Alphatec Holdings, Inc.
Form 10-K
March 04, 2009
Table of Contents

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, 2008

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 Act:

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

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 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, 2008 was approximately $110.0 million.

The number of outstanding shares of the registrant s common stock, par value $0.0001 per share, as of March 2, 2009 was 47,377,953.

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 2009 Annual Meeting of Stockholders.

Table of Contents

ALPHATEC HOLDINGS, INC.

FORM 10-K ANNUAL REPORT

For the Fiscal Year Ended December 31, 2008

Table of Contents

Table of Contents

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 and our includes Alphatec Holdings, Inc., or Alphatec or Alphatec Holdings, and our subsidiaries.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and, accordingly, file reports, proxy statements and other information with the Securities and Exchange Commission, or the SEC. Such reports, proxy statements and other information can be read and copied at the public reference facilities maintained by the SEC at the Public Reference Room, 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Information regarding the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The Securities and Exchange Commission maintains a website (http://www.sec.gov) that contains material regarding issuers that file with the Securities and Exchange Commission.

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. Our broad product portfolio and pipeline includes a variety of spinal disorder products and systems focused on solutions addressing the cervical, thoracolumbar, intervertebral, minimally invasive, vertebral compression fracture, osteoporotic bone, and spinal stenosis markets. Our principal product offerings are focused on the market for orthopedic spinal disorder solution products, which is estimated in the U.S. to be more than $5.8 billion in revenue in 2008 and is expected to grow more than 10% annually over the next three years. 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 and a strong, heat resistant, radiolucent, biocompatible plastic called polyetheretherketone, or PEEK. We also sell products made of allograft, a precision-milled and processed human bone that surgeons can use in place of metal and synthetic materials. We also sell bone-grafting products that are comprised of both tissue-based 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. have been cleared by the U.S. Food and Drug Administration, or the FDA, and these products have been used in over 10,700 and 8,600 spine disorder surgeries in 2008 and 2007, respectively. In addition to selling our products in the U.S., we also sell our products in Japan, the European Union and Hong Kong.

Strategy

Our strategy is to be the 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 dealing with 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

Table of Contents

will incorporate minimally invasive access techniques, and integrated biologic solutions to improve patient outcomes across our product portfolio. 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 to market innovative products, we understand that surgeons make the ultimate decision as to whether our products are used in a surgical procedure. 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 Offering. We currently 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 offering 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 osteoporatic bones, 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.

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 information 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, while improving patient outcomes.

License or Acquire Complementary Spine Products and Technologies. In addition to building our product portfolio through internal product development efforts, we have licensed and will continue to license or acquire complementary spine products and technologies. By licensing or acquiring complementary products and technologies, we believe we can leverage our expertise at bringing new products to market and provide additional marketing opportunities for our sales organization.

Focus on Rapid Responsiveness and Total Surgeon Satisfaction. We believe that our focus on rapid responsiveness to surgeon needs and the support we provide to surgeons differentiate us in the marketplace. We have the capability to manufacture substantially all of our non-allograft products at our facilities, which enables us to rapidly modify implants and instruments to satisfy surgeons needs and rapidly replenish inventory. This allows us to respond quickly to unexpected increases in market demand for our products. Our ability to respond to surgeons needs through rapid prototyping and manufacturing of customized products allows us to continually differentiate ourselves from our competitors. Responding quickly to the needs of surgeons is central to our corporate culture.

Enhance U.S. Sales and Marketing Efforts. Our products are sold in the U.S. through a network of approximately 85 independent distributors, which we believe employ approximately 240 agents. We also employ 17 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 educate and support our independent distributors, often our first point of contact with surgeons, as if they were part of our organization.

Table of Contents

Increase the Exclusivity of our Sales Force. We believe that having a sales force dedicated to selling only our spinal products will lead to greater market penetration and increased sales. In 2008, we increased the percentage of exclusive distributors in the U.S. from approximately 40% as of December 31, 2007 to approximately 70% as of December 31, 2008.

Grow our International Business. We have an established presence in Japan. We plan to continue expanding our distribution network and product offerings throughout Asia. In 2008 we obtained the necessary regulatory clearances and began selling our products in Europe through distribution agents that exclusively sell our spinal products. We also plan 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.

A picture of the spinal column and vertebral bodies of the spine is depicted below.

Table of Contents

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, bone cement for use in a vertebroplasty and various biologic offerings. In addition, in Europe we sell an additional solution for treating vertebral compression fractures. Generally, spine screws are inserted into the vertebrae in order to affix rods, plates and other stabilizing devices during spine procedures using our products. Spinal spacers are inserted between vertebrae and are used to provide spinal support in order to restore lost disc space, alignment, and weight-bearing function. Plates are attached to adjacent vertebrae to further stabilize the vertebrae and facilitate healing. Polymethylmethacrylate, or PMMA, bone cement is inserted into a vertebral compression fracture to stabilize the fracture. In addition, in Europe we sell our OsseoFix implant, which provides additional stabilization of a VCF prior to the use of PMMA. Certain of our biologics offerings are used as an alternative to our polyetheretherketone, or PEEK, or metal products while others complement such products by promoting fusion.

We currently sell our spinal solution products as spine systems, categorized by the spinal disorder and the method of treatment. The chart below illustrates our broad portfolio of currently marketed spine systems and our systems under development and includes the distinguishing features and components for our systems.

Table of Contents

Current Products:

Category	Alphatec System	System Features and Components
Thoracolumbar Fixation Systems	Zodiac Degenerative Fixation	Polyaxial pedicle screws, rods and cross connectors, with instrumentation
	CORE Lumbar Plating	Fixed-post pedicle screws and rigid connector plates, with instrumentation
Deformity Fixation Systems	Zodiac Deformity Fixation	Screws, hooks, rods, and connectors comprised of either titanium or stainless steel, with instrumentation
Spinal Spacers	Novel PEEK and Titanium Spacers	Spinal spacers made of PEEK or titanium in various shapes and sizes for use in both the lumbar and cervical regions of the spine, with instrumentation
Allograft Spacers	Connect, Connect II, Solo and Duet Allograft Spacers	Spinal spacers made of dense, porous, cancellous human tissue, in various shapes and sizes, with instrumentation
Anterior Cervical Plating	Trestle Anterior Cervical Plate	Cervical plates, and fixed and variable screws, with instrumentation
	Reveal Anterior Cervical Plate	Cervical plates, and fixed and variable screws, with instrumentation
Posterior Cervico/Thoracic Fixation	Solanas Posterior Cervico/Thoracic Fixation	Polyaxial pedicle screws, rods, hooks and connectors, with instrumentation
Trauma/Tumor	Tamarack Anterior Thoracolumbar Plating	Spinal fusion plates and screws, with instrumentation
Bone Grafting Materials	Alphagraft and Alphagrans	Tissue-based and synthetic bone grafting materials
	ProFuse Bone Grafting Scaffold	Sponge-like demineralized bone matrix designed for use with our spinal spacers that allows for enhanced contact with endplates after the spacer is inserted
Treatments for Vertebral Compression Fractures	OsseoFix+	Stand-alone verteboplasty system using proprietary PMMA bone cement.
Minimally Invasive Access Systems and Techniques	Illico Minimally Invasive System	Minimally invasive access system that includes a retractor and implant delivery system
Proprietary Packaging Systems	Vacuum Infusion Packaging (VIP) System	Packaging system for allografts and Profuse Scaffold that uses a vacuum to provide rapid hydration

Table of Contents

Products in Development:

Category	Alphatec System	System Features and Components
Treatments for Vertical Compression Fractures	OsseoFix	Minimally invasive device that stabilizes the vertebral body. The FDA has required a clinical study in the U.S. in connection with its 510(k) application. This product is only available for sale in Europe.
Treatments for Osteoporotic Patients	OsseoScrew	Polyaxial pedicle screw that is designed to expand after implantation to increase screw fixation purchase in patients with poor bone density
Minimally Invasive Access Systems and Techniques	Guided Lumbar Interbody Fusion System, or GLIF System	Minimally invasive access system that is designed to allow multiple access planes to the patient s spinal pathology through one incision point
Cervico/Thoracic Occipital Plate	Posterior Occipital Plate	Occipital plate used with a posterior cervico/thoracic fixation systems
Stand-Alone Anterior Plates and Spacers	Anterior Lumbar Interbody Fusion Plate	Stand-alone fusion plating system that is designed to enable surgeons to perform anterior lumbar fusions without the need for the use of posterior spine implants
	Anterior Lumbar Spacer	Stand-alone spinal cage with a proprietary locking mechanism to prevent migration after insertion
Treatments for Lumbar Spinal Stenosis	Helifix/Helifuse	Minimally invasive devices used to treat lumbar spinal stenosis
	Interspinous Process Plating System	Plating system used to treat spinal stenosis
Expandable Implants	Expandable Interbody Device	An expandable interbody device that is designed to be implanted into the disc space and then expanded during spine surgery

Our Current Products

Thoracolumbar Fixation Systems

Thoracolumbar fixation systems are used to facilitate fusion, the growth of a bony connection between two adjacent vertebrae. The purpose of fusion is to stop the motion caused by the instability between the vertebrae, which is intended to reduce the pressure on the spinal cord. Our systems are designed to reduce the motion of the vertebrae during the period it takes for the vertebrae to fuse together. Our Zodiac systems consist of multiple components made of titanium or stainless steel, including screws, rods, and cross connectors. Pedicle screws are surgically positioned from the posterior, or back, of the spine and are placed into the pedicle. The screws are inserted through the midline of the pedicle and act as anchors for the rods that connect two or more vertebrae. Once the rods and screws are put in place, the system provides a fixed environment with corrected alignment to facilitate the fusion.

Table of Contents

Because each vertebra varies in size, shape and alignment, screw heads that pivot relative to the post of the screw allows surgeons to achieve proper screw placement. Most pedicle screws are available with either a fixed or polyaxial head design. The pivoting head of a polyaxial screw makes it possible to implant a rod through multiple screw heads, despite the fact that the screws connected to the rod may be out of alignment with each other due to the positioning of the patient s vertebrae. Once the screws and rods are in place, a set screw is used to lock the rod to the head of the screw and secure the polyaxial head of the screw. Often a cross connector, which is a device that connects the two rods, is also used to laterally connect the rods in order to further stabilize the construct.

Zodiac Degenerative Fixation System

Our Zodiac Degenerative Fixation System is a comprehensive spinal system that offers a wide variety of polyaxial pedicle screws, fixed-angle 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 Allograft Spacers.

CORE Lumbar Plating System

Our CORE Lumbar Plating System is a posterior lumbar plating system that provides an alternative to traditional screw and rod constructs. The CORE system is comprised of a rigid pre-contoured plate that is anchored by fixed-post pedicle screws. We believe that this design makes the CORE system particularly effective in the treatment of spondylolisthesis.

Deformity Fixation Systems

Screw, hook and rod constructs have become the standard of care in the surgical treatment of spinal deformities such as scoliosis. These constructs aid in the correction of spinal deformities because they allow movement of the spine into the correct alignment while providing fixation and stability to help achieve fusion.

Zodiac Deformity Fixation System

Our Zodiac Deformity Fixation System is designed to be used in conjunction with many of our other products, including our Zodiac Degenerative Fixation System, our Zodiac Trauma/Tumor Fixation System, our Novel Spacers and our Allograft Spacers. Our Zodiac Deformity Fixation System has components such as fixed-angle and polyaxial screws and instrumentation that are designed to enable the surgeon to address patient-specific spinal deformities.

Spinal Spacers

A spinal spacer is intended to be inserted in the space between vertebrae to provide support in order to restore disc space height, alignment, and the spine s weight-bearing function. In a typical surgical procedure, the surgeon will use a spacer to replace the diseased or damaged space between vertebrae. Spinal spacers are used in combination with screw, rod and plate constructs. All spinal spacers, regardless of composite material, are available in a variety of shapes and sizes to fit the patient s anatomy. While our first spinal spacers were principally fabricated from titanium, we now offer products fabricated from PEEK as well as titanium.

Table of Contents

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 five unique implant designs, each of which is available in numerous shapes and heights. Our Novel PEEK spinal spacers have also 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, or MRI, which allows the surgeon to better assess the progress of the healing process post surgery.

Allograft Spacers

The use of allograft-derived products appeals to many surgeons because such surgeons believe that the use of allograft allows patients to accelerate the creation of living bone cells and eventually incorporate the allograft into the newly created, living bone. Allograft-derived products are fabricated from cadaver bone and precision-machined into standardized shapes resembling PEEK or titanium spacers. Tissue banks are responsible for recovering and processing donated tissue from cadavers in accordance with standards developed by the American Association of Tissue Banks and the FDA.

Connect, Connect II, Solo and Duet 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 four 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 each 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 less-dense allograft.

Anterior Cervical Plating

Anterior solutions to cervical, or neck, pathologies are considered to be the standard of care in cervical fusion. In cases where surgery is needed to alleviate pressure on a nerve or the spinal cord, often the surgeon removes large portions of the disc material or vertebrae. The more disc material that is removed or vertebrae that are affected, the less stable the surgical site becomes, which increases the need to use a cervical plate to stabilize the surgery site. The most common cervical fusion performed is anterior cervical plating, or ACP. In an ACP procedure, a metal plate is inserted across adjacent neck vertebrae and secured in place by interlocking screws. The cervical plate stabilizes the vertebrae to facilitate fusion.

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 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 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.

Reveal Anterior Cervical Plate System

Our Reveal Anterior Cervical Plate System features a large window that enables the surgeon to see the graft site during surgery which is designed to allow for better placement of the plate. The Reveal Plate system s

Table of Contents

locking mechanism reduces the number of steps required by the surgeon to lock the screws to the plate, which saves time during surgery and allows a surgeon to visually confirm whether the mechanism has been locked.

Posterior Cervico/Thoracic Fixation

Solanas Posterior Cervico/Thoracic Fixation

Our Solanas Posterior Cervico/Thoracic Fixation System consists of rods, polyaxial screws and connection devices that provide a solution for posterior cervico/thoracic 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.

Trauma/Tumor Systems

Some pathologies in the thoracolumbar, or upper chest region, such as burst fractures or collapsed vertebrae, require surgical access from the anterior plane of the patient. In such instances, systems comprised of rods or plates are affixed with screws and staples to achieve stabilization. In anterior thoracolumbar procedures, these constructs also can be used in some cases to treat degenerative disc disease and other deformities.

Tamarack Anterior Thoracolumbar Plating System

Our Tamarack Anterior Thoracolumbar Plating System consists of a plate that sits on top of two smaller plates at each of its ends. These smaller plates act as a locking mechanism that prevent post-surgery expulsion of the screw and reduces possible irritation and internal complications. We believe this dual-plate design provides a unique solution for trauma or tumor conditions. Our Tamarack Plating system also has a large interior opening that allows the surgeon to see the graft site both during surgery and in a post-surgery MRI, which permits unrestricted operative and post-operative evaluation of the surgery site.

Bone Grafting Materials

Bone grafting materials are often used by a surgeon during surgery to fill voids or gaps that are caused by trauma or the surgical procedure.

Alphagraft and Alphagrans

Our Alphagraft product is a demineralized bone matrix, or DBM, mixed with a bioabsorbable carrier that is used for bone grafting. Our Alphagrans product consists of bioabsorbable synthetic granules that are used for bone grafting.

Profuse Bone Grafting Scaffold

Our Profuse product consists of a sponge-like DBM that has been cut into precise sizes to fit within our spinal spacers. The 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 scaffolds expands for maximum contact between the spinal spacer and the endplate of the vertebral body and is designed to promote fusion. The ProFuse scaffold comes pre-packaged in the vacuum infusion packaging system.

Table of Contents

Treatments for Vertebral Compression Fractures

OsseoFix+

The PMMA bone cement used in an OsseoFix procedure, OsseoFix+, can also be used in a stand-alone verteboplasty procedure to treat a VCF. In a verteboplasty procedure OsseoFix+ is put directly into the VCF to stabilize the area.

Minimally Invasive Access Systems and Techniques

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 retractor that contains 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.

Proprietary Packaging Systems

Vacuum Infusion Packaging (VIP) 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 allows for enhanced infusion of fluids into the 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.

Our Products In Development

We intend to continue to expand our current product offering as well as develop complementary systems and products. Products that we are currently developing include the following:

Treatments for Vertical Compression Fractures

OsseoFix

Our OsseoFix system is focused on providing a solution for VCF indications. The OsseoFix implant is an expandable titanium cage that is designed to be implanted minimally invasively into a vertebral body to treat a VCF. The OsseoFix system is designed to 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 addition, the OsseoFix system is designed to use less bone cement than current standards of care, which we believe carries a benefit to the patient. The OsseoFix System is undergoing clinical testing in the U.S. in connection with its 510(k) application. The OsseoFix system is only for sale in Europe.

Treatments for Osteoporotic Patients

OsseoScrew

The OsseoScrew 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 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.

Table of Contents

Minimally Invasive Access Systems and Techniques

Guided Lumbar Interbody Fusion System, or GLIF System

Our GLIF 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 System is intended to reduce the length of the procedure, reduce trauma to the patient and reduce the post-surgery recovery period. Prototype development and product design engineering are in process.

Cervico/Thoracic Occipital Plate

Posterior Occipital Plate

We are developing an occipital plate to be used with a posterior cervico/thoracic fixation system to provide additional stabilization to the atlanto/cervicol and crainial areas during a posterior fixation procedure. We have developed a prototype, and further engineering of the product design is in process.

Stand-Alone Anterior Plates and Spacers

Anterior Lumbar Interbdy FusionPlate System, or ALIF Plate System

Our stand-alone 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. We are developing prototypes of this product.

Anterior Lumbar Spacer

Our stand-alone anterior spinal spacer is intended to offer comparable stabilization to pedicle screw and rod systems. This spacer, which contains a proprietary locking mechanism to prevent migration of the implant after insertion, is designed to provide surgeons with the option of performing a single anterior procedure to treat the patient. We are developing prototypes of this product.

Treatments for Lumbar Spinal Stenosis

Helifix/Helifuse

Our Helifix and Helifuse products are designed to be minimally invasively inserted 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 providing flexion in the posterior elements. Helifuse is similar in design to Helifix, but will be a fusion device that may be combined with percutaneous spinal fixation. We are developing prototypes of this product.

Interspinous Process Plating System

Our interspinous process plating system is designed to use a plating system on the interspinous process to reduce nerve compression and create spinal stability for patients with spinal stenosis. We are developing prototypes of this product.

Table of Contents

Expandable Implants

Expandable Interbody Device

We are developing an expandable interbody device that is designed to be implanted into the disc space and then expanded during spine surgery. The in vivo expansion of the device is designed to permit optimal fit and deformity correction by allowing the surgeon to expand the device to precisely fit the patient s anatomy. We are developing prototypes of this product.

Sales and Marketing

Our sales force consists of approximately 85 independent distributors, which we believe employ approximately 240 employees dedicated to selling our products in the U.S., 17 direct sales representatives and sales management employees and executives in the U.S., 24 direct direct sales representatives and sales management employees and executives in Japan, three direct sales representatives in Hong Kong, three sales agents in Europe, and an executive-level General Manager that oversees all European operations. Although surgeons make the ultimate decision to use our products in the U.S., we invoice products directly to hospitals and pay commissions to our independent distributors and direct sales agents based on payments received from the hospital. 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 and through organized surgical training courses, and advertise our products 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 Japan, our sales and marketing activities are conducted through our subsidiary Alphatec Pacific, Inc., or Alphatec Pacific. We believe that having a direct presence in Japan gives us greater control over the introduction process of our products into the Japanese market and allows us to be more responsive to our Japanese customers. Alphatec Pacific has 26 sales and marketing employees as of December 31, 2008. 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 Hong Kong, our sales and marketing activities are conducted through our subsidiary Milverton Ltd., or Milverton. Milverton has three direct sales representatives that support its sales efforts.

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

Table of Contents

surgeons 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 poor bone density, a VCF, adult deformity, or spinal stenosis. 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 integrated biologic solutions to improve patient outcomes across all of our product lines.

Manufacture and Supply

We conduct our manufacturing operations at our facilities in Carlsbad, California. 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 under our own private label. 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, allograft and PEEK. Only one company, Invibio, is currently approved in the U.S. to distribute PEEK for use 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. from Invibio. As consideration for the PEEK materials, we pay Invibio a dollar amount depending on the weight or the length of either the raw material or stock product that Invibio processes for us. The dollar amount 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, 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 allograft implants are processed from human tissue, maintaining a steady supply can sometimes be challenging.

Table of Contents

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 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 tissue products, we are FDA-registered and licensed in the states of California, New York and Florida, the only states that 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. Our last FDA inspection was in November 2003, and minor non-compliance items were cited on an FDA Form 483 that we received following the inspection. Following receipt of the Form 483, we submitted a formal response in which we indicated the steps that we had taken to correct the noted deficiencies and have not received any further request from the FDA with respect to the Form 483 we received.

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 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. To date, these non-operative treatments have not caused a reduction in the demand for surgical treatment of spinal disorders.

Table of Contents

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, 2008, we owned 22 issued U.S. patents, six issued foreign patents and 42 pending patent applications, including 19 pending U.S. applications, 11 pending international applications and 12 pending foreign national applications. In addition, as of December 31, 2008 we have licensed or otherwise acquired rights to 40 U.S. patents, and patent pending applications.

The issued patents that we own begin to expire in 2009, although we do not expect that such expiration will have a negative impact on our business or operations because such expiring patents do not cover intellectual property that is material to our business. 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 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

Table of Contents

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 operation.

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

License Agreements Executed in 2007

Bottom-Manufactured Pedicle Screw License Agreement

In April 2007, Alphatec Spine entered into a license agreement with Roger P. Jackson, M.D. pursuant to which Alphatec Spine licensed rights to develop and commercialize certain polyaxial screw, helical flange, and proprietary instrumentation technology designed by Dr. Jackson. The polyaxial screw technology licensed by Alphatec Spine incorporates a bottom-loaded cam-capture manufacturing process and certain other proprietary technologies. Pursuant to the agreements Alphatec Spine also acquired rights to manufacture and sell a set screw that incorporates Dr. Jackson s proprietary helical flange technology. The agreement provides that Alphatec Spine will pay royalties on net sales of products incorporating the licensed technology with quarterly payments of minimum royalties. The term of the license agreement is for as long as Alphatec Spine continues to sell products that contain the licensed technology. Each party has the right to terminate the license agreement for material uncured breach by the other party.

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 with minimum annual royalties beginning in 2009. 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.

GLIF License Agreement

In September 2007, Alphatec Spine entered into an exclusive license agreement with JGMG Bengochea, LLC, or JGMG, that 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 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