a material adverse effect on our business, financial condition and results of operations.

If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval in the U.S., we will be unable to commercialize these products.

Several investigational devices in our development pipeline, including our OsseoFix Spinal Fracture Reduction System, require either a 510(k) with clinical trial data or a PMA from the FDA before we can market such product in the U.S. The clinical trial is required by the FDA to demonstrate to the FDA s satisfaction the safety and effectiveness of the device for its intended use. As a result, to receive regulatory approval in the U.S. for OsseoFix, we must conduct, at our own expense, a clinical trial to demonstrate efficacy and safety in humans. Clinical testing is expensive and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. Our failure to adequately demonstrate the efficacy and safety of any of our devices would prevent receipt of regulatory approval and, ultimately, the commercialization of that device.

Our international operations may expose us to liabilities under the Foreign Corrupt Practices Act and Money Laundering Laws.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act, or FCPA, which generally prohibits companies and their intermediaries from making corrupt payments to foreign officials for the purpose of obtaining or keeping business or otherwise obtaining favorable treatment, and requires companies to maintain adequate record keeping and internal accounting practices to accurately reflect the transactions of the company. We are also subject to a number of other laws and regulations relating to money laundering, international money transfers and electronic fund transfers, which we collectively refer to as Money Laundering Laws. These laws apply to companies, individual directors, officers, employees and agents.

We operate in a number of jurisdictions with developing economies that pose a high risk of potential violations of the FCPA and Money Laundering Laws, and we utilize third-party distributorships that have government customers. If our employees, third-party distributors or other agents are found to have engaged in such practices, we could suffer severe penalties, including criminal and civil penalties, disgorgement and other remedial measures, any of whi