SeaSpine Holdings Corp
Form 10-K
March 16, 2016
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, 2015
or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to
COMMISSION FILE NO. 001-36905

SeaSpine Holdings Corporation
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	47-3251758
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NO.)
5770 Armada Drive, Carlsbad, California	92008
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)	(ZIP CODE)

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE: (760) 727-8399

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT:

Title of Each Class	Name of Exchange on Which Registered
Common Stock, Par Value $.01 Per Share	The Nasdaq Stock Market LLC

SECURITIES REGISTERED PURSUANT TO SECTION 12(g) OF THE ACT:
NONE

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act. Yes o
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 o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

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

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

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer x (Do not check if a smaller reporting company)		Smaller reporting company	o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ý

As of July 2, 2015, the aggregate market value of the registrant’s common stock held by non-affiliates was approximately $9,069,768 based upon the closing sales price of the registrant’s common stock on The Nasdaq Global Market on such date. The number of shares of the registrant’s Common Stock, $0.01 par value, outstanding as of February 29, 2016 was 11,101,777.

DOCUMENTS INCORPORATED BY REFERENCE:
Certain portions of the registrant’s definitive proxy statement relating to its scheduled June 7, 2016 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

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PART I

ITEM 1. BUSINESS

Overview

SeaSpine Holdings Corporation ("SeaSpine" or "Company") is a global medical technology company focused on the design, development and commercialization of surgical solutions for the treatment of patients suffering from spinal disorders. We have a comprehensive portfolio of orthobiologics and spinal fusion hardware solutions to meet the varying combinations of products that neurosurgeons and orthopedic spine surgeons need to perform fusion procedures in the lumbar, thoracic and cervical spine. Our orthobiologics products consist of a broad range of advanced and traditional bone graft substitutes that are designed to improve bone fusion rates following a wide range of orthopedic surgeries, including spine, hip, and extremities procedures. We manufacture most of our orthobiologics products at our Irvine, California manufacturing facility. Our spinal fusion hardware portfolio consists of an extensive line of products to facilitate spinal fusion in minimally invasive surgery ("MIS"), complex spine, deformity and degenerative procedures. We believe this broad combined portfolio of orthobiologics and spinal fusion hardware products is essential to meet the "complete solution" requirements of neurosurgeons and orthopedic spine surgeons.

Mission

We believe spine surgery patients should benefit from the most advanced scientific knowledge and technology available. The SeaSpine team is dedicated to improving the lives of spine patients, collaborating with surgeons and developing advanced and effective spinal surgery technologies. Our team collaborates closely with leading spine surgeons, global distributors and other partners on the cutting edge of spinal solutions. From research and development, to product design and engineering, to commercialization and distribution - SeaSpine's product portfolio is dedicated to assist in restoring mobility and quality of life to patients.

Our Products

Our comprehensive offering of orthobiologics and spinal fusion hardware products has evolved to meet the surgical needs for our customers. Bone grafts and bone graft substitutes are frequently used to promote the bone healing process in orthopedic surgical procedures where a bone void or defect has been created. Our hardware products such as metal plates, rods and screws, and metal, polyetheretherketone ("PEEK"), PEEK NanoMetalene coated or machined allograft bone spacers, are used to restore and stabilize the bone structure, and our orthobiologics products can be used to support the fusion of bone. Most often autograft, the patient's own bone, is not adequate for the complete bone healing process, so bone graft substitutes are used to either replace or supplement and extend the autograft. Bone healing requires three components-osteogenic cells which build new bone, an osteoinductive signal, which stimulates the cells to build bone, and an osteoconductive scaffold, or conductive matrix, over which the cells can migrate. Our broad orthobiologics portfolio employs these principles to provide osteoinductive and/or osteoconductive properties to support the patient's own cells in the formation of new bone. We believe our expertise in both orthobiologic sciences and spinal fusion hardware product development allows us to offer our surgeon customers a differentiated portfolio and a "complete solution" to meet their fusion requirements.

Our orthobiologics products include a variety of bone graft substitutes including demineralized bone matrices ("DBM") and collagen ceramic matrices that have a balance of osteoinductive and osteoconductive properties. Demineralized bone matrices consist of human cadaver (allograft) bone that has been processed to remove the mineral content but preserve the protein content and osteoinductive properties of the bone. Our most advanced bone graft substitute solution, marketed as Accell Evo3® and OsteoSurge® 300, is our third-generation demineralized bone matrix product. Utilizing our proprietary Accell technology, this optimized formulation also incorporates a standard particulate DBM in a unique biocompatible carrier designed to provide better handling and containment characteristics as compared to competitive demineralized bone matrix products. Accell Bone Matrix is an open

structured, dispersed form of DBM, which provides accessibility to bone proteins without the need to be broken down after implantation in the patient. Standard particulate DBM is dense and requires more time to break down. Until these dense particles break down, access to natural bone proteins is limited. As a result, the combination of these two forms of DBM creates a favorable environment for the formation of bone over time. In addition, the carrier allows Accell Evo3 to meet the needs of challenging surgical applications where robust handling is essential. The material is considered to be a reverse-phase carrier, which means at room temperature, it is less viscous and thereby more moldable, while at body temperature after implantation, it becomes more viscous, thereby resisting irrigation and minimizing graft migration. We also offer first- and second-generation demineralized bone matrix products which also include some of the technologies in our most advanced formulation. Additional demineralized bone matrix product configurations include products designed specifically for use in spine fusion procedures. Our collagen ceramic matrix product, marketed as Isotis MozaikTM and OsteoStrux, is an engineered collagen framework with ceramic components that together provide a scaffold for bone cell migration. The ceramic components provide mineral content to foster bone formation

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during the healing process. This product is offered in strip, putty and moldable morsel configurations to meet the varying needs and preferences of our surgeon customers. We also offer allograft cancellous bone in sponge, chips and crushed preparations, as well as synthetic beta-tricalcium phosphate synthetic bone void fillers.

Spinal fusion utilizes the body's own bone growth processes to fuse two or more spinal vertebrae. Spinal fusion consists of a variety of different approaches or techniques and is used to treat a range of spinal conditions. Our spinal fusion hardware portfolio includes a broad offering of products to facilitate spinal fusion in MIS, complex spine, deformity and degenerative procedures. We offer MIS products consisting of multiblade adjustable retractors, tube retractors and mini-open and percutaneous solutions. We also offer rods, screws and instrumentation for posterior lumbar fusion and a broad range of PEEK and titanium coated PEEK anterior, posterior and lateral approach interbody devices, including an expandable interbody system intended for one or two adjacent levels.

Our complex spine and deformity products are used to treat multilevel conditions, including traumatic injury, tumors and abnormal curvatures of the spine. These product offerings include our Vu Mesh™ system which features a system of cages, spacers and endplates in a modular design that provide surgeons with intraoperative flexibility for their most challenging cases such as the surgical removal of a vertebral body. Our Malibu™ pedicle screw system is used in complex spine cases where its specialty screws can be leveraged to extend and capture the rod, and its specialty trauma screws can be used to help realign the vertebrae before fusing. Our Daytona® Deformity System addresses complex deformity cases by utilizing extended tab uniplanar and polyaxial screws with multiple rod options and intuitive instrumentation to create a versatile system adaptable to surgeon preference.

Our extensive line of products for degenerative cases includes devices for cervical and thoracolumbar procedures, and primarily consists of screw and plating systems and interbody devices that are typically used in open procedures. Degenerative disease refers to a variety of conditions including the degeneration of one or more of the cartilaginous discs located between the vertebral bones of the spine. Our Hollywood™, Ventura™ and Cambria NanoMetalene® Interbody Devices offer the combined benefits of a PEEK device with an innovative titanium coating. These devices are composed of PEEK-OPTIMA®, an engineered thermoplastic polymer, which has undergone a proprietary process that creates a titanium coating around the entire implant. We believe that this coating process has significant advantages over other existing material processes as it allows for the surface benefits of titanium, which is believed by scientists to encourage bone growth and cell migration, without compromising the mechanical and imaging benefits of PEEK-OPTIMA. The ultrathin NanoMetalene coating does not impair postoperative imaging, allowing surgeons to view the operative area and determine the extent of fusion of the vertebral bodies. Our cervical portfolio consists of a complete line of anterior cervical screw and plating systems, a full range of anterior cervical interbody devices and posterior cervical rod, screw and hook systems.

We currently market and sell our products in the United States and in over 30 countries worldwide. Our U.S. sales organization consists of regional business managers who oversee direct orthobiologics sales specialists and a broad network of independent orthobiologics and spine sales agents that receive commissions from us for sales that they generate. Our international sales organization is composed of a sales management team that oversees a network of independent orthobiologics and spine stocking distributors that purchase our products directly from us and independently sell them. International sales represented approximately 10%, 10% and 12% of our total revenue for the year ended December 31, 2015, 2014 and 2013, respectively.

Our History

SeaSpine was incorporated in Delaware on February 12, 2015 in connection with the spin-off of Integra LifeSciences Holdings Corporation's (Integra) spinal fusion hardware and orthobiologics business from Integra's diversified medical technology business on July 1, 2015. Our corporate offices are located at 5770 Armada Drive, Carlsbad, California.

We operate three facilities: our headquarters in Carlsbad, California, from which our orthobiologics and spinal fusion hardware products are designed, developed, and marketed; our Vista, California site from which our spinal fusion hardware products are procured, inspected, kitted and distributed; and our orthobiologics manufacturing facility in Irvine, California from which virtually all of our orthobiologics products are designed, developed, manufactured and distributed. We distribute our orthobiologics and spinal fusion hardware products in certain international markets through third-party logistics provider facilities in Belgium and the Netherlands.

Industry Overview

The bone graft substitutes market consists of surgical procedures in which a bone graft substitute made from donated human bone tissue or a synthetic material is implanted in the patient to augment or stimulate bone growth to aid healing. According to iData, this market was estimated at $0.9 billion in 2014 in the United States and will grow at a compound annual growth rate of 3.4% through 2021. According to the same source, spinal fusion procedures are where bone graft substitutes are most commonly

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used, representing approximately 45% of the market, and are expected to grow faster than the other major uses with a compound annual growth rate of 4.2% through 2021. Demineralized bone matrix grafts are the largest component of the bone graft substitutes market representing approximately 43% of the overall bone graft substitute market or approximately $0.4 billion in 2014. iData estimates our share of the bone graft substitutes and demineralized bone matrices markets in the United States in 2014 to be 8.6% and 12.3%, respectively, which place us as fourth and third in market position in these markets, respectively. Orthopedic stem cell and cell therapy as well as orthopedic growth factor represent additional segments in the orthobiologics market. Products in these segments are typically used in the same surgical procedures as traditional bone graft substitutes and iData estimates these segments, collectively, at approximately $0.7 billion in 2014.

According to iData, the spinal fusion procedure market consists of products for cervical fixation, thoracolumbar fixation and interbody devices. The market for these products was $4.4 billion in 2014 in the United States and is expected to grow at a compound annual growth rate of 0.7% through 2021. The fastest growing sub segment of this market, according to iData, is the $1.6 billion interbody device market, which will grow at a compound annual growth rate of 2.9% through 2021.

Spine Anatomy

The spine is a column of bone and cartilage that consists of 33 interlocking bones, called vertebrae, which stack upon each other at a slight angle to form the spine's S-shaped curve. With the exception of the bottom nine vertebrae, the vertebrae are separated by thin regions of cartilage known as intervertebral discs, which act as shock absorbers that facilitate motion and absorb stress during movement. The spine protects the spinal cord and acts as the core of the human skeleton, extending from the pelvis to the base of skull. Soft tissues, including ligaments, tendons and muscles are attached to the vertebrae and provide stability to the vertebral segment. The spine encloses and protects the spinal cord which carries nerves that exit through openings between the vertebrae and deliver sensation and control to the body.

Lateral View of Spine

The spine consists of five regions, of which the cervical, thoracic and lumbar are the three primary regions. The cervical region consists of the seven vertebrae extending from the base of the skull to the shoulders. The thoracic, or central, region of the spine consists of the next twelve vertebrae in the middle of the back. Each vertebra in the thoracic region is connected to two ribs that protect the body's vital organs. Below the thoracic region, the lumbar region consists of five vertebrae in the lower back and is the primary load-bearing region of the spine. The thoracic and lumbar regions are commonly referred to as thoracolumbar and many of the products and procedures to treat these regions are similar. The final two regions of the spine, the sacrum and coccyx, consist of nine naturally fused vertebrae connected to the hip bones to provide support for the spine.

In spinal fusion procedures, two or more of the vertebrae in the spine are fused together to eliminate instability as a result of deformity, degeneration or trauma affecting the vertebrae and intervertebral discs. During the surgical procedure, hardware products are used to stabilize the spine and the surgeon will often remove the damaged intervertebral disc and place a bone graft substitute product in its place to allow new bone to grow and bridge the affected vertebrae together. In addition to the bone graft substitute, the surgeon may replace the disc which was removed with an interbody device ("IBD"). An IBD may be made out of machined bone or PEEK polymer and is designed to maintain spine alignment and appropriate spacing while allowing bone to grow between the vertebrae to achieve bone fusion. Procedures that include the implantation of IBDs are often referred to by the surgical approach used to place the IBD in the disc space. A Posterior Lateral Interbody Fusion ("PLIF") uses a direct posterior approach from the patient's back, a Transforaminal Lumbar Interbody Fusion ("TLIF") uses an angled approach from either the left or right side of the back, and an Anterior Lumbar Interbody Fusion ("ALIF") uses a direct anterior approach from the patient's front (stomach) area.

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Our Competitive Strengths

We provide a broad portfolio of advanced and traditional orthobiologics and spinal fusion hardware solutions to assist our surgeon customers in treating patients suffering from spinal and other orthopedic disorders. Our executive management team has extensive experience in the spine and medical technology industries. We believe that our focused and experienced management team, combined with the following competitive strengths will enable us to grow our revenue and increase our presence in the markets that we serve.

- An extensive, scaled and differentiated offering of orthobiologics products. We offer a broad range of orthobiologics products consisting of advanced and traditional bone graft substitutes that enables us to fulfill a greater portion of the orthobiologics needs of neurosurgeons and orthopedic spine surgeons than our competitors who focus primarily on offering spinal fusion hardware products. Despite our relatively small size, we are a significant participant in the U.S. market for these products, with an estimated 8.6% share in 2014 of the U.S. bone graft substitutes market, representing the fourth-largest position, according to iData. We believe that our orthobiologics portfolio offers differentiated products. For example, our third-generation demineralized bone matrix is formulated using our proprietary Accell technology and is designed to provide both immediate and sustained availability of the natural array of osteoinductive bone proteins It also provides flexibility in handling as a result of its carrier which is more moldable at room temperature and more viscous at body temperature after implantation, resisting irrigation and minimizing graft migration. Demand for this product and our other demineralized bone products has garnered us a 12.3% market share in demineralized bone matrix products in the United States in 2014, which is the third-largest position in the U.S. market, according to iData.

- A range of innovative, titanium coated PEEK interbody devices. Our NanoMetalene technology is an ultra-thin layer of commercially pure titanium molecularly bonded to a PEEK implant that is applied in a proprietary high-energy, low-temperature surface process and encompasses the entire implant, including the center graft aperture. We believe that our NanoMetalene technology offers advantages over existing materials as it allows for the surface benefits of titanium, which is believed by scientists to encourage bone growth and cell migration, while maintaining the mechanical and imaging benefits of PEEK, which has a modulus of elasticity similar to bone and a radiolucency for postoperative imaging, allowing surgeons to view the operative area and determine the extent of fusion of the vertebral bodies. We currently offer the NanoMetalene technology in our Ventura and Hollywood Nanometalene interbody devices for lumbar fusion and our Cambria NanoMetalene interbody device for cervical fusion. We have received U.S. Food and Drug Administration (FDA) 510(k) clearance for a number of other NanoMetalene coated PEEK interbody devices our current portfolio and we expect to launch these additional products in 2016 and beyond.

- A synergistic channel strategy for orthobiologics products. We maintain a dual branding strategy that allows us to market orthobiologics into territories in which we do not maintain independent spine sales agents who currently sell our hardware products. We achieve this result by marketing these products under an alternative brand through independent orthobiologics sales agents, many of whom carry competitive spinal fusion hardware products, or products for other orthopedic procedures, such as those used in large joint reconstruction. For example, we market our third-generation demineralized bone matrix product as both Accell Evo3 and OsteoSurge300 to allow differentiation between independent sales agents who sell our spinal fusion hardware, and those that sell our orthobiologics products alongside other orthopedic hardware. We believe this dual branding strategy allows us to penetrate a greater number of customer accounts than we would otherwise serve if we marketed a single line of orthobiologics brands.

- Our own orthobiologics design, development and manufacturing operations. While many of our spine competitors source their orthobiologics products from original equipment manufacturers to supplement their spinal fusion hardware portfolio, we design, develop and manufacture the vast majority of our orthobiologics products at our facility in Irvine, California. By controlling our own manufacturing processes, we believe we should be able to control the cost of our products more tightly and provide operational leverage with volume increases.

Our Strategy

Our goal is to continue to scale our business in order to enhance our market position in orthobiologics and become a leader in the spinal fusion hardware market. To achieve our goals, we are investing in the following strategies:

- Research and development to bring new products and techniques to market. We have recently increased, and intend to continue to increase our annual research and development spending as a percentage of revenue in order to drive higher revenue growth through new product sales. We plan to invest significant resources to expand our product portfolio and develop next-generation products for our existing core product lines. In order to achieve this goal, we intend to collaborate with our surgeon customers to innovate, design and develop new orthobiologics and spinal fusion hardware products. We plan to make further investments in our infrastructure by hiring additional dedicated orthobiologics engineers and

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scientists with expertise in material sciences and biology and hardware engineers with expertise in product design and development. By promoting a corporate culture of accountability, innovation and responsiveness to our customer needs, we plan to expedite our product launch process and bring a greater number of new products to market in the next few years than we have in recent years.

- Commercial infrastructure to further penetrate the U.S. orthobiologics and spinal fusion hardware markets and increase our focus in international markets where we currently have a presence. We have recently increased, and intend to continue to increase the size and geographic breadth of our sales management team and network of independent sales agents in the United States. To support these efforts, we aim to develop comprehensive marketing support and physician training programs to communicate the strengths of our product platforms. We plan to expand the current schedule of hands-on cadaveric laboratory training opportunities for physicians and sales agents at our Carlsbad, California facility. In addition, we plan to increase our presence within teaching institutions that provide spinal surgery fellowship programs to educate new surgeons on the use of our products. These programs will aid surgeons in becoming comfortable with our spinal fusion hardware products and techniques. Internationally, we intend to focus our sales and marketing efforts on expanding our presence in those markets where we currently have relationships with stocking distributors.

- Clinical affairs programs to generate data on product efficacy. We plan to invest in additional clinical development programs to generate peer-reviewed clinical data that we believe will validate the efficacy of select orthobiologics and spinal fusion hardware solutions over competing technologies. Specifically, we believe that our third-generation demineralized bone matrix technology has benefits over other commercially available advanced bone graft substitutes in the stimulation of bone formation and bone fusion. Additionally, we plan to initiate studies to generate data on the unique surface characteristics of titanium and the mechanical properties and radiolucency of PEEK-OPTIMA as are incorporated together in a single device using our NanoMetalene technology. We believe this technology has significant advantages over existing implant materials.

- Opportunities to enhance our product offering through strategic alliances and acquisitions. We currently market several products under distribution agreements and licenses with third-party companies. We intend to continue to pursue alliances that will provide us with technologies to strengthen our market position. Our current business is the result of the acquisition of several companies, and we plan to continue to evaluate product alliances and acquisition opportunities as they arise to help grow our business.

Our Products

We offer a broad portfolio of orthobiologics and spinal fusion hardware products for the treatment of patients suffering from spinal and other orthopedic disorders. The tables below group our core products into key categories and provide a summary of each technology’s features.

Orthobiologics

Our orthobiologics portfolio is used in orthopedic and dental procedures, and consists of a broad range of traditional and advanced bone graft substitutes intended to address key elements of bone regeneration, which are osteoinduction, osteoconduction and osteogenesis. Osteoinduction refers to the ability of an implant to stimulate bone forming cells based primarily on soluble growth factor signals. Osteoconduction refers to the ability of an implant to promote bone formation based primarily on a physical matrix or scaffold, when placed adjacent to viable bone tissue. Osteogenesis refers to the ability to promote new bone formation based primarily on the cells contained within the bone graft. Bone graft substitutes composed of natural biologic proteins and synthetic materials are designed to reduce the amount of autologous bone grafts needed for spinal fusion procedures. Bone graft substitutes, depending on their design, can be used entirely in place of the patient’s own bone tissue, referred to as an autograft, or by extending the volume of bone graft material from the patient by combining it with the bone graft substitute. Our products include demineralized bone matrices, collagen ceramic matrices, demineralized cancellous allograft bone and synthetic bone void fillers. We

offer these products in the form of putties, pastes and strips for a range of surgical applications.

Demineralized Bone Matrix Technology

Demineralized bone matrix formulations are designed to provide proteins and other growth factors at varying stages of the bone healing process. Developed in the early 1990s, our first-generation demineralized bone matrix formulations combined particulate-demineralized bone matrix with an inert carrier engineered for easy graft handling and graft containment. The inert carrier is a highly biocompatible synthetic polymer, known as a reverse-phase medium, and has a unique property which allows the product to remain moldable at room temperature, but becomes more viscous at body temperature once implanted. In 2002, we developed a proprietary process to transform particulate-based demineralized bone matrix into a dispersed form in order to enhance the performance of the graft material. The result of this process was our second-generation demineralized bone matrix, which we refer to as Accell Bone Matrix. Accell Bone Matrix is an open structured, dispersed form of DBM, which provides accessibility

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to bone proteins without the need to be broken down following implantation in the surgical site. Standard particulate DBM is dense and requires more time to break down. Until these dense particles break down, access to natural bone proteins is limited. Our third-generation and most advanced demineralized bone matrix solution, marketed as Accell Evo3 and OsteoSurge 300, provides an optimized formulation of Accell Bone Matrix, particulate-based demineralized bone matrix, and our reverse-phase medium carrier. Our third-generation products have an advanced handling property for bone grafting procedures and contain three times the amount of the Accell Bone Matrix compared to our second-generation technology.

Accell Technology

Our proprietary Accell technology combines our patented highly dispersed Accell Bone Matrix with a standard particulate-based demineralized bone matrix. Using a process of demineralization during manufacturing, mineral is carefully removed from the underlying organic structure, leaving behind a framework of densely packed type-1 collagen and the natural array of osteoinductive bone proteins, including bone morphogenetic proteins ("BMPs"), such as BMP-2, BMP-7 and BMP-4, and Transforming Growth Factor Beta 1. While the demineralization process allows access to the osteoinductive bone proteins, this standard particulate-form of demineralized bone matrix structure requires the body to break down the dense collagen structure in order to gain access to osteoinductive bone proteins. By contrast, during the Accell Bone Matrix production process, normal particulate-based demineralized bone matrix is converted into Accell Bone Matrix by carefully disrupting and dispersing the dense particles. This process yields a matrix with increased surface area providing for more rapid availability of the natural array of osteoinductive bone proteins. We believe that providing both the early-stage and late-stage accessibility of osteoinductive bone proteins provided by a composite of Accell Bone Matrix and the particulate-based demineralized matrix makes our product unique compared to competitive demineralized bone matrix products. The Pure Strip is a pre-shaped demineralized bone implant with an open matrix allowing bone ingrowth and providing exposure to a range of growth factors and BMP's. When hydrated, the implants can be contoured to the defect site.

Collagen Ceramic Matrix Technologies

Our collagen ceramic matrix technology leverages our long history of experience in regenerative technology and collagen engineering. Our leading products in this category are currently marketed as IsoTis Mozaik and OsteoStrux and are specifically engineered to provide a porous scaffold architecture and osteoconductivity. These products also support osteogenesis, as they are indicated for use with bone marrow aspirate, which contains osteogenic cells. They are composed of highly purified beta-tricalcium phosphate granules, which provide mineral content to foster bone formation during the healing process in a framework of type-1 collagen that provides a scaffold for bone cell migration. These products are engineered with a resorption profile consistent with the rate of natural bone formation.

Other Bone Graft Substitutes

Our other bone graft substitutes products consist of allograft cancellous bone scaffolds and synthetic bone void fillers.

Spinal Fusion Hardware

Our spinal fusion hardware portfolio consists of an extensive line of products for spinal fusion in MIS, complex spine, deformity and degenerative procedures throughout the lumbar, thoracic and cervical regions of the spine.

Minimally Invasive Surgery

Our MIS products enable a surgeon to perform a procedure less invasively than traditional open surgery, which may result in reduced postoperative pain, faster rates of healing and fewer procedure complications by minimizing incision size and tissue dissection. Our surgeon customers utilize our iPassage™ MIS Retractors and NewPort™ Tube Retractors to perform MIS fusions and decompression procedures, a surgical technique used to alleviate pain caused from compression on the spinal cord or the nerves that emanate from it. During the procedure, the surgeon makes a small incision and inserts the retractor through the skin and soft tissues down to the spinal column, creating a tunnel to the spine. The retractor is kept in place to hold the muscles open throughout the procedure. Through this tunnel, the surgeon accesses the spine, using small instruments inserts any implants necessary for fusion, such as the screws and rods of our Coral® MIS and NewPort MIS solutions. The Coral MIS product offers a mini-open muscle splitting rod

delivery option for surgeons new to MIS procedures. The NewPort MIS product features extended tabs for a small incision profile and two rod delivery options for both mini-open and percutaneous approaches. Our MIS portfolio also includes interbody devices and screw systems that facilitate access to the treatment area while providing minimal anatomical disruption. These include our expandable interbody device, which is designed to minimize the amount of implant insertion force needed and an endoscopy system, which includes a complete set of decompression instruments.

Complex Spine and Deformity

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Our spinal fusion hardware products are used in complex spine and deformity procedures involving multiple spine segments, challenging anatomy, tumors, traumatic injury and revision of previous fusion surgeries. Our complex fusion hardware portfolio allows surgeons to combine various product lines and approaches, offering several treatment options for the most difficult cases. We define deformity as any variation in the natural curvature of the spine, the most common of which is scoliosis, an abnormal lateral curvature of the spine. Our deformity platform consists of several technologies to address the needs of our deformity surgeons and the various derotation techniques that they use to correct the curvature of the spine. For example, our Daytona Deformity System addresses complex deformity cases by utilizing extended tab uniplanar and polyaxial screws with multiple rod options and intuitive instrumentation to create a versatile system adaptable to surgeon preference. Our systems are provided in multiple configurations and materials to address patient requirements, including stainless steel, titanium alloy and cobalt chrome alloy rod options, as well as 5.5 millimeter and 6.35 millimeter rod diameters. The ability to offer products with varying rod diameter and materials provides the surgeon different rod stiffness to treat individual patients. We offer both implant- and instrument-based reduction capabilities with our extended tab and locking cap products as well as our uniplanar and D-planar screws and rapid sequential reduction towers.

Degenerative

Our degenerative products include systems that are typically used in open procedures. Open procedures are still the most common surgical approach and involve a midline incision followed by retraction of the skin and soft tissues. We offer an extensive portfolio of degenerative products that are designed for use in both thoracolumbar and cervical spine cases.

Our Hollywood and Ventura NanoMetalene Interbody Device for TLIF procedures fuse the anterior column of the spine through a posterior approach that starts off to one side of the patient’s back and our Cambria NanoMetalene Interbody Device fuses the cervical spine through an anterior approach. These devices are composed of PEEK-OPTIMA® polymer, which has undergone a proprietary process that creates a titanium coating around the entire implant. We believe that this coating process has significant advantages over existing materials as it allows for the surface benefits of titanium, which is believed by scientists to encourage bone growth and cell migration, without compromising the mechanical and imaging benefits of PEEK-OPTIMA. In addition, the ultrathin NanoMetalene coating does not impair postoperative imaging, allowing surgeons to view the operative area and determine the extent of fusion of the vertebral bodies. We will continue to introduce new products for thoracolumbar and cervical applications that incorporate this unique NanoMetalene coating technology.

Thoracolumbar

We offer a comprehensive portfolio of products for the thoracic and lumbar regions of the spine, consisting of rods, screws and instrumentation for posterior lumbar fusion and a broad range of anterior, posterior and lateral interbody devices (“IBDs”), including stand-alone, zero-profile and low-profile systems and traditional PEEK-OPTIMA and innovative NanoMetalene-coated devices. Our Malibu and Coral screw and plating systems are our core products used for treating degenerative thoracolumbar spine cases. Both the Malibu and Coral screw and plating systems offer a full range of screw sizes, rod materials and lengths and unique locking caps, which minimize cross-threading and fully capture the rod.

Cervical

We offer a range of devices to treat disorders in the cervical region of the spine. Our degenerative cervical portfolio includes a full range of interbody devices including stand-alone, zero-profile systems, integrated plate interbody devices and traditional PEEK-OPTIMA and innovative NanoMetalene-coated interbody systems. In addition, we offer a variety of screw and plating systems.

Product Pipeline

We are committed to supplementing our portfolio of orthobiologics and spinal fusion hardware products through continuous innovation and bringing next-generation products to the market. We have more than ten products currently in our development pipeline, with a focus on MIS, complex spine, deformity and degenerative procedures, including advanced coating technology, as well as extensions of our orthobiologics products offering to further differentiate this portfolio from those of our competitors.

We are in the process of launching our MIS Facet Screw, a comprehensive system with a variable washer for more bone contact and a locking screwdriver to enhance stability as well as our MIS Spinous Process Clamp, a low profile, small footprint plating system. We are also launching our Smart TLIF device, a sterile packed TLIF cage prefilled with a synthetic graft material (outside the United States only).

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Over the next 24 months, we plan to continue to build our portfolio and expect to launch a greater number of new products than we did in the past 24 months. Some of the products in our development pipeline include a next generation pedicle screw platform, a consolidated cervical stand-alone system, and our NewPort complex MIS extension. We also plan to add our NanoMetalene coating technology to more of our commercialized PEEK-OPTIMA IBD products including our ALIF and lateral systems as well as hyperlordotic cages, highly angled IBDs, which are used to ensure appropriate spine curvature.

Research and Development

We have an established research and development organization dedicated to advancing our portfolio of orthobiologics and spinal fusion hardware products. Our clinical and regulatory personnel work in parallel with our product engineering personnel to facilitate regulatory clearances of our orthobiologics and spinal fusion hardware products. These teams work in close collaboration with our surgeon customers to design technologies that will aid us in increasing our competitive advantage in the United States and international markets. We have recently invested in, and intend to continue to invest in, additional resources to increase our product development efforts by expanding the size of our current orthobiologics and spinal fusion hardware product development and clinical affairs teams and by integrating both teams together in our new Carlsbad facility to better collaborate to serve the design needs of our surgeon customers and develop market ready next-generation products.

We plan to create new, innovative orthobiologics technologies that will continue to reduce the amount of autologous bone graft needed for spinal fusion procedures by extending the volume of harvested material or replacing the need for such harvesting altogether. Therefore, we are dedicated to developing technologies that have the appropriate balance of osteoinductive, osteoconductive and osteogenic properties. Our orthobiologics research and development team has extensive experience in biomaterial sciences and bringing next generation technologies to market. In addition, we collaborate with surgeons and key opinion leaders to evaluate and design new products to ensure greater acceptance of our products.

We are also committed to developing new spinal fusion hardware products that leverage our innovative NanoMetalene technology and provide next generation solutions for our existing products or extend the range of solutions that we provide. One of our primary focuses in developing new spinal fusion hardware products is to further build out our complex spine and deformity procedures platform. One particular area of effort is developing products for pediatric populations including indications in small stature pediatric deformity as well as technologies that support growth. Our organization is also committed to providing products, such as hyperlordotic cages and additional expandable technology solutions, to achieve appropriate curvature of the spine and that can improve sagittal balance, correcting the patient’s spinal alignment so that their head and shoulders are above their hips so that the patient does not lean forward. We also plan to continue to develop next generation technologies that meet global demand, particularly with respect to cost and delivery methods in a manner which supports a scalable commercial model.

Our product development efforts employ an integrated team approach that involves collaboration between surgeons, our highly skilled engineers, our machinists, as well as our regulatory personnel. Our product development team, in consultation with designing surgeons, formulates a design for the product and then our machinists build prototypes for testing in our prototyping development and testing operation at our Vista, California facility. We utilize a broad scope of technologies to allow us to meet the complex engineering related to customer requirements. As part of the development process, spine surgeons test the implantation of the products in our in-house cadaveric laboratory to ensure that all new products meet the needs of both surgeon and patient. Our team refines or redesigns the prototype as necessary based on the results of the product testing, allowing us to perform rapid iterations of the design-prototype-test development cycle. We believe that these product development efforts allow us to provide solutions that respond to the needs of neurosurgeons and orthopedic spine surgeons and their patients.

In 2016, we began the process of moving our cadaveric training laboratory and our prototyping development and testing operation from our Vista, California facility and our orthobiologics product development laboratory from our Irvine, California facility into our new Carlsbad facility. We believe that this investment will provide for better

collaboration between our orthobiologics and spinal fusion hardware product development teams and further our mission to provide surgeons with the most advanced and effective spinal surgery technologies to improve the quality of patients' lives. We expect to complete these moves into our Carlsbad facility in the second quarter of 2016.

Global Spine Community Involvement

As a key part of our strategy we continuously educate and collaborate with surgeons globally to develop and market our technologies, as well as maintain active involvement in the global spine surgeon community. We believe surgeon education on the most effective use of our products is critical to our ability to help our customers realize the value potential of our products. We provide remote and on-site cadaver training throughout the year for surgeons. Our Vista, California facility has a cadaveric laboratory which enables us to conduct hands-on training to communicate the safe and most effective use of our products.

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In addition to surgeon education, we solicit feedback from surgeons throughout the product development process and during post market evaluation. We also work with healthcare professionals in the area of clinical research in order to support the necessary requirements for product clearances and registrations. Surgeons also actively support the training of sales agents and other salesforce personnel on end-user functionality of our products.

Sales and Distribution

We currently market and sell our products in the United States and in over 30 countries worldwide. Our U.S. sales organization consists of regional business managers who oversee direct orthobiologics sales specialists and a broad network of independent orthobiologics and spine sales agents. Our international sales organization is composed of a sales management team that oversees a network of independent orthobiologics and spine stocking distributors.

In the United States, we typically consign our orthobiologics products and consign or loan our spinal fusion hardware sets to hospitals and independent sales agents, who in turn deliver them to the hospital for a single surgical procedure or leave them with hospitals that are high volume users for use in multiple procedures. The spinal fusion hardware sets typically contain the instruments, including disposables, and spinal implants required to complete a surgery. Our sales are generated by building and maintaining relationships with the neurosurgeons and orthopedic spine surgeons who use our products in surgeries or from the hospitals that order our products directly. In international markets, we predominantly sell complete instrument and implant sets to our independent spine stocking distributors, who consign or loan these sets to surgeons. Our international sales organization is composed of a sales management team that oversees a network of independent orthobiologics and spine stocking distributors in over 30 countries that purchase our products directly from us and independently sell them. We maintain sales and marketing personnel in Switzerland and France to manage and support our stocking distributors in Europe and use third-party distribution facilities in Belgium and The Netherlands to support international distribution efforts.

We recently increased the size of our spinal fusion hardware sales management team and independent sales agents in 2015 and we anticipate adding additional independent sales agents in the United States in 2016. We also plan to invest in additional instrument sets and marketing and education efforts to support this expansion. Internationally, we intend to focus our sales and marketing efforts on expanding our presence in those markets where we currently have relationships with stocking distributors. We believe the expansion of our U.S. sales efforts will provide us with significant opportunity for future growth as we continue to penetrate existing and new markets.

Suppliers and Raw Materials

In general, raw materials essential to our businesses are readily available from multiple sources. For reasons of quality assurance, availability or cost effectiveness, certain components and raw materials are available only from sole suppliers. Our relationships with such suppliers that could not be replaced without a material expense or delay are governed by written contracts which are generally supply agreements. These agreements set forth the process by which we order components or raw materials, as applicable, from such suppliers (which process is either on a purchase order basis or based on quarterly or annual forecasts and in some cases require us to purchase minimum amounts) and the related fees for purchasing such components or raw materials. These agreements have terms from one to five years, but in most instances are terminable by us (and in limited instances the other party) for convenience, subject to a specified notice period, and are also terminable upon mutual agreement by the parties, by either party upon material breach by the other and by either party in the event the other party enters bankruptcy. These agreements also outline the rights of each party with respect to quality assurance, inspection and compliance with applicable law and contain what we believe to be customary indemnification provisions for commercial agreements. Each of these agreements is entered into in the ordinary course of our business, immaterial in amount and significance and not a contract upon which our business is substantially dependent. In addition, our policy is to maintain sufficient inventory of components and raw materials so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time.

Most of our biomaterial products contain material derived from human or bovine tissue. We take great care to provide products that are safe and free of agents that can cause disease. Only donated tissue from FDA-registered and AATB accredited tissue banks is qualified to source for our raw materials. The donors are rigorously screened, tested and

processed by the tissue banks in accordance with FDA and AATB requirements. Additionally, each donor must pass all of the FDA-specified bacterial and viral testing before the raw material is distributed to us for further processing. We receive with each donor lot a certification of the safety of the raw material from the tissue bank's medical director. As an added assurance of safety, each lot of bone is released into the manufacturing process only after our staff of quality assurance microbiologists screen the incoming bone and serology test records. During our manufacturing process, the bone particles are subjected to our proprietary process and terminally sterilized. We have demonstrated through our testing that this type of rigorous processing supports the safety and effectiveness of our demineralized bone material products.

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The collagen used in our collagen ceramic matrix products is derived only from the deep flexor tendon of cattle less than 24 months old from the United States or New Zealand. The World Health Organization classifies different types of cattle tissue for relative risk of BSE transmission. Deep flexor tendon is in the lowest-risk category for BSE transmission (the same category as milk, for example) and is therefore considered to have a negligible risk of containing the agent that causes BSE (an improperly folded protein known as a prion).

Intellectual Property

We seek patent and trademark protection for our key technology, products and product improvements, both in the United States and in selected foreign countries. When determined appropriate, we plan to continue to enforce and defend our patent and trademark rights. In general, however, we do not rely solely on our patent and trademark estate to provide us with any significant competitive advantages as it relates to our existing product lines. We also rely upon trade secrets and continuing technological innovations to develop and maintain our competitive position. In an effort to protect our trade secrets, we have a policy of requiring our employees, consultants and advisors to execute proprietary information and invention assignment agreements upon commencement of employment or consulting relationships with us. These agreements also provide that all confidential information developed or made known to the individual during the course of their relationship with us must be kept confidential, except in specified circumstances. IsoTis OrthoBiologics, Inc., one of our subsidiaries, owns a group of patents (6 U.S. patents and 9 foreign patents) related to reverse phase medium and the Accell process and materials. This patent group protects the Accell family of demineralized bone matrix products. The patents in this group will expire over a period of time from 2017 to 2023. SeaSpine has licensed three U.S. paten