Alphatec Holdings, Inc.
Form 10-K
March 05, 2012
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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, 2011

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: None

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 x 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, 2011 was approximately $192.0 million.

The number of outstanding shares of the registrant s common stock, par value $0.0001 per share, as of February 29, 2012 was 89,592,795.

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 2012 Annual Meeting of Stockholders.

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ALPHATEC HOLDINGS, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2011

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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. By referring to our website, we do not incorporate the website or any portion of the website by reference into this Annual Report. 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. Our principal product offerings are focused on the global market for orthopedic spinal disorder solutions. 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. 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.

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

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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 115 independent distributors, which we believe employ approximately 275 sales representatives. We also employ 30 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, sales management employees and executives.

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, Africa, Asia and Latin America. We plan to continue expanding our distribution network and product offerings throughout the world.

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.

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.

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Some of the most common degenerative conditions and deformities 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 synthetic products while others complement our synthetic 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
	Trestle Luxe Anterior Cervical Plate
	Solanas Posterior Cervico/Thoracic Fixation System
	Avalon Occipital Plate
	DiscoCerv Artificial Disc*
	PCB Evolution*
Thoracolumbar Fixation	Zodiac Degenerative Fixation System
	Zodiac Deformity Fixation System with Smart Set
	TTL IN Fixation System
	Xenon Fixation System
	Isobar Evolution Dynamic Rod*
	Aspida Anterior Lumbar Interbody Plate System
	TTL-D Fixation System*
	Hemi Fixation System
Spinal Spacers	Novel Spinal Spacers
	Alphatec 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	Preview Anterior Cervical Plate
Thoracolumbar	Next-Generation Degenerative and Deformity Fixation Systems
MIS	Raptor Facet Fixation System
Aging Spine	OsseoFix Next-Generation Implant

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Cervical and Cervico-Thoracic Products

Trestle Luxe Anterior Cervical Plate System

Our Trestle Luxe 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 Luxe 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 irritation of the tissue adjacent to the plate following surgery. Other key features of the Trestle Luxe 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.

Solanas Posterior Cervico/Thoracic Fixation System and Avalon Occipital Plate

Our Solanas Posterior Cervico/Thoracic Fixation System consists of rods, polyaxial screws, hooks, and connectors that provide a solution for posterior cervico/thoracic fusion procedures. We also designed the Solanas Posterior Cervico/Thoracic System to be used in combination with our existing Zodiac Degenrative Fixation System and our Avalon Occipital Plate, thereby providing surgeons with a solution for occipito-cervico-thoracic fixation. The Avalon Occipital Plate has a unique buttress design for optimal bone graft placement and superior fusion, including three points of plate rotation and translation, which is designed to ease the placement of the plate.

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, connectors 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 Spinal Spacers and our AlphaGraft Structural Allograft Spacers.

Zodiac Deformity Fixation System with Smart Set

Our Zodiac Smart Set Deformity Fixation System is a comprehensive system of instrumentation and implants designed to enable the surgeon to address patient-specific spinal deformity procedures. Our Zodiac Smart Set is designed to be used in conjunction with the Zodiac Deformity Fixation System, as well as many of our other products, including our Zodiac Degenerative Fixation System, our Novel Spinal Spacers and our AlphaGraft Structural Allograft Spacers. Our Zodiac Smart Set has several components that are frequently used in deformity surgeries, such as fixed and uniplanar screws, rods in multiple alloys, hooks, connectors and deformity specific instrumentation.

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 Aspida 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 Aspida ALIF Plate System is designed to be anatomically shaped and have a low profile, which is intended to minimize the risk of irritation or damage to the adjacent tissue.

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Spinal Spacers

Novel PEEK and Titanium Spinal Spacers

Our family of Novel 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. Certain of our Novel spacers are made of titanium and others are made of a strong, heat resistant, radiolucent, biocompatible plastic called polyetheretherketone, or PEEK. Our Novel PEEK spinal spacers have been approved for use in both the lumbar and cervical regions of the spine. A PEEK spacer is not visible during a magnetic resonance imaging, which allows the surgeon to better assess the progress of the healing process following surgery. 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.

Alphatec Solus Locking ALIF Spacer

Our Alphatec Solus locking spinal spacer is a zero-profile PEEK and titanium device offering four points of fixation for improved stability. Alphatec Solus features a one-step insertion and deployment feature and is used in ALIF procedures. We believe that Alphatec Solus locking mechanism is a substantial upgrade over similar products currently on the market.

Minimally Invasive Surgery, or MIS Products

Illico Minimally Invasive Surgery System

The Illico Minimally Invasive Surgery 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 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 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 PMMAbone 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. In early 2012, the Company filed an Investigational Device Exemption with the U.S. FDA to begin a clinical study of the OsseoFix System. The OsseoFix System is available for sale in the European Union.

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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. The OsseoScrew System is not available for sale in the U.S. 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 widening 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. In addition, many of our allograft spacers are packaged in our VIP packaging system. VIP is a packaging and fluid delivery system that allows for fast and efficient infusion of the surgeon s choice of hydration fluid. The VIP system provides rapid and uniform hydration reducing the brittleness of the graft and reducing the length of a surgical procedure.

PureGen Osteoprogenitor Cell Allograft

Our PureGen Osteoprogenitor Cell Allograft is a unique adult stem cell that supplements the body s own cells and helps to stabilize the repair site allowing the healing process to advance naturally and efficiently. There is a significant clinical need to improve fusion rates, especially in patients with impaired wound healing due to age, obesity, diabetes, smoking, anti-inflammatory meds, and other factors. PureGen is a safe and natural alternative to autograft, and other expensive fusion options.

AlphaGraft ProFuse Demineralized Bone Scaffold

Our AlphaGraft ProFuse Bone Scaffold consists of a sponge-like demineralized bone matrix that has been pre-cut into sizes to fit within a spinal spacer. 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.

Amnioshield Amniotic Tissue Barrier

Our Amnioshield Amniotic Tissue Barrier is an allograft for spinal surgical barrier applications. The composite amniotic membrane reduces inflammation and enhances healing at the surgical site, reduces scar tissue formation and provides an excellent dissection plane.

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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.

Sales and Marketing

Our U.S. sales force consists of over 115 independent distributors, which we believe employ approximately 275 agents dedicated to selling our products in the U.S., and 30 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 sales and product training to each of our independent distributors and direct sales representatives. 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 approximately 20 direct sales representatives, and in the rest of Europe we have approximately 50 independent distributors. We have 15 direct sales representatives in Japan and 11 independent distributors in the rest of Asia. In Latin America and South America we conduct our sales and marketing activities through our subsidiary, Cibramed Products Medicos Ltda., which we plan to rename Alphatec Spine do Brazil. Currently, we have 5 sales and marketing employees in Latin America and South America, and 12 independent distributors selling our products in Latin America and South 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 direct sales and distribution network and product offerings throughout the world. Similar to our sales and marketing activities in the U.S., outside of 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 and South America.

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 benefits and 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.

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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, VCFs, 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 a large portion of our manufacturing operations at our facilities in Carlsbad, California, although we also manufacture products at our facility in Beaurains, France. We manufacture a significant amount of our non-biologic 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.

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.

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. 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 in implantable devices.

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. See Item 1A Risk Factors. Our manufacturing operations and those of the third-party manufacturers we use are subject to extensive regulation by the FDA or similar entities outside of the U.S. under its quality systems regulations, or QSRs, and other applicable device-related good manufacturing practices, or GMPs, or tissue-related tissue practices, or GTPs, and applicable local regulations. With respect to biologics products, we are FDA-registered and licensed in the states of California, New York and Florida, the only states that currently require licenses. Our facility and the facilities

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of the third-party manufacturers we use 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 February 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 February inspection. We have responded to the Warning Letter and completed corrective actions that we believe fully address the observations. Subsequent to a follow-up audit of our Carlsbad, California facility in December 2010, the FDA issued a close-out letter dated September 28, 2011 in which the FDA stated that the Company has resolved all the deficiencies contained in the Warning Letter.

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.

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 spinal implant 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,

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distributors and advisors to execute agreements governing the ownership of proprietary information and use and disclosure of confidential information in connection with their relationship with us. In general, 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, 2011, we owned 58 issued U.S. patents, 31 pending U.S. patent applications and 341 issued or pending foreign patents. 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.

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 manufacture or market infringes their patents.

If we are accused of patent infringement, 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 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.

Trademarks

As of December 31, 2011, we owned these registered US marks: Adonys, Aging Spine Center design/logo, Aladyn, Alpha symbol design/logo, Alphagraft, Alphagraft Duofuse, Alphagraft Nanoblast, Alphagraft Profuse, Alphatec, Alphatec Spine, Inc. logo, Alphatec Spine design/logo, Amnioshield, Antelys, ARC, Aspida, Aurys, Biofill, Bone x, Calisto, Cerviplaque, Chorus, Claris, Corelys, Corlok, Cortek, C design, Cortek design/logo, Deltaloc, Discocerv, Dovetome, Dynoss, Dynamic-TTL Rod, Easys, Electra, Elfix, Ellys, Helifix, Illico,

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Inspiration, Isobar, Isobar Duo, Isobar Evolution, Isobar Hemispherical Screw, Isobar LP, Isobar SL, Isobar TTC, Isobar TTL, Isobar U-Screw, Majorys, MX System, Novel, Openview, Oria, OsseoFix, OsseoFix+, Osseoscrew, Pach, Pantheon, Preview, Samarys, Scient x, Solanas, Solo, Solutions for the Aging Spine, Stella, Tamarack, Trestle, Tribeca, X, Xenon, and Zodiac.

License and Supply Agreements

As part of our product development strategy, we enter 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.

License Agreement with Vertebration, Inc.

In March 2011, we entered into a License Agreement, or, the Vertebration Agreement with Vertebration, Inc., or, Vertebration that provides us with an exclusive license to develop and commercialize Vertebration s proprietary licensed technology related to its Xycor implant and related instrumentation. The Xycor implant has received 510(k) approval for marketing by the FDA. The financial terms of the Vertebration License Agreement include: (i) a cash payment of $0.5 million following the execution of the Vertebration License Agreement, of which $0.1 million will be credited against amounts payable to Vertebration at a future date and $0.1 million will be repaid by Vertebration in March 2014; (ii) additional cash payments totaling $0.2 million which were paid and expensed in 2011; (iii) development and sales milestone payments in cash that could begin to be achieved and paid in 2012; and (iv) payments consisting of either: (a) a royalty based on net sales of licensed products or (b) a payment of percentage of our gross margin, with the type of payment dependent on the manner in which the product was sold, with minimum annual payments beginning in the year after the first commercial sale of a licensed product. During the first quarter of 2011, we recorded an intangible asset of $0.4 million following the execution of the Vertebration License Agreement. We are amortizing this asset over seven years, the estimated life of the Xycor product.

Our additional key agreements are described in Note 5 to our consolidated financial statements under Part II, Item 8 Financial Statements and Supplementary Data.

Government Regulation

Our products are 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;
- 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.

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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, or 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.

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

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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, application 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;