

SeaSpine Holdings Corp
Form 10-K
March 01, 2019
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

or

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

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

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

DELAWARE
(STATE OR OTHER JURISDICTION OF
INCORPORATION OR ORGANIZATION)

47-3251758
(I.R.S. EMPLOYER
IDENTIFICATION NO.)

5770 Armada Drive, Carlsbad, California
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) (ZIP CODE) 92008
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 No

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

No

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 No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements

incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. x

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

Large accelerated filer Accelerated filer

Non-accelerated filer Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

As of June 30, 2018, the aggregate market value of the registrant's common stock held by non-affiliates was approximately \$145,318,669 based upon the closing sales price of the registrant's common stock on The Nasdaq Global Select Market on such date. The number of shares of the registrant's Common Stock, \$0.01 par value, outstanding as of February 25, 2019 was 18,880,072.

DOCUMENTS INCORPORATED BY REFERENCE:

Certain portions of the registrant's definitive proxy statement relating to its scheduled May 29, 2019 Annual Meeting of Stockholders are incorporated by reference in Part III of this report.

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PART I

This Annual Report on Form 10-K (this “Form 10-K” or this “report”) contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that involve risks and uncertainties. Many of the forward-looking statements are located in Part II, Item 7 of this report under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Forward-looking statements provide current expectations of future events based on certain assumptions and include any statement that does not directly relate to any historical or current fact. Forward-looking statements can also be identified by words such as “future,” “anticipates,” “believes,” “estimates,” “expects,” “intends,” “plans,” “predicts,” “will,” “would,” “could,” “can,” “may,” and similar terms. Forward-looking statements are not guarantees of future performance and our actual results may differ significantly from the results discussed in the forward-looking statements. Factors that might cause such differences include, but are not limited to, those discussed in Part I, Item 1A of this report under the heading “Risk Factors,” which are incorporated herein by reference. We assume no obligation to revise or update any forward-looking statements for any reason, except as required by law.

The terms “we,” “us,” “our,” “SeaSpine” or the “Company” refer collectively to SeaSpine Holdings Corporation and its wholly-owned subsidiaries, unless otherwise stated. All information presented in this report is based on our fiscal year. Unless otherwise stated, references to particular years, quarters, months or periods refer to our fiscal years ending December 31 and the associated quarters, months and periods of those fiscal years.

ITEM 1. BUSINESS

Overview

SeaSpine 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. SeaSpine has a comprehensive portfolio of orthobiologics and spinal implants solutions to meet the varying combinations of products that neurosurgeons and orthopedic spine surgeons need to perform fusion procedures on the lumbar, thoracic and cervical spine. SeaSpine’s 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. SeaSpine’s spinal implants portfolio consists of an extensive line of products to facilitate spinal fusion in degenerative, minimally invasive surgery (MIS), and complex spinal deformity procedures. Expertise in both orthobiologic sciences and spinal implants product development allows SeaSpine to offer its surgeon customers a differentiated portfolio and a complete solution to meet their fusion requirements. SeaSpine currently markets its products in the United States and in approximately 30 countries worldwide.

SeaSpine was incorporated in Delaware on February 12, 2015 in connection with the spin-off of the orthobiologics and spinal implants business of Integra LifeSciences Holdings Corporation (Integra), a diversified medical technology company. The spin-off occurred on July 1, 2015. Our corporate offices are at 5770 Armada Drive, Carlsbad, California.

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. Except for 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 base of the skull to the pelvis. Soft tissues, including ligaments, tendons and muscles, are attached to the vertebrae and provide stability to the vertebral segment. The spinal cord carries nerves that exit through openings between the vertebrae and deliver sensation and control to the body. Below is a diagram of the lateral view of the spine:

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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 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 called 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 vertebrae are fused to eliminate instability as a result of deformity, degeneration or trauma affecting the vertebrae and intervertebral discs. During the procedure, spinal implant products are used to decompress, align, and stabilize the spine and the surgeon will often remove the damaged intervertebral disc and replace it with a bone graft substitute to allow new bone to grow and to fuse the affected vertebrae together. In addition to the bone graft substitute, the surgeon may replace the removed disc with an interbody device. An interbody device may be made out of machined bone, titanium, or polyetheretherketone (PEEK), 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 interbody devices are often referred to by the surgical approach used to place the interbody device in the disc space. A lateral lumbar interbody fusion uses an approach that accesses the spine from the side of the patient's body; a posterior lateral interbody fusion uses a direct posterior approach from the patient's back; a transforaminal lumbar interbody fusion uses an angled approach from either the left or right side of the back; and an anterior lumbar interbody fusion uses a direct anterior approach from the patient's front (stomach) area.

Our Competitive Strengths

We provide a broad portfolio of advanced and traditional orthobiologics and spinal implant 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 management team, combined with the following competitive strengths, will enable us to continue to grow our revenue and increase our presence in the markets we serve.

An extensive and differentiated offering of orthobiologics products. We offer a broad range of differentiated orthobiologics products that better positions us to meet the needs of our surgeon customers compared to our competitors who focus primarily on spinal implant products. For example, our proprietary Accell bone matrix technology is designed to provide both immediate and sustained availability of the natural array of osteoinductive bone proteins and, in addition, provides flexibility in handling as a result of its reverse-phase carrier. We estimate we have a 14% share of the demineralized bone matrices (DBM) market in the United States.

A range of innovative, PEEK interbody devices that incorporate NanoMetalene, a proprietary titanium surface technology. We currently offer a wide range of sterile-packaged interbody devices that incorporate our proprietary NanoMetalene surface technology and we expect to continue to launch additional products incorporating NanoMetalene technology. NanoMetalene describes a sub-micron layer of commercially pure titanium molecularly bonded to a PEEK implant using a high-energy, low-temperature process called atomic fusion deposition. NanoMetalene is designed to provide implants a bone-friendly titanium surface on endplates and throughout graft apertures, while retaining the benefits associated with traditional PEEK implants, such as biocompatibility, a modulus of elasticity similar to bone, and excellent radiographic visibility for post-operative imaging. We have exclusive rights to NanoMetalene technology within the spine market.

A synergistic channel strategy for orthobiologics products. Our dual branding strategy that allows us to market our orthobiologics products through independent sales agents who carry competitive spinal implant products. For example, we market one of our advanced DBM products as both Accell Evo3 and OsteoSurge300, which allows sales agents who sell spinal implant products competitive with ours to continue to represent our orthobiologics products. We believe this dual branding strategy allows us to penetrate a greater number of customer accounts than we would otherwise serve if we marketed our orthobiologics products under a single brand.

Our own orthobiologics design, development and manufacturing operations. While many of our spinal implant competitors source their orthobiologics products from tissue banks or original equipment manufacturers to supplement their spinal implant portfolio, we design and develop the vast majority of our orthobiologics products internally and manufacture them at our facility in Irvine, California. By controlling the manufacturing processes, we should be able to better control the cost of our products 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 implant market. To achieve our goal, we are investing in these 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 an effort to drive higher revenue growth through new product sales. We plan to continue to invest resources and to work with our surgeon customers to understand their needs and develop new and next-generation orthobiologics and spinal implant products designed to improve clinical outcomes. We employ dedicated orthobiologics engineers and scientists with expertise in material sciences, and biology and hardware engineers with expertise in product design and development. Commercial infrastructure to further penetrate the U.S. orthobiologics and spinal implant 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 quality, size, exclusivity and geographic breadth of our network of independent sales agents in the United States. To support these efforts, we are investing more in, and are developing comprehensive support for, sales agent and surgeon training and education programs. We have a hands-on cadaveric training facility in Carlsbad, California where we provide training for surgeons and sales agents. 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. We believe these combined efforts will help surgeons become adept with our spinal implant products and techniques, thereby improving outcomes for their patients. Internationally, we intend to continue to focus our sales and marketing efforts on expanding and strengthening our presence in those markets where we currently have relationships with stocking distributors and to selectively expand into new markets.

Clinical affairs programs to generate postmarket data. We plan to invest in additional clinical development programs designed to generate peer-reviewed clinical data that we believe will support the performance of select orthobiologics and spinal implant solutions that may be compared to competing technologies. We believe that our NanoMetalene technology may have advantages over many existing implant materials and surface options, and that our fibers-based OsteoStrand and OsteoStrand Plus tissue products are as efficacious as, and more cost effective than, higher cost cellular allografts bone grafts. We have initiated studies to generate data on the surface characteristics of titanium and the mechanical properties and radiolucency of PEEK interbody implants, which NanoMetalene technology combines into a single device, and on the performance of our fibers-based products.

Opportunities to enhance our product offering through strategic alliances and acquisitions. We currently market several products under distribution agreements and licenses with third-parties. We intend to continue to pursue alliances and acquisition opportunities that we believe will provide us with technologies to strengthen our market position and grow our business.

Our Products

We offer a portfolio of orthobiologics and spinal implant products for the treatment of patients suffering from spinal and other orthopedic disorders. Information regarding the amount and percentage of total revenue contributed by our orthobiologics and spinal implant products for each of the last two fiscal years may be found in Part II, Item 7 of this report under the sections entitled “Year Ended December 31, 2018 Compared to Year Ended December 31, 2017—Revenue” and in Part II, Item 8 of this report in the Notes to Consolidated Financial Statements in Note 11, “Segment and Geographic Information.”

Orthobiologics

Our orthobiologics products are used in orthopedic and dental procedures and consist of a broad range of traditional and advanced bone graft substitutes intended to address the key elements of bone regeneration - 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 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, called an autograft, or by extending the volume of bone graft material from the patient by combining it with the bone graft substitute.

Our orthobiologics portfolio includes particulate and fibers-based DBM, collagen ceramic matrices, demineralized cancellous allograft bone and synthetic bone void fillers. We offer our orthobiologics products in the form of fibers, putties, pastes, strips and DBM in a resorbable mesh for a range of surgical applications.

Demineralized Bone Matrix and Accell Technology

DBM 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 DBM formulations combined particulate-demineralized bone matrix with an inert carrier engineered for easy graft handling and graft containment. The carrier is a biocompatible synthetic polymer with an advantageous property that allows the product to remain moldable at room temperature, but becomes more viscous at body temperature once implanted, which we call reverse-phase. Subsequently, we developed a proprietary process to transform particulate-based DBM into a dispersed form to enhance the performance of the graft material. The result of this process was a DBM product we call Accell bone matrix. Accell bone matrix is an open structured, dispersed form of DBM, which increases the bioavailability of bone proteins at an earlier time in the healing cascade. Standard particulate DBM is dense and therefore the bone proteins release more slowly and in a sustained manner over time. The properties of Accell bone matrix and DBM are both desirable, which is why our advanced DBM products include both components to harness both the early and sustained release of bone proteins. Our Accell Evo3 and OsteoSurge 300 DBM products provide an optimized formulation of Accell bone matrix, particulate-based DBM, and our reverse-phase carrier. These products have a handling property for bone grafting procedures and contain three times the amount of the Accell bone matrix compared to earlier products. 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 differentiates our product compared to competitive DBM products.

In 2017, we launched our OsteoStrand™ and Strand™ Demineralized Bone Fibers product lines as well as our OsteoStrand Plus and Strand Plus product lines, which incorporate our proprietary Accell Bone Matrix. These products provide 100% demineralized bone fibers and are designed to facilitate and aid in fusion by maximizing osteoinductive content while providing an improved conductive matrix. The fibers were developed through a process that evaluated a variety of fiber geometries to optimize osteoinductivity and osteoconductivity, intraoperative handling and controlled expansion in order to facilitate surgical placement, to maintain surgical position and to allow the fibers to better fill the surgical defect with the overriding goal to improve fusion potential.

Also in 2017, we launched our OsteoBallast™ and Ballast™ Demineralized Bone Matrix in Resorbable Mesh product lines, which are also designed to facilitate and aid in fusion. These products, which consist of a resorbable mesh

containing 100% DBM without a carrier, are designed to simplify graft placement and help prevent graft migration while maximizing DBM content. OsteoBallast is designed to provide surgeons with a simple means for delivering bone graft in posterior spine surgery that contours to the local anatomy while maintaining shape and volume under compression. The simplified technique is intended to be particularly valuable in MIS procedures, where placing the graft accurately through tubes and small incisions can be challenging.

We believe that our recently launched and existing product offerings deliver clinical value as payors and hospitals seek more cost effective orthobiologic solutions.

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Collagen Ceramic Matrix Technologies

Our collagen ceramic matrix technology leverages a history of regenerative technology and collagen engineering. Our leading products in this category are currently marketed as IsoTis Mozaik and OsteoStrux and are 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. These products 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 substitute products consist of allograft cancellous bone scaffolds and synthetic bone void fillers.

Spinal Implants

Our spinal implant portfolio consists of an extensive line of products for spinal decompression, alignment, and stabilization. Such products are typically used to facilitate fusion in degenerative, minimally invasive, and complex spinal deformity procedures throughout the lumbar, thoracic and cervical regions of the spine. Our products are increasingly focused on restoring adequate spinal balance and profile in the sagittal (front to back) plane, which we believe is widely recognized as an important factor to improve the quality of life in patients undergoing surgery for spinal degeneration or deformity.

Degenerative

Our degenerative products include systems 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 designed for use in both thoracolumbar and cervical spine cases.

Our innovative line of interbody devices with various footprint and lordotic options is designed to maintain spine alignment and appropriate spacing while allowing bone to grow between the vertebrae to achieve bone fusion. Our Hollywood, Hollywood VI, and Ventura NanoMetalene interbody device for transforaminal lumbar interbody fusion procedures can be used to fuse the lumbar spine through a posterior approach that starts off to one side of the patient's back. Our Vu a·POD™ Prime NanoMetalene® interbody device for anterior lumbar interbody fusion procedures can be used to fuse the spine through an anterior approach. Our Regatta NanoMetalene Lateral System, which we launched in late 2018, is a comprehensive lateral lumbar interbody system that can be used to fuse the spine through a lateral approach. Our Shoreline® Anterior Cervical Standalone System, featuring the NanoMetalene technology, is a modular plate and interbody device designed to maximize intraoperative flexibility to address a wide range of anatomy, surgical situations or bone in anterior cervical disc fusions. Our Cambria NanoMetalene interbody device can be used to fuse the cervical spine through an anterior approach.

We offer a comprehensive portfolio of spinal fixation products for the cervical, thoracic and lumbar regions of the spine, consisting of rods, screws, plates and instrumentation to facilitate spinal decompression and fusion. Our Mariner Posterior Fixation System is a pedicle screw system featuring modular threaded technology and accompanying instrumentation designed to reduce the number of trays needed for surgery and that provides surgeons with multiple intra-operative options to facilitate posterior lumbar fixation. We also offer a variety of screw and plating systems, such as our Cabo™ ACP Anterior Cervical Plating System, that combine large graft viewing windows

and a visual confirmation locking system for cervical fixation.

Minimally Invasive Surgery

MIS procedures are less invasive than traditional open surgery procedures, and may result in reduced post-operative 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 and inserts implants necessary for fusion, such as the screws

and rods of our NewPort and Coral® MIS solutions. Our NewPort MIS product has extended tabs for a small incision profile and offers two rod delivery options for both mini-open and percutaneous approaches. Our Coral MIS product offers a mini-open muscle splitting rod delivery option for surgeons new to MIS procedures. Our MIS portfolio also includes a comprehensive set of decompression instruments, static and expandable interbody devices, and screw systems designed to facilitate access to the treatment area while minimizing anatomical disruption.

Complex Spinal Deformity

Our spinal implant products are used in complex spinal deformity procedures involving multiple spine segments, challenging anatomy, tumors, traumatic injury and revision of previous fusion surgeries. 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. We offer several technologies designed to address the needs of our surgeon customers who perform complex deformity procedures and the various derotation techniques they use to correct spine curvature. For example, our Daytona® Deformity System uses extended tab uniplanar and polyaxial screws with multiple rod options and intuitive instrumentation to create a versatile system adaptable to surgeon preference. Our Daytona Small Stature System, which has an adolescent idiopathic scoliosis indication, is designed to address standard to complex deformity cases in smaller-sized patients who need a lower profile construct due to anatomy constraints. We provide our systems in multiple configurations and materials to address patient requirements, including stainless steel, titanium alloy and cobalt chrome alloy rod options, as well as multiple rod diameters. Offering 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. Our complex spinal implant portfolio allows surgeons to combine various product lines and approaches, offering several treatment options for the most difficult cases.

Product Pipeline

We are committed to supplementing our portfolio of orthobiologics and spinal implant products through continuous innovation and bringing next-generation products to the market. Our development pipeline consists of modular MIS, revision and deformity systems based on our Mariner platform technology, an expandable interbody device system, a posterior cervical fixation system, and additional applications for our NanoMetalene technology, as well as extensions of our orthobiologics product offerings to further differentiate this portfolio from those of our competitors.

We plan to continue to build and update our product and technology portfolio and expect to continue to launch a similar number of products and product line extensions as we have in recent years. We believe that our future success and ability to continue to drive revenue growth depends on our ability to sustain this cadence of new and next-generation product launches and innovation.

Research and Development

We have a research and development organization dedicated to advancing our portfolio of orthobiologics and spinal implant products through product development and clinical affairs programs. Our product development efforts employ an integrated team approach that involves collaboration between surgeons, our engineers, our machinists, as well as our regulatory personnel.

Our spinal implants 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 Carlsbad, California facility. We use a broad scope of technologies designed to allow us to meet the

complex engineering requirements of customers. As part of the development process, spine surgeons test the implantation of the products in our in-house cadaveric laboratory, which helps us design new products intended to 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. Our clinical and regulatory personnel work in parallel with our product engineering personnel to facilitate regulatory clearances of our orthobiologics and spinal implant products. We believe that these product development efforts allow us to provide solutions that respond to the needs of our surgeon customers and their patients.

We plan to develop line extensions for our innovative orthobiologics technologies that will continue to reduce the amount of autologous bone graft needed for spinal fusion procedures. Our orthobiologics research and development team has experience in biomaterial sciences and bringing next generation technologies to market.

We are also committed to developing new spinal implant products that leverage the NanoMetalene and expandable interbody platforms technology and provide next generation solutions for our existing products or extend the range of solutions that we provide. We are 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. 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.

Sales and Distribution

We currently market and sell our products in the United States and in approximately 30 countries worldwide. Our United States sales organization consists of regional and territory business managers who oversee a broad network of independent orthobiologics and spinal implant sales agents that receive commissions from us based on sales they generate. Our international sales organization consists of a sales management team that oversees a network of independent orthobiologics and spinal implant stocking distributors that purchase our products directly from us and independently sell them. During 2018, our domestic and international revenues accounted for 89% and 11%, respectively, of total revenue. Information regarding financial data by geographic segment is set forth in Part II, Item 8 of this report in the Notes to Consolidated Financial Statements in Note 11, "Segment and Geographic Information."

In the United States, we typically consign our orthobiologics products and consign or loan our spinal implant 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. Our spinal implant sets typically contain the instruments, including disposables, and spinal implants required to complete a surgery.

In international markets, we predominantly sell complete instrument and implant sets to independent stocking distributors, who consign or loan these sets to surgeons. We maintain sales and marketing personnel in France to manage and support our stocking distributors in Europe and use third-party distribution facilities in Belgium and the Netherlands to support European distribution efforts.

We have recently increased, and intend to continue to increase, the quality, size, exclusivity and geographic breadth of our network of independent sales agents in the United States. During 2017 and 2018, we gained representation in parts of the country where we had no representation or were significantly underrepresented. We anticipate adding additional independent sales agents in the United States in 2019. With certain of the new sales agents that we bring on board in territories with a high potential for growth, we focus on entering into relationships in which they carry our spinal implants exclusively, except with respect to clinical markets that our products do not address. We believe these more exclusive relationships will allow us to grow faster and more cost effectively in these territories over the long term. We also plan to continue to invest in additional instrument sets and marketing and education efforts to support the expansion of our independent sales agent footprint.

To support our expansion efforts in the United States, we have invested more in, and developed comprehensive support for, sales agent and surgeon training and education programs. To this end, we have leveraged the capacity of our hands-on cadaveric training laboratory at our Carlsbad, California facility and constructed a hands-on cadaveric training laboratory in our Wayne, Pennsylvania facility to increase the number of training opportunities for surgeons and sales agents. We believe training and education will help surgeons become adept with our spinal implant products and techniques, thereby improving outcomes for their patients.

We believe the expansion of our U.S. sales efforts will provide us with the opportunity to sustain revenue growth as we continue to penetrate existing and new markets.

Internationally, we intend to continue to focus our sales and marketing efforts on expanding and strengthening our presence in those markets where we currently have relationships with stocking distributors and to selectively expand into 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 one supplier. Our relationships with suppliers that cannot 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 agreement by the parties, by either party upon material breach by the other and by either party if 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, and except for our supply agreement with PcoMed, LLC ("PcoMed"), is immaterial in amount and significance and not a contract upon which our business is substantially dependent. In addition, we endeavor 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 only source our raw materials from tissue banks registered with the U.S. Food and Drug Administration (FDA) and accredited by the American Association of Tissue Banks (AATB). The donors are screened, tested and processed by the tissue banks in accordance with FDA and AATB requirements. Additionally, each donor must pass FDA-specified bacterial and viral testing before 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 safety assurance, each lot of bone is released into the manufacturing process only after our 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. This process is designed to support the safety and effectiveness of our DBM products.

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 bovine spongiform encephalopathy (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 select foreign countries. When we determine 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 proprietary information, we typically require our employees, consultants and advisors to execute agreements that provide that confidential information developed or provided to the individual by us or on our behalf during their relationship with us must be kept confidential, except in specified circumstances.

IsoTis OrthoBiologics, Inc., one of our subsidiaries, owns a group of patents related to the reverse-phase carrier and Accell process and materials. This patent group protects the Accell family of DBM products. The patents in this group expire over time through 2023.

We licensed three U.S. patents related to certain of our pedicle screw systems from Dr. Thomas T. Haider. The license agreement, as amended, expired when the last-to-expire licensed patent expired in December 2016. Sales of the products covered under this license agreement represented approximately 6% of our total revenue in 2018.

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Our material registered and unregistered trademarks include: Accell®, Evo3®, Accell Evo3®, Accell Evo3®C, DynaGraft® II , IsoTis®, IsoTis OrthoBiologics®, OrthoBlast® II , Atoll™, Capistrano™, Coral®, Daytona®, Hollywood™, Malibu™, NanoMetalene®, NewPort™, Vu aPOD™, Vu aPOD™ Prime, OsteoSurge® 100 (or 300), SeaSpine Sierra™, Sonoma™, Shoreline®, Mariner®, TruProfile®, Ballast™, OsteoBallast™, Strand®, OsteoStrand®, SkipJack®, SkipJack Expandable Interbody®, and RAPID® and Regatta®.

Competition

The global orthobiologics and spine markets are highly competitive. We face significant competition in both markets from the spine divisions of large multinational medical device companies, established companies focused solely or primarily on spine, as well as smaller, emerging players focused on product innovation. These competitors are focused on bringing new technologies to market and acquiring technologies and technology licenses that directly compete with our products or have potential product advantages that could render our products obsolete or noncompetitive.

Our primary competitors in the combined orthobiologics and spinal implant markets include Medtronic, DePuy Synthes Spine (a Johnson & Johnson company), NuVasive, Stryker, Globus Medical, Zimmer-Biomet, Orthofix, RTI Surgical, Alphatec, XTANT Medical, Baxter, Bioventus, Cerpedics and several smaller, biologically-focused companies.

We anticipate that our currently marketed products and any future marketed products will be subject to intense competition. Many of our competitors have significantly greater financial, manufacturing and marketing resources than we do, which could make scaling our business challenging. In addition, these competitors have more tenured relationships with parties in distribution channels and we anticipate they will continue to dedicate significant resources to marketing and distributing their products and to developing and commercializing competing products. Our ability to compete will depend on our ability to launch innovative new products that demonstrate superior clinical outcomes.

Regulation

We are a manufacturer and marketer of medical devices and a tissue bank, and therefore are subject to extensive regulation by the FDA, and the Center for Medicare Services of the U.S. Department of Health and Human Services and other federal governmental agencies and, in some jurisdictions, by state and foreign governmental agencies. The regulations to which we are subject govern the introduction of new medical devices, the observance of certain standards with respect to the design, manufacture, testing, labeling, promotion and sales of devices, record maintenance, the ability to track devices, potential and actual product defect reporting, import and export of devices, and other matters.

The regulatory process of obtaining product approvals and clearances can be onerous and costly. The FDA requires, as a condition to marketing a medical device in the United States, and as applicable based on product type and classification, that we secure a Premarket Notification clearance pursuant to Section 510(k) of the United States Federal Food, Drug, and Cosmetic Act (FDCA) or an approved premarket approval (PMA) application (or PMA supplement). Obtaining these approvals and clearances can take up to several years and may involve preclinical studies and clinical trials. The FDA may also require a post-approval clinical trial as a condition of approval.

To perform clinical trials for significant risk devices in the United States on an unapproved product, we are required to obtain an Investigational Device Exemption from the FDA. The FDA may also require a filing for FDA approval prior to marketing products that are modifications of existing products or new indications for existing products. Moreover, after clearance/approval is given, if the product is shown to be hazardous or defective, the FDA and foreign regulatory agencies have the power to withdraw the clearance or require us to change the device, its manufacturing process or its labeling, to supply additional proof of its safety and effectiveness or to recall, repair, replace or refund the cost of the medical device.

The FDA Safety and Innovation Act of 2012 (FDASIA), which includes the Medical Device User Fee Amendments of 2012, as well as other medical device provisions, went into effect October 1, 2012. This includes performance goals and user fees paid to the FDA by medical device companies when they register and list with the FDA and when they apply to market a device in the United States. The FDASIA also imposes additional requirements regarding FDA Establishment Registration and Listing of Medical Devices. All U.S. and foreign manufacturers must have an FDA Establishment Registration and complete Medical Device listings for sales in the United States.

We manufacture medical devices derived from human tissue (demineralized bone tissue). The FDA has specific regulations governing human cells, tissues, and cellular and tissue-based products (HCT/Ps). An HCT/P is a product containing, or consisting of, human cells or tissue intended for transplantation into a human patient. Examples include bone, ligament, skin and cornea. Some HCT/Ps fall within the definition of a biological product, medical device or drug regulated under the FDCA. These biologic, device or drug HCT/Ps must comply both with the requirements exclusively applicable to HCT/Ps and, in addition, with requirements applicable to biologics, devices or drugs, including premarket clearance or approval from the FDA.

Section 361 of the Public Health Service Act authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as 361 HCT/Ps are subject to requirements relating to registering

facilities and listing products with the FDA, screening and testing for tissue donor eligibility, Good Tissue Practice when processing, storing, labeling, and distributing HCT/Ps, including required labeling information, stringent record keeping, and adverse event reporting.

The AATB has issued operating standards for tissue banking. Accreditation is voluntary, but compliance with these standards is a requirement to become an AATB-accredited tissue establishment. In addition, some states have their own tissue banking regulations. We are licensed or have permits for tissue banking in California, Florida, New York, Maryland, and other states that require specific licensing or registration.

National Organ Transplant Act. Procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act (NOTA), which prohibits the transfer of certain human organs, including skin and related tissue for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue they provide to us for processing. We include in our pricing structure amounts paid to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with processing, preservation, quality control and storage of the tissue, marketing and medical education expenses, and costs associated with development of tissue processing technologies. NOTA payment allowances may be interpreted to limit the amount of costs and expenses that we may recover in our pricing for our products, thereby reducing our future revenue and profitability.

Postmarket Requirements. After a device is cleared or approved for commercial distribution, numerous regulatory requirements apply. These include, but are not limited to, the FDA's Quality System Regulations which cover the procedures and documentation of the design, testing, production processes, controls, quality assurance, labeling, packaging, storage and shipping of medical devices; the FDA's general prohibition against promoting products for off-label uses; the Federal Medical Device Reporting regulation, which requires that manufacturers provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or that a malfunction occurred which would be likely to cause or contribute to a death or serious injury upon recurrence; and the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field corrective actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA.

We are also required to register with the FDA as a medical device manufacturer. As such, our manufacturing sites are subject to periodic inspection by the FDA for compliance with the FDA's Quality System Regulations. These regulations require that we manufacture our products and maintain our documents in a prescribed manner with respect to design, manufacturing, testing and control activities. Further, we are required to comply with various FDA requirements and other legal requirements for labeling and promotion. If the FDA believes that a company is not in compliance with applicable regulations, it may issue a warning letter, institute proceedings to detain or seize products, issue a recall order, impose operating restrictions, enjoin future violations and assess civil penalties against that company, its officers or its employees and may recommend criminal prosecution to the U.S. Department of Justice (DOJ). Similar requirements to those outlined above also apply to tissue products.

Medical device regulations also are in effect in many of the countries in which we do business outside the United States. These laws range from comprehensive medical device approval and quality system requirements for some or all of our medical device products to simpler requests for product data or certifications. The number and scope of these requirements are increasing. Under the EU Medical Devices Directive, medical devices must meet the Medical Devices Directive requirements and receive CE Mark Certification prior to marketing in the EU. CE Mark Certification requires a comprehensive quality system program, comprehensive technical documentation and data on

the product, which are then reviewed by a Notified Body. A Notified Body is an organization designated by the national governments of the EU member states to make independent judgments about whether a product complies with the requirements established by each CE marking directive. The Medical Devices Directive and ISO 13485 are recognized international quality standards designed to ensure that we develop and manufacture quality medical devices. Other countries are also instituting regulations regarding medical devices. Compliance with these regulations requires extensive documentation and clinical reports for all of our products, revisions to labeling, and other requirements such as facility inspections to comply with the registration requirements. A recognized Notified Body audits our facilities annually to verify our compliance with these standards.

In the EU, our products that contain human-derived tissue, including demineralized bone material, are not medical devices as defined in the Medical Device Regulation (MDR) EU 2017/745 replacing prior directives Medical Devices Directive (93/42/EC) and 2001/83/EC respectively. They are also not medicinal products as defined in Directive 2001/83/EC. Today, regulations, if applicable, are different from one EU member state to the next. Because of the absence of a harmonized regulatory framework

and the proposed regulation for advanced therapy medicinal products in the EU, the approval process for human-derived cell or tissue-based medical products may be extensive, lengthy, expensive, and unpredictable.

Certain countries, as well as the EU, have issued regulations that govern products that contain materials derived from animal sources. Regulatory authorities are particularly concerned with materials infected with the agent that causes BSE. These regulations affect our biomaterial products for the spine, which contain material derived from bovine tissue. Although we take steps designed to provide that our products are safe and free of agents that can cause disease, products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for prion transmission. Significant new regulations, a ban of our products, or a movement away from bovine-derived products because of an outbreak of BSE could have a material and adverse effect on our business or our ability to expand our business. See “Risk Factors-Risks Relating to Our Regulatory Environment-Certain of our products contain materials derived from animal sources and may become subject to additional regulation.”

We are subject to laws and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws that regulate how companies in the health care industry may market their products to hospitals and health care professionals and may compete by discounting the prices of their products. The delivery of our products is subject to regulation regarding reimbursement, and federal healthcare laws apply when a customer submits a claim for a product that is reimbursed under a federally funded healthcare program. These rules require that we exercise care in structuring our sales and marketing practices and customer discount arrangements. See “Risk Factors-Risks Relating to Our Regulatory Environment-Oversight of the medical device industry might affect the way may sell medical devices and compete in the marketplace.”

Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs, import-export, laws regarding transactions in foreign countries, the FCPA and local anti-bribery and other laws regarding interactions with healthcare professionals. Among other things, these laws restrict, and in some cases prohibit, United States companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices in foreign countries.

Our research, development and manufacturing processes involve the controlled use of certain hazardous materials. We are subject to country-specific, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these materials and certain waste products. We believe that our environmental, health and safety (EHS) procedures for handling and disposing of these materials comply with the standards prescribed by the controlling laws and regulations. However, risk of accidental releases or injury from these materials is possible. These risks are managed to minimize or eliminate associated business impacts. In the event of this type of accident, we could be held liable for damages that may result, and any liability could exceed our resources. We could be subject to a regulatory shutdown of a facility that could prevent the distribution and sale of products manufactured there for a significant period of time and we could suffer a casualty loss that could require a shutdown of the facility in order to repair it, any of which could have a material and adverse effect on our business. Although we continuously strive to maintain full compliance with respect to all applicable global EHS laws and regulations, we could incur substantial costs to fully comply with future laws and regulations, and our operations, business or assets may be impacted.

In addition to the above regulations, we are and may be subject to regulation under country-specific federal and state laws, including, but not limited to, requirements regarding record keeping, and the maintenance of personal information, including personal health information. We also are subject to other present, and could be subject to possible future, local, state, federal and foreign regulations.

Reimbursement Overview

Healthcare providers that purchase medical devices generally rely on third-party payors, including the Medicare and Medicaid programs, and private payors, such as indemnity insurers, employer group health insurance programs and managed care plans, to reimburse all or part of the cost of the device. As a result, demand for our products is and will continue to depend in part on the coverage and reimbursement policies of these third-party and private payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the device is furnished and utilized. Reimbursement from Medicare, Medicaid and other third-party payors may be subject to periodic adjustments as a result of legislative, regulatory and policy changes and budgetary pressures. Possible reductions in, or eliminations of, coverage or reimbursement by third-party and private payors, or denial of, or provision of uneconomical reimbursement for new products, as a result of these changes may affect our customers' ability to purchase our products. Any changes in the healthcare regulatory, payment or enforcement landscape relative to our customers' healthcare services may significantly affect our operations and revenue.

Facilities

We have four facilities: our headquarters in Carlsbad, California, from which our orthobiologics and spinal implant products are designed, developed, and marketed and from which our more recently launched spinal implant products are inspected, kitted and distributed; a manufacturing and distribution facility in Irvine, California, from which most of our orthobiologics products are manufactured and all are distributed; office space in Wayne, Pennsylvania, where we design spinal implants and which facilitates our interactions with customers on the East Coast; and our European sales and marketing office in Lyon, France.

We inspect, kit, and distribute most of our spinal implant products through a third-party logistics provider facility in Olive Branch, Mississippi. We distribute our orthobiologics and spinal implant products in certain international markets through third-party logistics provider facilities in Belgium and the Netherlands.

Additional information regarding our facilities may be found in Part I, Item 2 of this report.

Employees

As of February 25, 2019, we had 361 regular employees, 48 of whom were engaged in research and development, 108 in manufacturing, 108 in sales and marketing and 97 in general and administrative activities.

Available Information

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended, (the Exchange Act). In accordance with the Exchange Act, we file or furnish annual, quarterly and current reports, amendments to those reports, proxy statements and other information with the SEC. We make these reports and other information available free of charge on our website at www.seaspine.com under the investors page as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. All such reports were made available in this fashion during 2018.

The SEC maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at www.sec.gov.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below, together with the other information in this Form 10-K, in evaluating the Company and our common stock. If any of the risks described below actually occurs, our business, financial results, financial condition and stock price could be materially and adversely affected.

Risks Relating to our Business

We expect to incur losses for the foreseeable future and cannot assure you that we will be able to generate sufficient sales to achieve or sustain profitability.

We expect to incur losses for the foreseeable future as we dedicate significant resources to our marketing and product development strategy, including as we continue to: (i) develop new and next generation products and product line extensions (all of which we call “new products”); (ii) develop new medical techniques designed to enhance the utility of our products; (iii) collect clinical data and conduct clinical studies to differentiate our products from those of our competitors and to demonstrate the value of our products to current and prospective customers and payors; (iv) add independent sales agents and stocking distributors to increase our geographic sales coverage and penetration; (v) increase product inventory to raise the likelihood of success of new product launches; and (vi) expand our marketing campaigns and surgeon education and training programs. We cannot assure you that we will ever generate sufficient

revenues from our operations to achieve profitability and, even if we achieve profitability, we cannot assure you that we will remain profitable. Our failure to achieve or maintain profitability could negatively affect the value of our securities and our ability to attract and retain personnel, raise capital, execute our business strategy or continue operations.

We operate in an industry and in market segments that are highly competitive and we may not compete successfully

There is intense competition among medical device companies that serve the spinal surgery market. We compete with established medical technology companies, as well as earlier-stage companies that often have differentiated technology and potentially superior solutions for the challenges facing our neurosurgeon and orthopedic spine surgeon customers and their patients.

Our primary competitors include Medtronic, DePuy Synthes Spine (a Johnson & Johnson company), NuVasive, Stryker, Globus Medical, Zimmer-Biomet, Orthofix, RTI Surgical, Alphatec, XTANT Medical, Baxter, Bioventus, Cerpedics and several smaller, biologically-focused companies.

Many of our competitors may have access to greater financial, technical, research and development, marketing, manufacturing, sales, distribution, administrative, consulting and other resources than we do. Our competitors may be more effective at developing products, at differentiating their products from our and other competitor products and at designing, executing, analyzing the results of and publishing data from clinical studies. Our competitors may also have: stronger intellectual property portfolios; broader spine surgery product offerings and products supported by more extensive clinical data; more established distribution networks; entrenched relationships with surgeons; significantly greater name recognition and more recognizable trademarks for products similar to the products we sell; more established relationships with healthcare providers and payors; greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancement; and greater experience in launching, marketing and selling products than we do. Many of our competitors specialize in a specific product or focus on a particular market segment, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are, or claim to be, superior to our products, or that are alternatives to our existing or planned products may also create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the spine market generally.

Our competitive position depends on our ability to achieve market acceptance for our current and future products. Market acceptance for any of our products requires, among other things, that we timely secure regulatory approval; demonstrate the value of our products, both to our surgeon customers and payors, which may require that we collect clinical data and/or conduct clinical studies; effectively educate and train our surgeon customers and their staff on the proper use of our products; obtain and maintain coverage and adequate reimbursement for our products, both within and outside the U.S., including under Medicare and Medicaid and from private payors; attract and retain a network of independent sales agents and stocking distributors focused on neurosurgeons and orthopedic spine surgeons; develop and execute an effective marketing strategy; protect the proprietary positions of our products, including through patent protection; and consistently produce quality products in sufficient quantities to meet demand. Significant risks are associated with each of these activities and other activities required to achieve market acceptance of both our current and future products, some of which are more fully described elsewhere in this “Risk Factors” section.

In addition, at any time our competitors or other companies may develop alternative treatments, products or procedures for the treatment of spine disorders that compete directly or indirectly with our products, including ones that prove to be superior to our products.

For these reasons, we may not compete successfully against our existing or potential competitors. Any such failure could lead us to modify our strategy, to lower our prices, or to increase the commissions we pay on sales of our products and could have a significant adverse effect on our business, financial condition and results of operations. If we cannot compete effectively, our sales and operating results may suffer.

To be commercially successful, we must effectively demonstrate to neurosurgeon and orthopedic spine surgeons the merits of our products compared to those of our competitors.

Neurosurgeons and orthopedic spine surgeons play a significant role in determining the course of treatment and, ultimately, the product used to treat a patient. As a result, our success depends, in large part, on demonstrating to these surgeons the value of our products in the treatment of their patients. To do so requires that we, along with our independent sales agents and stocking distributors, demonstrate the merits of our products and underlying technology compared to those of our competitors. Surgeons who do not use our products may be hesitant to do so for the following or other reasons:

- lack of experience with our products, techniques, or technologies, or with the equipment necessary to use any of the foregoing;

- existing relationships with those who sell competitive products;
- the time required for surgeon and medical staff education and training on new products, techniques and equipment and technologies;
- lack or perceived lack of clinical evidence supporting patient benefit relative to competing products;
- our products not being included on hospital formularies, in integrated delivery networks or on group purchasing organization preferred vendor lists;
- less attractive coverage and/or reimbursement within healthcare payment systems for our products and procedures compared to other products and procedures;

• other costs associated with introducing new products and the equipment necessary to use new products; and
• perceived risk of liability that could be associated with the use of new products, techniques or technologies.

In addition, we believe recommendations and support of our products by influential neurosurgeons and orthopedic spine surgeons are essential for market acceptance and adoption. If we do not receive support from such surgeons or long-term data does not show the benefits of using our products, surgeons may not use our products.

If we are not successful in convincing surgeons of the merits of our products, we may not maintain or grow our sales or achieve or sustain profitability.

We must successfully educate and train surgeons and their staff on the proper use of our products.

Although most neurosurgeons and orthopedic spine surgeons may have adequate knowledge on how to use most of our products based on their clinical training and experience, we believe that the most effective way to introduce and build market demand for our products is by directly training such surgeons in the use of our products. Convincing surgeons to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you we will succeed in these efforts. If surgeons are not properly trained, they may not use our products, and, as a result, we may not maintain or grow our sales or achieve or sustain profitability. If surgeons are not properly trained they may also misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could have a significant adverse effect on our business, financial condition and results of operations.

Although we believe our training methods for surgeons are conducted in compliance with FDA and other applicable regulations developed both nationally and in third countries, if the FDA or other regulatory agency determines that our training constitutes promotion of an unapproved use or promotion of an intended purpose not covered by the CE mark affixed to our products or FDA approved labeling, they could request that we modify our training or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalty. See also "Oversight of the medical device industry might affect the way we sell medical devices and compete in the marketplace" below.

Changes in third-party payment systems and in the healthcare industry may require us to decrease the selling price for our products, may reduce the size of the market for our products, or may eliminate a market, any of which could have a material and adverse effect on our financial performance.

Our operations may be substantially affected by fundamental changes in the political, economic and regulatory landscape of the healthcare industry. Government and private sector initiatives to limit the growth of healthcare costs are continuing in the U.S., and in many other countries where we do business, causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. These initiatives include price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements.

Maintaining and growing sales of our products depends on the availability of adequate coverage and reimbursement from third-party payors, both within and outside the U.S., including government programs such as Medicare and Medicaid, private insurance plans and managed care organizations. Hospitals and other healthcare providers that purchase our products generally rely on third-party payors to cover all or part of the costs associated with the procedures performed with our products, including the cost to purchase our product. Both the patients' and our customers' access to adequate coverage and reimbursement for the procedures performed with our products by government and private insurance plans is central to the acceptance of our current and future products. We may be unable to sell our products on a profitable basis, or at all, if third-party payors deny coverage or reduce their levels of payment. In addition, if our cost of production increases at a rate greater than increases in reimbursement levels for our products, our profitability may be adversely affected.

The healthcare industry, both within and outside the U.S., has experienced a trend toward cost containment as government and private insurers seek to control rising healthcare costs by imposing lower payment and negotiating reduced contract rates with service providers. Third-party payors continually review their coverage and reimbursement policies for procedures involving the use of our products and can, without notice, eliminate or reduce coverage or

reimbursement for our products. For example, a major national third-party insurer in the U.S. recently reduced coverage (from all or most cases to limited indications) for biomechanical devices (e.g., spine cages) used in cervical fusion procedures, stating that the devices had not been shown to be more effective than bone graft. In addition, certain insurers have limited coverage for vertebral fusions in the lumbar spine and other insurers may adopt similar coverage decisions in the future. Patients covered by these insurers may be unwilling or unable to afford lumbar fusion surgeries to treat their conditions, which could materially harm or limit our ability to sell our products designed for such surgeries. Further, third-party payors of hospital services and hospital outpatient services annually revise their payment

methodologies, which could result in stricter standards for or the elimination or reduction of reimbursement of hospital charges for certain medical procedures.

Further, in the U.S., several provisions of the U.S. Patient Protection and Affordable Care Act (the Affordable Care Act) and the Health Care and Education Reconciliation Act of 2010 address access to health care products and services and establish certain fees for the medical device industry. These provisions may be modified, repealed, or otherwise invalidated, in whole or in part. Future rulemaking could affect rebates, prices or the rate of price increases for health care products and services, or required reporting and disclosure. We cannot predict the timing or impact of any future rulemaking or changes in the law.

To the extent we sell our products internationally, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country. As in the U.S., our products may not obtain coverage and reimbursement approvals in a timely manner, if at all, in a particular international market. In addition, even if we obtain country-specific coverage and reimbursement approvals, we could incur considerable expense to do so. Our failure to obtain such coverage and approvals would negatively affect market acceptance of our products in the international markets in which such failure occurs and the expenses incurred in connection with obtaining such coverage and approvals could outweigh the benefits of obtaining them.

If the trend by governmental agencies and other third-party payors to reduce coverage of and/or reimbursement for procedures using our products continues, our business, results of operations and financial condition could be materially and adversely affected. Further, we cannot be certain that, under current and future payment systems, the cost of our products will be adequately incorporated into the overall cost of the procedure and, accordingly, we cannot be certain that the procedures performed with our products will be reimbursed at a cost-effective level, or at all. Industry trends have resulted in increased downward pricing pressure on medical services and products, which may affect our ability to sell our products at prices necessary to support our current business strategy.

The trend toward healthcare cost containment through aggregating purchasing decisions and industry consolidation, along with the growth of managed care organizations, is placing increased emphasis on the delivery of more cost-effective medical therapies. For example:

There has been consolidation among healthcare facilities and purchasers of medical devices, particularly in the U.S. One of the results of such consolidation is that group purchasing organizations, integrated delivery networks and large single accounts use their market power to consolidate purchasing decisions, which intensifies competition to provide products and services to healthcare providers and other industry participants, resulting in greater pricing pressures and the exclusion of certain suppliers from important market segments. For example, some group purchasing organizations negotiate pricing for its member hospitals and require us to discount, or limit our ability to increase, prices for certain of our products.

Surgeons increasingly have moved from independent, out-patient practice settings toward employment by hospitals and other larger healthcare organizations, which align surgeons' product choices with their employers' price sensitivities and adds to pricing pressures. Hospitals have introduced and may continue to introduce new pricing structures into their contracts to contain healthcare costs, including fixed price formulas and capitated and construct pricing.

Certain hospitals provide financial incentives to doctors for reducing hospital costs (known as gainsharing), rewarding physician efficiency (known as physician profiling) and encouraging partnerships with healthcare service and goods providers to reduce prices.

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Existing and proposed laws, regulations and industry policies, in both domestic and international markets, regulate or seek to increase regulation of sales and marketing practices and the pricing and profitability of companies in the healthcare industry.

More broadly, other provisions of the Affordable Care Act could meaningfully change the way healthcare is developed and delivered in the U.S., and may adversely affect our business and results of operations. For example, the Affordable Care Act encourages hospitals and physicians to work collaboratively through shared savings programs, such as accountable care organizations, as well as other bundled payment initiatives, which may ultimately result in the reduction of medical device purchases and the consolidation of medical device suppliers used by hospitals. It is unclear what the full impact of the legislation will be. Some of the provisions of the Affordable Care Act have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act and to alter the implementation of the Affordable Care Act and related laws. We cannot predict

accurately what healthcare programs and regulations will ultimately be implemented at the U.S. federal or state level, or the effect of any future legislation or regulation in the U.S. or elsewhere. However, any changes that have the effect of reducing reimbursements for our products or reducing medical procedure volumes could have a material and adverse effect on our business, financial condition and results of operations.

Further, the proliferation of medical device sales agents that are owned, directly or indirectly, by physicians (commonly called physician-owned distributorships, or PODs) could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with these sales agents. These physicians derive a proportion of their revenue from selling or arranging for the sale of medical devices for use in procedures they perform on their own patients at hospitals that agree to purchase from or through the POD, or that otherwise furnish ordering physicians with income based, directly or indirectly, on those orders of medical devices. The number of PODs in the spine industry may continue to grow as economic pressures increase throughout the industry and as hospitals, insurers and physicians search for ways to reduce costs and, in the case of the physicians, search for ways to increase their incomes. PODs and the physicians who own, or partially own, them have significant market knowledge and access to the surgeons who use our products and the hospitals that purchase our products. Growth in the number of PODs may reduce our ability to compete effectively for business from physicians who own, or partially own, them, which could have a material and adverse effect on our business, results of operations and financial condition.

In addition, the largest device companies with multiple product franchises have increased their effort to leverage and contract broadly with customers across franchises by providing volume discounts and multi-year arrangements that could prevent our access to these customers or make it difficult (or impossible) to compete on price.

We may not develop new products in a timely and consistent manner, and failure to do so may adversely affect the attractiveness of our overall product portfolio to our surgeon customers and negatively impact our sales and market share.

To be and remain competitive, we need to introduce new products and enhancements or modifications to our existing products on a regular basis and successfully respond to technological advances. Doing so is technologically challenging and involves significant risks and uncertainty. Despite substantial investments of time and resources, our research and development efforts may not result in technically feasible new products. Even if technically feasible, the anticipated time and cost of obtaining regulatory approval and/or commercializing a new product may be too great to justify continued development. In addition, competitors could develop products that are more effective, are less expensive to manufacture, are priced more competitively or are ready for commercial introduction before our products. The introduction of new products by our competitors may lead us to reduce the prices of our products, may lead to reduced margins or loss of market share, and may render our products obsolete or noncompetitive. The success of any of our new product offerings or enhancement or modification to our existing products will depend on several factors, including our ability to:

- properly identify and anticipate surgeon and patient needs;
- develop new products or enhancements or modifications in a timely manner;
- obtain the regulatory approvals for new products or product enhancements or modifications in a timely manner;
- provide adequate training to potential users of new products and product enhancements or modifications;
- receive adequate reimbursement approval of third-party payors such as Medicaid, Medicare and private insurers; and
- develop an effective marketing and distribution network.

If we cannot develop technically and commercially viable new products and enhancements or modifications to our existing products on a consistent basis and before our competitors, our prospects could be materially and adversely affected.

It is also important that we carefully manage our introduction of new products and enhancements or modifications to our existing products. If potential customers delay purchases until new or enhanced or modified products are available, it could negatively impact our sales. In addition, to the extent we have excess or obsolete inventory as we transition to new or enhanced or modified products, it would result in margin reducing write-offs for obsolete inventory, and our results of operations may suffer.

If we are unable to maintain and expand our network of independent sales agents and stocking distributors, we may not maintain or grow our revenue.

Our ability to generate revenue depends on the sales and marketing efforts of independent sales agents and stocking distributors. Some of our independent sales agents account for a significant portion of our sales volume. If our independent sales agents and stocking distributors fail to adequately promote, market and sell our products, our sales could significantly decrease.

Further, we face significant challenges and risks in managing our geographically dispersed distribution network and retaining the independent sales agents and stocking distributors who make up that network, and as we launch new products and increase our marketing efforts with respect to existing products, we plan to expand the reach of our marketing and sales efforts and may need to hire new independent sales agents and stocking distributors. Independent sales agents and stocking distributors require significant technical expertise in various areas such as spinal care practices, spine injuries and disease, and spinal health and they require training and time to achieve full productivity. Because of the intense competition for their services, we may not attract or retain qualified independent sales agents or stocking distributors or enter into agreements with them on favorable or commercially reasonable terms, if at all. Even if we enter into agreements with additional qualified independent sales agents or stocking distributors, it often takes 6 to 12 months for new sales agents or stocking distributors to reach full operational effectiveness and they may not generate revenue as quickly as we expect them to, commit the necessary resources to effectively market and sell our products, or ultimately succeed in selling our products. Our success will depend largely on our ability to continue to hire, train, retain and motivate qualified independent sales agents and stocking distributors. If we cannot expand our sales and marketing capabilities domestically and internationally, if we fail to train new independent sales agents and stocking distributors adequately, or if we experience high turnover in our sales network, we may not commercialize our products adequately, or at all, which would adversely affect our business, results of operations and financial condition.

Moreover, our independent sales agents and stocking distributors are not our employees, we have limited control over their activities and, generally, we do not enter into exclusive relationships with them. If one or more of them were to be retained by a competitor, whether on an exclusive or non-exclusive basis, they may divert business from us to our competitor, which could materially and adversely affect our sales.

Sales of, or the price at which we sell, our products may be adversely affected unless the safety and efficacy of our products, alone and relative to competitive products, is demonstrated in clinical studies.

Generally, we have obtained 510(k) clearance to manufacture, market and sell the products we market in the U.S. and the right to affix the CE mark to the products we market in the European Economic Area, or EEA. To date, we have not been required to generate new clinical data to support our 510(k) clearances, CE marks, or product registrations in other countries and, accordingly, we do not have our own clinical data regarding our marketed products. As a result, neurosurgeons and orthopedic spine surgeons may be slow to adopt our products and we may be subject to greater regulatory and product liability risks. In addition, certain of our competitors have clinical data supporting the safety and efficacy of their products, which may place our products at a competitive disadvantage.

In part due to the increased emphasis on the delivery of more cost-effective treatments, purchasing decisions of our customers increasingly will be based on clinical data that demonstrates the value of our products or the effectiveness of our products relative to others. Conducting clinical studies is expensive and time-consuming and outcomes are uncertain. See “Risks Relating to Our Regulatory Environment—Clinical studies are expensive and subject to extensive regulation and their results may not support our product candidate claims or may result in the discovery of adverse effects,” below. We may elect not to, or may be unable to, fund the clinical studies necessary to generate the data required for all of our products to compete effectively, in part due to the breadth of our product portfolio. Currently, we do not expect to undertake such clinical studies for all of our products and only expect to do so where we anticipate the benefits will outweigh the costs on a risk-adjusted basis. However, even when we elect and are able to fund such clinical studies on one or more of our products, such studies may not succeed. Data we generate may not be consistent with our existing data and may demonstrate less favorable safety or efficacy, which could reduce demand for our products and negatively impact future sales. Neurosurgeons and orthopedic spine surgeons may be less likely

to use our products if more robust, or any, clinical data supporting the safety and efficacy of competing products is available. If we are unable to or unwilling to generate clinical data supporting the safety and efficacy of our products, our business, results of operations and financial condition could be materially and adversely affected.

Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes.

With the passage of the American Recovery and Reinvestment Act of 2009, funds have been appropriated for the U.S. Department of Health and Human Services' Healthcare Research and Quality to conduct comparative effectiveness research to determine the effectiveness of different drugs, medical devices, and procedures in treating certain conditions and diseases. Some of our products or procedures performed with our products could become the subject of such research. It is unknown what effect, if any, this research may have on our business. Further, future research or experience may indicate that treatment with our products does not improve patient outcomes or improves patient outcomes less than we initially expected. Such results would reduce demand for our products, affect sustainable reimbursement from third-party payers, significantly reduce our ability to achieve expected revenue, and could cause us to withdraw our products from the market and could prevent us from sustaining or increasing profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability, negative publicity, and damage to our reputation, and we could experience a dramatic reduction in sales of our products, all of which would have a material adverse effect on our business, financial condition and results of operations. The spine medical device market has been particularly prone to potential product liability claims that are inherent in the testing, manufacture and sale of medical devices and products for spine surgery procedures.

If any of our manufacturing, development or research facilities are damaged and/or our manufacturing processes are interrupted, we could experience supply disruptions, lost revenues and our business could be seriously harmed. Damage to our manufacturing, development or research facilities or disruption to our business operations for any reason, including due to natural disaster (such as earthquake, wildfires and other fires or extreme weather), power loss, communications failure, unauthorized entry or other events, such as a flu or other health epidemic, could cause us to discontinue development and/or manufacturing of some or all of our products for an undetermined period of time. In addition, our facilities would be difficult to replace and would require substantial lead time to repair or replace. The property damage and business interruption insurance coverage on these facilities that we maintain might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs. In particular, we manufacture our orthobiologics products in one facility in Irvine, California and any damage to that facility could adversely affect our ability to timely satisfy demand for those products. Any significant disruption to our manufacturing operations and to our ability to meet market demand likely would have an adverse impact on our sales and revenues as key stakeholders, including our independent sales agents and stocking distributors and surgeon customers, transition to what they perceive as more reliable sources of products.

We rely on an exclusive license and supply agreement with PcoMed, LLC ("PcoMed") for NanoMetalene surface technology incorporated in certain of our products. The termination of, or loss of exclusivity under, this license agreement could harm sales of certain of our products.

We have an exclusive license and supply agreement with PcoMed allowing the incorporation of their NanoMetalene surface technology into certain of our products, the net sales of which represent approximately 10% of our revenue for the year ended December 31, 2018. In order to maintain our exclusive license rights under the agreement, we must satisfy certain commercialization obligations. If we fail to satisfy these obligations, we lose our exclusive rights to this technology and PcoMed might license some or all this technology to one or more parties, any of which could be one of our competitors, and our ability to compete may be substantially and adversely diminished. In addition, PcoMed serves as our sole supplier for the licensed technology. If PcoMed is unable to meet our demand for the product or if their supply is otherwise disrupted, it could adversely impact our business. Furthermore, if we fail to comply with material obligations under the agreement or if it were terminated for any reason, we could lose rights to this technology that are important to our business. The agreement terminates in December 2020; if we need to renew the license, there is no guarantee we will be able to renew it on commercially reasonable terms, if at all.

In addition to PcoMed, we depend on a limited number of third-party suppliers for components and raw materials and losing any of these suppliers, or their inability to provide us with an adequate supply of materials that meet our quality and other requirements, could harm our business.

Outside suppliers, some of whom are sole-source suppliers, provide us with products and raw materials and components used in manufacturing our orthobiologics and spinal implant products. We strive to maintain sufficient inventory of products, raw materials and components so that our production will not be significantly disrupted if a particular product, raw material or component is not available to us for a period of time, including as a result of a supplier's loss of its ISO or other certification. Any such disruption in our production could harm our reputation, business, financial condition and results of operations.

Although we believe there are alternative supply sources, replacing our suppliers may be impractical or difficult in many instances. For example, we could have difficulty obtaining similar products from other suppliers that are acceptable to the FDA

or other foreign regulatory authorities. In addition, if we are required to transition to new suppliers for certain components of our products, the use of components or materials furnished by these alternative suppliers could require us to alter our operations, and if we are required to change the manufacturer of a critical component of our products, we will have to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of those systems.

If we are unable to obtain sufficient quantities of spinal implant products, raw materials or components that meet our quality and other requirements on a timely basis for any reason, we may not produce sufficient quantities of our products to meet market demand until a new or alternative supply source is identified and qualified and, as a result, we could lose customers, our reputation could be harmed and our business could suffer. In 2013, we experienced supply shortages in collagen ceramic matrix bone void fillers, which adversely affected sales of our orthobiologics products, even after the supply shortage was resolved. Furthermore, an uncorrected defect or supplier's variation in a component or raw material that is incompatible with our manufacturing, unknown to us, could harm our ability to manufacture products.

Further, under the FDA Safety and Innovation Act of 2012, or the FDASIA, which includes the Medical Device User Fee Amendments of 2012, as well as other medical device provisions, all U.S. and foreign manufacturers must have a FDA Establishment Registration and complete Medical Device listings for sales in the U.S. While we believe that our facilities materially comply with these requirements, we also source products from foreign contract manufacturers. It is possible that some of our foreign contract manufacturers will not comply with applicable requirements and choose not to register with the FDA. In such an event, we will need to determine if there are alternative foreign contract manufacturers who comply with the applicable requirements. If such a foreign contract manufacturer is a sole supplier of one of our products, there is a risk that we may not be able to source another supplier.

In addition, we rely on a small number of tissue banks accredited by the American Association of Tissue Banks for the supply of human tissue, a crucial component of our orthobiologics products that serve as bone graft substitutes. Any failure to obtain tissue from these sources or to have the tissue processed by these sources for us in a timely manner will interfere with our ability to meet demand for our orthobiologics products effectively. The processing of human tissue into orthobiologics products is labor intensive and maintaining a steady supply stream is challenging. In addition, due to seasonal changes in mortality rates, some scarce tissues used for our orthobiologics products are at times in particularly short supply. We cannot be certain that our supply of human tissue from our suppliers will be available at current levels or will meet our needs or that we will be able to successfully negotiate commercially reasonable terms with other accredited tissue banks.

We depend on information technology and if our information technology fails to operate adequately or fails to properly maintain the integrity of our data, our business could be materially and adversely affected.

We depend significantly on sophisticated information technology, or IT, for our infrastructure and to support business decisions. Our IT needs require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and to develop new systems to keep pace with new technology, evolving regulatory standards, the increasing need to protect patient and customer information and changing customer patterns. We do not have a comprehensive IT disaster recovery plan. Any significant breakdown, intrusion, interruption, corruption or destruction of any component of our IT systems could have a material and adverse effect on our business, financial condition and results of operations.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we collect and store sensitive data, including legally protected patient health information, credit card information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on-site systems.

These applications and data encompass a wide variety of business critical information including research and development information, commercial information and business and financial information.

Although our computer and information systems are protected through physical and software safeguards, they are still vulnerable to system malfunction, computer viruses, cyber-attacks, breaches or interruptions due to employee error or malfeasance, terrorist attacks, earthquakes (and other natural disasters), fire, flood, power loss, computer systems failure, data network failure, Internet failure, or lapses in compliance with privacy and security mandates. If any of our systems were to become subject to any of the foregoing, our networks could be compromised, and the information stored there could be accessed by unauthorized parties,

publicly disclosed, lost or stolen. These events could lead to the unauthorized access and result in the misappropriation or unauthorized disclosure of confidential information belonging to us or to our employees, partners, customers or suppliers. We have measures in place designed to detect and respond to security incidents and breaches of privacy and security mandates. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. If our IT systems are compromised, due to a data breach or otherwise, we could be subject to legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA, government enforcement actions and regulatory penalties, fines, damages, and enforcement actions, and we could lose trade secrets or other confidential information, the occurrence of any of which could have a material and adverse effect on our business, financial condition and results of operations. Unauthorized access, loss or dissemination could also interrupt our operations, including our ability to bill our customers, provide customer support services, conduct research and development activities, process and prepare company financial information, manage various general and administrative aspects of our business, and could damage our reputation, any of which could adversely affect our business.

We expend substantial resources to comply with laws and regulations relating to public companies, and any failure to maintain compliance could subject us to regulatory scrutiny and cause investors to lose confidence in our company, which could harm our business and have a material adverse effect on our stock price.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the Sarbanes-Oxley Act of 2002 (SOX), and the related rules and regulations adopted by the U.S. Securities and Exchange Commission (SEC), and by the Nasdaq Stock Market increase our accounting, legal and financial compliance costs and make some activities more time-consuming and costly. We cannot predict or estimate with any reasonable accuracy the total amount or timing of the costs we may incur to comply with these laws and regulations. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these matters. For example, compliance with Section 404 of SOX, including performing the system and process documentation and evaluation necessary to issue our annual report on the effectiveness of our internal control over financial reporting and, if applicable, obtain the required attestation report from our independent registered public accounting firm, requires us to incur substantial expense and expend significant management time. Further, we (through our former parent company) have in the past discovered, and in the future may discover, areas of internal controls that need improvement. If we identify deficiencies in our internal controls deemed to be material weaknesses, we could become subject to scrutiny by regulatory authorities and we could lose investor confidence in the accuracy and completeness of our SEC filings, including the financial statements included therein, which could have a material adverse effect on our stock price. Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations, including the possibility of human error and circumvention by collusion or overriding of controls. Accordingly, even an effective internal control system may not prevent or detect material misstatements on a timely basis, or at all. Also, previously effective controls may become inadequate over time because of changes in our business or operating structure, and we may fail to take measures to evaluate the adequacy of and update these controls, as necessary, which could lead to a material misstatement.

In addition, new laws and regulations could make it costlier or more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the coverage that is the same or similar to our current coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve as our executive officers or on our board of directors or on its committees.

Our business could suffer if we lose the services of key members of our senior management or fail to hire and retain other personnel on whom our business relies.

Our ability to execute our business strategy and compete in the highly competitive medical device industry depends, in part, on our ability to attract and retain highly qualified personnel. Companies in the medical device industry in general have experienced a high rate of personnel turnover. Loss of key employees, including any of our scientific,

technical and managerial personnel, could adversely affect our ability to successfully execute our business strategy, which could have a material and adverse effect on our business, results of operations and financial condition. We would be adversely affected if we fail to adequately prepare for future turnover of our senior management team. Moreover, replacing key employees may be a difficult, costly and protracted process, and we may not have other personnel with the capacity to assume all of the responsibilities of a departing employee. Competition for qualified personnel, particularly for key positions, is intense among companies in our industry, particularly in the San Diego, California area, and many of the organizations against which we compete for qualified personnel have greater financial and other resources and different risk profiles than our company, which may make them more attractive employers. All of our employees, including our management personnel, may terminate their employment with us at any time without notice. If we cannot

attract and retain highly qualified personnel, as needed, we may not achieve our financial and other goals. Moreover, future internal growth could impose significant added responsibilities on our management, and we will need to identify, recruit, maintain, motivate and integrate additional employees to manage growth effectively. If we do not effectively manage such growth, our expenses may increase more than expected, we may not achieve our goals, and our ability to generate and/or grow revenue could be diminished.

We may have significant product liability exposure and our insurance may not cover all potential claims.

We are exposed to product liability and other claims. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. In addition, if neurosurgeons and orthopedic spine surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects, or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients. In addition, the development of allograft implants and technologies for human tissue repair and treatment may entail particular risk of transmitting diseases to human recipients, and any such transmission could result in the assertion of product liability claims against us.

Product liability claims are expensive to defend, divert our management's attention and, if we are not successful in defending the claim, can result in substantial monetary awards against us or costly settlements. Further, successful product liability claims made against one or more of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. Any product liability claim brought against us, with or without merit and regardless of the outcome or whether it is fully pursued, may result in: decreased demand for our products; injury to our reputation; significant litigation costs; product recalls; loss of revenue; the inability to commercialize new products or product candidates; and adverse publicity regarding our products. Any of these may have a material and adverse effect on our reputation with existing and potential customers and on our business, financial condition and results of operations.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or more than our insurance coverage, our business could suffer. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

Our insurance policies are expensive and protect us only from some risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk to which our business is or may be exposed. Some of the policies we maintain include general liability, foreign liability, employee benefits liability, property, umbrella, employment practices, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Even if we obtain insurance, a claim could exceed the amount of our insurance coverage or it may be excluded from coverage under the terms of the policy. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

Our strategy could involve growth through acquisitions, which would require us to incur substantial costs and potential liabilities for which we may never realize the anticipated benefits.

We may grow our business through acquisitions, a strategy which ultimately could prove unsuccessful. Any new acquisition could result in material transaction expenses, increased interest and amortization expense, increased depreciation expense, increased operating expense and possible in-process research and development charges for acquisitions that do not meet the definition of a "business," any of which could have a material and adverse effect on our operating results.

In addition, businesses we acquire may not have adequate financial, disclosure, regulatory, quality or other compliance controls in place when we acquire them, which may create uncertainty regarding the actual condition and financial results of the acquired business and our assumptions regarding synergies and future results. Following any acquisition, we must integrate the new business, which includes incorporating it into our financial, compliance,

regulatory and quality systems. Failure to timely and successfully integrate acquired businesses may result in non-compliance with regulatory or other requirements and may result in unexpected costs, including as a result of inadequate cost containment and unrealized economies of scale. In addition, acquisitions divert management and other resources, and involve other risks, including, risks associated with entering markets in which our

marketing and sales personnel may have limited experience and with disruption to existing relationships with employees, suppliers, customers and sales agents, both with respect to us and the acquired company. As a result of any of the foregoing, we may not realize the expected benefit from any acquisition. If we cannot integrate acquired businesses, products or technologies, our business, financial conditions and results of operations could be materially and adversely affected.

Furthermore, as a result of acquisitions of other healthcare businesses, we may be subject to the risk of unanticipated business uncertainties, regulatory and other compliance matters or legal liabilities relating to those acquired businesses for which the sellers of the acquired businesses may not indemnify us, for which we may not be able to obtain insurance (or adequate insurance) or for which the indemnification may not be sufficient to cover the ultimate liabilities.

We are exposed to a variety of risks relating to our international sales and operations.

During the year ended December 31, 2018, approximately 11% of our net revenue was attributable to our international sales and operations. We are seeking to increase our international sales over the foreseeable future. Our international business operations are subject to a variety of risks, including:

- difficulties in staffing and managing foreign and geographically dispersed operations;
- having to comply with various U.S. and international laws, including the U.S. Foreign Corrupt Practices Act of 1977 and anti-money laundering laws (see also, “Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs and import-export practices, laws regarding transactions in foreign countries, the Foreign Corrupt Practices Act of 1977 and local anti-bribery and other laws regarding interactions with healthcare professionals, and product registration requirements” below);
- having to comply with export control laws, including, but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce;
- differing regulatory requirements for obtaining clearances or approvals to market our products;
- changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the United States;
- tariffs, trade barriers and export regulations that adversely impact, and other regulatory and contractual limitations on, our ability to sell our products in certain foreign markets, the scope and consequences of which may increase in light of the Trump Administration’s approach to trade policy, including its stated intent to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements;
- fluctuations in foreign currency exchange rates;
- limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;
- differing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- differing labor laws and standards;
- economic, political or social instability in foreign countries and regions;
- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action; and
- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us.

Any reduction in international sales, or our failure to further develop our international markets, could have a material adverse effect on our business, results of operations and financial condition.

Our results may be impacted by changes in foreign currency exchange rates.

As a result of our international sales and operations, we generate revenues in various foreign currencies including euros, British pounds, and Swiss francs, and in U.S. dollar-denominated transactions conducted with customers who generate revenue in currencies other than the U.S. dollar. We also incur operating expenses in euros. We cannot predict accurately the consolidated effects of exchange rate fluctuations upon our future operating results because of

the variability of currency exposure in our revenues and operating expenses and the potential volatility of currency exchange rates. Although we address currency risk management through regular operating and financing activities, those actions may not prove to be fully effective. In addition, for those foreign customers who purchase our products in U.S. dollars, currency exchange rate fluctuations between the U.S. dollar and the currencies in which those customers do business may have a negative effect on the demand for our products in foreign countries where the U.S. dollar has increased in value compared to the local currency. Converting our earnings from international operations to U.S. dollars for use in the U.S. can also raise challenges, including problems moving funds out of the countries in

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which the funds were earned and difficulties in collecting accounts receivable in foreign countries where the usual accounts receivable payment cycle is longer. To date, we have not used risk management techniques to hedge the risks associated with foreign currency exchange rate fluctuations. Even if we implemented hedging strategies, not every exposure can be hedged and, where hedges are put in place based on expected foreign currency exchange exposure, they are based on forecasts that may vary or that may later prove to have been inaccurate. As a result, fluctuations in foreign currency exchange rates or our failure to successfully hedge against these fluctuations could have a material adverse effect on our operating results and financial condition.

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

Many of our employees were employed at other medical device companies, including our competitors or potential competitors, in some cases immediately prior to joining us. In addition, many of our independent sales agents and stocking distributors sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees or our independent sales agents or stocking distributors have intentionally, inadvertently or otherwise used or disclosed trade secrets or other proprietary information of former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Litigation is expensive, time-consuming and could divert management attention and resources away from our business. Even if we prevail, the cost of litigation could affect our profitability. If we do not prevail, in addition to any damages we might have to pay, we may lose valuable intellectual property rights or employees, independent sales agents or stocking distributors. There can be no assurance that this type of litigation or the threat thereof will not adversely affect our ability to engage and retain key employees, sales agents or stocking distributors. See also “If we are unable to maintain and expand our network of independent sales agents and stocking distributors, we may not be able to maintain or grow our revenue,” and “Our business could suffer if we lose the services of key members of our senior management or fail to hire and retain other personnel on whom our business relies,” above.

We are subject to continuing contingent liabilities of Integra.

Even after our separation from Integra, there are several significant areas where Integra’s liabilities may become our obligations. For example, under the Code and the related rules and regulations, each corporation that was a member of the Integra consolidated U.S. federal income tax reporting group during any taxable period or portion of any taxable period ending on or before the effective time of the distribution is jointly and severally liable for the U.S. federal income tax liability of the entire Integra consolidated tax reporting group for that taxable period. In addition, the Tax Matters Agreement allocates the responsibility for prior period taxes of the Integra consolidated tax reporting group between us and Integra. Under this allocation, we may be responsible for taxes that we would not have otherwise incurred, or that we would have incurred but in different amounts and/or at different times, on a standalone basis outside of the Integra consolidated group, and the amount of such taxes could be significant. If Integra is unable to pay any prior period taxes for which it is responsible, we could have to pay the entire amount of such taxes.

We have overlapping board membership with Integra, which may lead to conflicting interests, and one of our directors continues to own a substantial amount of Integra common stock and equity awards covering Integra stock.

Two of our board members also serve as board members of Integra. Our directors who are members of Integra’s board of directors have fiduciary duties to Integra’s stockholders, as well as fiduciary duties to our stockholders. In addition, several of our directors own or have rights to acquire Integra common stock (in at least one case, a substantial amount).

As a result of the foregoing, there may be the appearance of a conflict of interest and there is the potential for a conflict of interest with respect to matters involving or affecting both companies, such as when we or Integra consider acquisitions and other corporate opportunities that may be suitable for each company. In addition, potential conflicts of interest could arise in connection with the resolution of any dispute that may arise between Integra and us regarding the terms of the agreements governing our separation from Integra, the Tax Matters Agreement or under other agreements between Integra and us, including with respect to indemnification matters. From time to time, we may

enter into transactions with Integra and/or its subsidiaries or other affiliates. There can be no assurance that the terms of any such transactions will be as favorable to us, Integra or any of our or their subsidiaries or affiliates as would be the case were there no overlapping board membership or ownership interest.

Risks Relating to our Financial Results and need for Financing

Our sales volumes and our operating results may fluctuate.

Our sales volumes and our operating results, including components of operating results, such as gross margin and cost of goods sold, have fluctuated in the past and may fluctuate from time to time in the future, including over the course of a fiscal year, and such fluctuations could affect our stock price. Some factors that may cause these fluctuations include:

- economic conditions worldwide, which could affect the ability of hospitals and other customers to purchase our products and could result in a reduction in elective and non-reimbursed operative procedures;
- increased competition;
- market acceptance of our existing products, as well as products in development, and the demand for, and pricing of, our products and the products of our competitors;
- costs, benefits and timing of new product introductions;
- the timing of or failure to obtain regulatory clearances or approvals for new products;
- lost sales and other expenses resulting from stoppages in our or third parties' production, including as a result of product recalls or field corrective actions;
- the availability and cost of components and materials, including raw materials such as human tissue;
- our ability to purchase or manufacture and ship our products efficiently and in sufficient quantities to meet sales demands;
- the timing of our research and development expenditures;
- expenditures for major initiatives;
- reimbursement, changes in reimbursement or denials in coverage for our products by third-party payors, such as Medicare, Medicaid, private and public health insurers and foreign governmental health systems;
- the ability of our independent sales agents and stocking distributors to achieve expected sales targets and for new agents and stocking distributors to become familiar with our products in a timely manner;
- peer-reviewed publications discussing the clinical effectiveness of our products;
- inspections of our manufacturing facilities for compliance with the FDA's Quality System Regulations (Good Manufacturing Practices), which could result in Form 483 observations, warning letters, injunctions or other adverse findings from the FDA or equivalent foreign regulatory bodies, and corrective actions, procedural changes and other actions, including product recalls, that we determine are necessary or appropriate to address the results of those inspections, any of which may affect production and our ability to supply our customers with our products;
- the costs to comply with new regulations from the FDA or equivalent foreign regulatory bodies, such as the requirements to establish a unique device identification system to adequately identify medical devices through their distribution and use;
- the increased regulatory scrutiny of certain of our products, including products we manufacture for others, which could result in their being removed from the market;
- fluctuations in foreign currency exchange rates; and
- the impact of acquisitions, including the impact of goodwill and intangible asset impairment charges, if future operating results of the acquired businesses are significantly less than the results anticipated at the time of the acquisitions.

In addition, we may experience meaningful variability in our sales and gross profit among quarters, as well as within each quarter, as a result of several factors, including but not limited to (and in addition to those listed above):

- the number of products sold in the quarter;
- the unpredictability of sales of full sets of spinal implants and instruments to our international stocking distributors; and
- the number of selling days in the quarter.

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

Because we maintain substantial inventory levels to meet the needs of our customers, we are subject to the risk of inventory excess, obsolescence and shelf-life expiration. Many of our spinal implant products come in sets. Each set includes a significant number of components in various sizes so that the surgeon may select the appropriate spinal implant based on the patient's needs. In a typical surgery, not all of the implants in the set are used, and therefore certain sizes of implants placed in the set or that we

purchase for replenishment inventory may become obsolete before they can be used. In addition, to market our products effectively, we often must provide hospitals and independent sales agents with consigned sets that typically consist of spinal implants and instruments, including products to ensure redundancy and products of different sizes. Further, our orthobiologics products have a sterilization expiration date, which ranges from one to five years, and these products may expire before they can be used. If a substantial portion of our inventory is deemed excess, becomes obsolete or expires, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Our future financial results could be adversely affected by impairments or other charges.

We assess periodically impairment of our long-lived assets, including finite-lived intangible assets, whenever events or changes in circumstances indicate that the carrying value may not be recoverable. As of December 31, 2018, we had \$28.7 million of net finite-lived intangible assets, consisting of technology and customer relationships. In addition, we continually assess the profitability of our product lines and, after such assessment, may discontinue certain products or product lines in the future. As a result, we may record impairment charges or accelerate amortization on certain technology-related intangible assets in the future. Impairment charges as a result of any of the foregoing could be significant and could have a material and adverse effect on our reported financial results for the period in which the charge is taken, which could have a material and adverse effect on the market price of our common stock.

Continuing economic instability, including challenges faced by European countries, may adversely affect the ability of hospitals and other customers to access funds or otherwise have available liquidity, which could reduce orders for our products or impede our ability to obtain new customers, particularly in European markets.

Continuing economic instability, including challenges faced by European countries, may adversely affect the ability of hospitals and other customers to access funds to enable them to fund their operating budgets. As a result, hospitals and other customers may reduce budgets or put all or part of their budgets on hold or close their operations, which could have a negative effect on our sales and could impede our ability to obtain new customers, particularly in European markets. Governmental austerity policies in Europe and other markets have reduced and could continue to reduce the amount of money available to purchase medical products, including our products. If such conditions persist, they could have a material and adverse effect on our business, financial condition and results of operations.

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

We believe that our cash, investments and the amount currently available to us under our amended and restated credit agreement with Wells Fargo, N.A. will be sufficient to meet our projected operating requirements over the next 12 months. That said, continued expansion of our business will be expensive, and we likely will seek additional capital.

Our capital requirements will depend on many factors, including, but not limited to:

- the revenue generated by sales of our products;
- the costs associated with expanding our sales and marketing efforts;
- the expenses we incur in procuring, manufacturing and selling our products;
- the scope, rate of progress and cost of our clinical studies;
- the cost of obtaining and maintaining regulatory approval or clearance of our products and products in development;
- the costs associated with complying with state, federal and international laws and regulations;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third-party patent or other intellectual property rights;
- the cost of enforcing or defending against non-competition claims;
- the number and timing of acquisitions and other strategic transactions;
- the costs associated with increased capital expenditures, including fixed asset purchases of instrument sets which we consign to hospitals and independent sales agents to support surgeries; and
- anticipated and unanticipated general and administrative expenses, including insurance expenses.

We may seek to raise additional capital to:

- maintain, and, where necessary, increase appropriate product inventory and spinal instruments levels;
- fund our operations and clinical studies;
- continue, and, where appropriate, increase our research and development activities;
- file, prosecute and defend our intellectual property rights, and defend, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights;
- address the FDA or other governmental, legal or enforcement actions and remediate underlying problems and address investigations or inquiries into sales and marketing practices from governmental agencies worldwide;
- commercialize our new products, if any such products receive regulatory clearance or approval for sale;
- and
- acquire companies' new products, technology or intellectual property.

Such capital, which we may seek to raise through public or private equity offerings, issuing debt or existing, expanded or new credit facilities, or other sources, may not be available to us on favorable terms, or at all. For example, LIBOR is one of the reference rates under our credit agreement and is the subject of recent proposals for reform that could impact the interest rate we pay under the credit agreement. To the extent we have outstanding borrowings under the credit agreement at the time a LIBOR alternative becomes applicable, our borrowing costs under the credit agreement may increase. In addition, our credit agreement prohibits us from incurring indebtedness without the lender's consent. If we issue equity securities to raise additional capital, our existing stockholders may experience dilution, and the new equity securities may have rights, preferences and privileges senior to those of our existing stockholders. See "Risks Relating to Owning Our Common Stock-Your percentage of ownership in us may be diluted in the future and issuances of substantial amounts of our common stock, or the perception that such issuances may occur, could cause the market price of our common stock to decline significantly, even if our business is performing well.," and "Risks Relating to Owning Our Common Stock-We may issue preferred stock with terms that could dilute the voting power or reduce the value of our common stock," below. If we raise additional capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise capital on acceptable terms, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities or respond to competitive pressures, changes in our supplier relationships or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our business and financial goals or to achieve or maintain profitability, and could have a material and adverse effect on our business, results of operations and financial condition.

Risks Relating to our Regulatory Environment

We are subject to stringent domestic and foreign medical device regulation and any adverse regulatory action may materially and adversely affect our financial condition and business operations.

Our products, development activities and manufacturing processes are subject to extensive and rigorous regulation by numerous federal and state government agencies, including the FDA and comparable foreign agencies. To varying degrees, each agency monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our products. For example, we must comply with the FDA's Quality System Regulation, which mandates that manufacturers of medical devices adhere to certain quality assurance standards pertaining to, among other things, validation of manufacturing processes, controls for purchasing product components and documentation practices.

In addition, we must engage in extensive recordkeeping and reporting. For example, the Federal Medical Device Reporting regulation requires us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or that a malfunction occurred that would be likely to cause or contribute to a death or serious injury upon recurrence.

Compliance with applicable regulatory requirements is subject to continual review and we must make our manufacturing facilities and records available for periodic unscheduled inspections by governmental agencies,

including the FDA, state authorities and comparable agencies in other countries. If we fail to pass an FDA Quality System Regulation inspection or to comply with applicable regulatory requirements, we may receive a notice of a violation in the form of inspectional observations on Form FDA 483, a warning letter, or could otherwise be required to take corrective action and, in severe cases, we could suffer a disruption of our operations and manufacturing delays. If we fail to take adequate corrective actions, we could be subject to enforcement actions, including significant fines, suspension of approvals, seizures or recalls of products, operating restrictions and criminal prosecutions. The FDA has been increasing its scrutiny of the medical device industry and the government is expected to continue to scrutinize the industry closely. Moreover, allegations may be made against us or against our suppliers, including donor recovery

groups or tissue banks, claiming that the acquisition or processing of biomaterials products does not comply with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to investigate or take other action against us or our suppliers, or could cause negative publicity for us or our industry generally. If the FDA were to investigate us, because of an allegation or otherwise, and if the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize such medical devices, order a recall, repair, replacement or refund of such devices, require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health, restrict manufacturing and impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices and assess civil or criminal penalties against our officers, employees or us. The FDA may also recommend prosecution to the U.S. Department of Justice. Any notice or communication from the FDA regarding a failure to comply with applicable requirements, or negative publicity or product liability claims resulting from any adverse regulatory action, could materially and adversely affect our product sales and overall business.

Further, our suppliers also are subject to a wide array of regulatory and other requirements, including quality control, quality assurance and the maintenance of records and documentation. Our suppliers may be unable to comply with these requirements and with other FDA, state and foreign regulatory requirements. We have little control over their ongoing compliance with these regulations. Their failure to comply may expose us to regulatory action and other liability, including fines and civil penalties, suspension of production, suspension or delay in new product approval or clearance, product seizure or recall, or withdrawal of product approval or clearance.

There is no guarantee that the FDA will grant 510(k) clearance or premarket approval, or that equivalent foreign regulatory authorities will grant the foreign equivalent, of our future products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

In general, unless an exemption applies, a medical device and modifications to the device or its indications must receive either premarket approval or premarket clearance from the FDA before it can be marketed in the U.S. While in the past we have received such clearances, we may not succeed in the future in receiving approvals and clearances in a timely manner, or at all. The process of obtaining approval or clearance from the FDA and comparable foreign regulatory agencies for new products, or for enhancements or modifications to existing products, could:

- take significant time;
- require the expenditure of substantial resources;
- involve rigorous and expensive pre-clinical and clinical testing, as well as post-market surveillance;
- involve modifications, repairs or replacements of our products; and
- result in limitations on the indicated uses of our products.

Some of our new products will require FDA 510(k) clearance or approval of a premarket approval application, or PMA, prior to being marketed. Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. Similarly, modifications to PMA-approved products may require submission and approval of a supplement PMA. The FDA requires every manufacturer to determine whether a new 510(k) or supplement PMA is needed in the first instance, and the FDA has issued guidance on assessing modifications to 510(k)-cleared and PMA-approved devices to assist manufacturers with making these determinations. However, the FDA may review any such determination and the FDA may not agree with our determinations regarding whether new clearances or approvals are necessary. We have modified some of our 510(k)-cleared products and have determined, based on our understanding of FDA guidance, that certain changes did not require new 510(k) clearances. If the FDA disagrees with our determination and requires us to seek new 510(k) clearances, or PMA approval, for modifications to our cleared products, we may have to stop marketing or distributing our products, we may need to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Significant delays in receiving clearance or approval, or failing to receive clearance or approval for our new products would have a material and adverse effect

on our ability to expand our business.

Outside the U.S., clearance or approval procedures can vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain clearance or approval in other countries might differ from that required to obtain FDA clearance or approval. The regulatory process in other countries may include all of the risks to which we are exposed in the U.S., as well as other risks. Favorable regulatory action in one country does not ensure favorable regulatory action in another, but a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others. Failure to obtain clearance or approval in other countries or any delay or setback in obtaining such clearance or approval have a material and adverse effect on our business, including that our products

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may not be cleared or approved for all indications requested, which could limit the uses of our products and have an adverse effect on product sales.

In the EEA, we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned substantial change to our quality system or any change to our devices that could affect compliance with the Essential Requirements laid down in Annex I to the Medical Devices Directive or the devices' intended purpose. The Notified Body will then assess the change and verify whether it affects the products' conformity with the Essential Requirements or the conditions for the use of the device. If the assessment is favorable, the Notified Body will issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity attesting compliance with the Essential Requirements. If it is not, we may not be able to continue to market and sell the applicable product in the EEA, which could have a material and adverse effect on our business, results of operations and financial condition.

We cannot be certain that we will receive required approval or clearance from the FDA and foreign regulatory agencies for new products, including modifications to existing products, on a timely basis, or at all. Failing to receive approval or clearance for new products on a timely basis would have a material and adverse effect on our financial condition and results of operations.

Certain of our products are derived from human tissue and are or could be subject to additional regulations and requirements.

Some of our orthobiologics products are derived from human bone tissue, and as a result are also subject to FDA and certain state regulations regarding human cells, tissues and cellular or tissue-based products, or HCT/Ps. An HCT/P is a product containing or consisting of human cells or tissue intended for transplantation into a human patient.

Examples include bone, ligament, skin and cornea.

Some HCT/Ps also meet the definition of a biological product, medical device or drug regulated under the Federal Food, Drug and Cosmetic Act. Section 361 of the Public Health Service Act authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as "361 HCT/Ps" are subject to requirements relating to registering facilities and listing products with the FDA, screening and testing for tissue donor eligibility, Good Tissue Practice when processing, storing, labeling and distributing HCT/Ps, including required labeling information, stringent record keeping and adverse event reporting. These biologic, device or drug HCT/Ps must comply both with the requirements exclusively applicable to 361 HCT/Ps and, in addition, with requirements applicable to biologics, devices or drugs, including premarket clearance or approval. We have received required approvals for our products regulated as 361 HCT/Ps. However, there have been occasions in the past, and there could be occasions in the future, when the FDA requires us to obtain a 510(k) clearance for our products regulated as 361 HCT/Ps. The process of obtaining a 510(k) clearance could take time and consume resources, and failing to receive such a clearance would render us unable to market and sell such products, which could have a material and adverse effect on our business.

The American Association of Tissue Banks has issued operating standards for tissue banking. Accreditation is voluntary, but compliance with these standards is a requirement to become a licensed tissue bank. In addition, some states have their own tissue banking regulations. In addition, procurement of certain human organs and tissue for transplantation is subject to the National Organ Transplant Act, or NOTA, which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control and storage of human tissue and skin. We reimburse tissue banks for their expenses associated with the recovery, storage and transportation of donated human tissue they provide to us for processing. We include in our pricing structure amounts paid to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with processing, preservation, quality control and storage of the tissue, marketing and medical education expenses and costs associated with development of tissue processing technologies. NOTA payment allowances may be interpreted to limit the amount of costs and expenses we can recover in our pricing for our products, thereby reducing our future revenue and profitability. If we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject

to criminal enforcement sanctions, which could materially and adversely affect our results of operations. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the European Union, or EU, as well as for other countries, the approval process in the EU for human-derived cell or tissue-based medical products could be extensive, lengthy, expensive and unpredictable. Among others, some of our orthobiologics products are subject to EU member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage and distribution of HCT/Ps. These EU member states' regulations include requirements for registration, listing, labeling, adverse-event reporting and inspection and enforcement. Some EU member states have their own tissue banking regulations. Non-compliance with various regulations governing our products in any EU member state could result

in the banning of our products in such member state or enforcement actions being brought against us, which could have a material and adverse effect on our business, results of operations and financial condition.

Certain of our products contain materials derived from animal sources and may become subject to additional regulation.

Certain of our products contain material derived from bovine tissue. Products that contain materials derived from animal sources, including food, pharmaceuticals and medical devices, are subject to scrutiny in the media and by regulatory authorities. Regulatory authorities are concerned about the potential for the transmission of disease from animals to humans via those materials. This public scrutiny has been particularly acute in Japan and Western Europe with respect to products derived from animal sources, largely due to concern that materials infected with the agent that causes bovine spongiform encephalopathy, or BSE, otherwise known as mad cow disease, may, if ingested or implanted, cause a variant of the human Creutzfeldt-Jakob disease, an ultimately fatal disease with no known cure. Cases of BSE in cattle discovered in Canada and the U.S. have increased awareness in North America.

We take steps designed to minimize the risk that our products contain agents that can cause disease, such as obtaining our collagen from countries considered BSE-free. Nevertheless, products that contain materials derived from animals, including our products, could become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for the transmission of infectious or other agents. Significant new regulation, or a ban of our products, could have a material and adverse effect on our business or our ability to expand our business.

Certain countries, such as Japan, China, Taiwan and Argentina, have issued regulations that require our collagen products be processed from bovine tendon sourced from countries where no cases of BSE have occurred. The collagen raw material we use in our products is sourced from New Zealand. Our supplier has obtained approval from certain countries, including the U.S., the European Union, Japan, Taiwan, China and Argentina, for the use of such collagen raw material in products sold in those countries. If we cannot continue to obtain collagen raw material from a qualified source of tendon from a country that has never had a case of BSE, we will not be permitted to sell our collagen products in certain countries, which could have a material and adverse effect on our business, results of operations and financial condition.

Clinical studies are expensive and subject to extensive regulation and their results may not support our product candidate claims or may result in the discovery of adverse effects.

In developing new products or new indications for, or modifications to, existing products, we may conduct or sponsor pre-clinical testing, clinical studies or other clinical research. We are conducting post-market clinical studies of some of our products to gather information about their performance or optimal use. The data collected from these clinical studies may ultimately be used to support additional market clearance or approval for these products or future products. If any of our new products require premarket clinical studies, these studies are expensive, the outcomes are inherently uncertain and they are subject to extensive regulation and review by numerous governmental authorities both in the U.S. and abroad, including by the FDA and, if federal funds are involved or if an investigator or site has signed a federal assurance, are subject to further regulation by the Office for Human Research Protections and the National Institutes of Health. For example, clinical studies must be conducted in compliance with FDA regulations, local regulations, and according to principles and standards collectively called "Good Clinical Practices." Failure to comply with applicable regulations could result in regulatory and legal enforcement action, including fines, penalties, suspension of studies, and also could invalidate the data and make it unusable to support an FDA submission.

Even if any of our future premarket clinical studies are completed as planned, we cannot be certain that their results will support our product candidates and/or proposed claims or that the FDA or foreign authorities and Notified Bodies will agree with our interpretation and conclusions regarding the data they generate. Success in pre-clinical studies and early clinical studies does not ensure that later clinical studies will succeed, and we cannot be sure that the results of later studies will replicate those of earlier or prior studies. The clinical study process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical studies will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patient subjects enrolled in our clinical studies of our marketed products will

experience adverse side effects that are not currently part of the product candidate's profile and, if so, these findings may result in lower market acceptance, which could have a material and adverse effect on our business, results of operations and financial condition.

If the third parties on which we rely to conduct our clinical studies and to assist us with pre-clinical development do not perform as contractually required or expected, we may not obtain regulatory clearance, approval or a CE Certificate of Conformity for or commercialize our products.

We often must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to assist in conducting our clinical studies and other development activities. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory obligations or meet expected deadlines, or if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to failing to adhere to clinical protocols, to applicable regulatory requirements or otherwise, our pre-clinical development activities and clinical studies may be extended, delayed, suspended or terminated. Under these circumstances, we may not be able to obtain regulatory clearance/approval or a CE Certificate of Conformity for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be materially and adversely affected.

Oversight of the medical device industry might affect the way we sell medical devices and compete in the marketplace.

The FDA, the U.S. Office of the Inspector General for the U.S. Department of Health and Human Services, the U.S. Department of Justice and other regulatory agencies actively enforce regulations prohibiting the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside its cleared or approved indications is known as “off-label” use. Physicians may prescribe our products for off-label uses, as the FDA does not restrict or regulate a physician’s choice of treatment within the practice of medicine. However, if a regulatory agency determines that our promotional materials, training or activities constitute improper promotion of an off-label use, the regulatory agency could request that we modify our promotional materials, training or activities, or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and/or criminal penalties. Although our policy is to refrain from statements and activities that could be considered off-label promotion of our products, any regulatory agency could disagree and conclude that we have engaged in off-label promotion and, potentially, caused the submission of false claims. In addition, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. See “Risks Relating to our Business-We may have significant product liability exposure and our insurance may not cover all potential claims,” above.

There are also multiple other laws and regulations that govern how companies in the healthcare industry may market their products to healthcare professionals and may compete by discounting the prices of their products, including, for example, the federal Anti-Kickback Statute, the federal False Claims Act, the federal Health Insurance Portability and Accountability Act of 1996, state law equivalents to these federal laws that are meant to protect against fraud and abuse, the Foreign Corrupt Practices Act of 1977 and analogous laws in foreign countries. Violations of these laws are punishable by criminal and civil sanctions, including, but not limited to, penalties, fines and exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid, and imprisonment. Federal and state government agencies, as well as private whistleblowers, have significantly increased investigations and enforcement activity under these laws. Although we exercise care in structuring our sales and marketing practices, customer discount arrangements and interactions with healthcare professionals to comply with these laws and regulations, we cannot provide assurance that government officials will not assert that our practices are in compliance or that government regulators or courts will interpret those laws or regulations in a manner consistent with our interpretation. Even if an investigation is unsuccessful or is not fully pursued, we may spend considerable time and resources defending ourselves and the adverse publicity surrounding any assertion that we may have engaged in violative conduct could have a material and adverse effect on our reputation with existing and potential customers and on our business, financial condition and results of operations.

Federal and state laws are also sometimes open to interpretation, and from time to time we may find ourselves at a competitive disadvantage if our interpretation differs from that of our competitors. AdvaMed (U.S.), EucoMed (Europe), MEDEC (Canada) and MTAA (Australia), some of the principal trade associations for the medical device industry, have promulgated model codes of ethics that set forth standards by which its members should (and

non-member companies may) abide in the promotion of their products in various regions. We have implemented policies and procedures for compliance consistent with those promulgated by these associations, and we train our sales and marketing personnel on our policies regarding sales and marketing practices. Nevertheless, the sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies, we believe this trend will continue and that it could affect our ability to retain customers and other relationships important to our business.

For example, prosecutorial scrutiny and governmental oversight, at both the state and federal levels, over some major device companies regarding the retention of healthcare professionals have limited how medical device companies may retain healthcare professionals as consultants. Various hospital organizations, medical societies and trade associations are establishing their own practices that may require detailed disclosures of relationships between healthcare professionals and medical device companies or ban or restrict certain marketing and sales practices, such as gifts and business meals. In addition, the Affordable Care Act, as

well as certain state laws, require detailed disclosure of certain financial relationships, gifts and other remuneration made to certain healthcare professionals and teaching hospitals, the publicity surrounding which could have a negative impact on our relationships with our customers and ability to seek input on product design or involvement in research. As a result of laws, rules and regulations or our own or third-party policies that prohibit or restrict interactions, or the growing perception that any interaction between healthcare professionals and industry are tainted, we may be unable to engage with our healthcare professional customers in the same manner or to the same degree, or at all, as would otherwise be the case, which may adversely affect our ability to understand our customer's needs and to incorporate into our development programs feedback that addresses these needs. If we are unable to develop and commercialize new products that address the needs of our surgeon customers and their patients, our products may not be broadly accepted in the marketplace, or at all, which would have a negative effect on our business, results of operations and financial condition.

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

Our international operations subject us to laws regarding sanctioned countries, entities and persons, customs and import-export practices, laws regarding transactions in foreign countries, the Foreign Corrupt Practices Act of 1977 and local anti-bribery and other laws regarding interactions with healthcare professionals, and product registration requirements.

Foreign governmental regulations have become increasingly stringent and more common, and we may become subject to even more rigorous regulation by foreign governmental authorities. Numerous laws restrict, and in some cases prohibit, U.S. companies from directly or indirectly selling goods, technology or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices and effecting product registrations in foreign countries. Compliance with these regulations is costly.

The U.S. Foreign Corrupt Practices Act of 1977, or FCPA, and similar anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws. Our internal control policies and procedures may not always protect us from reckless or criminal acts committed by our employee shareowners, or agents. In recent years, both the United States and foreign government regulators have increased regulation, enforcement, inspections and governmental investigations of the medical device industry, including increased United States government oversight and enforcement of the FCPA. Despite implementation of a comprehensive global healthcare compliance program, we may be subject to more regulation, enforcement, inspections and investigations by governmental authorities in the future.

Any failure to comply with applicable foreign legal and regulatory obligations could adversely affect us in a variety of ways, that include, but are not limited to: the suspension or withdrawal of our CE Certificates of Conformity; the imposition of significant criminal, civil and administrative fines and penalties, including revocation or suspension of a business license and imprisonment of individuals; denial of export privileges; seizure of shipments and restrictions on certain business activities; disgorgement and other remedial measures; disruptions of our

operations; and significant management distraction.

Regulations related to “conflict minerals” may force us to incur additional expenses, may make our supply chain more complex and may result in damage to our reputation with customers.

We are subject to SEC regulations that require us to determine whether our products contain certain specified minerals, referred to under the regulations as “conflict minerals,” and, if so, to perform an extensive inquiry into our supply chain, to determine whether such conflict minerals originate from the Democratic Republic of Congo or an adjoining country. We have determined that certain of our products contain such specified minerals. We are continuing to conduct inquiries into our supply chain in connection with the preparation of our conflict minerals report for 2018. Compliance with these regulations has increased our costs

and has been time-consuming for our management and our supply chain personnel (and time-consuming for our suppliers), and we expect that continued compliance will continue to require significant money and time. In addition, to the extent any of our disclosures are perceived by the market to be “negative,” it may cause customers to refuse to purchase our products. Further, if we determine to make any changes to products, processes, or sources of supply, it may result in additional costs, which may adversely affect our business, financial condition and results of operations.

We are subject to requirements relating to hazardous materials which may impose significant compliance or other costs on us.

Our research, development and manufacturing processes involve the controlled use of certain hazardous materials. For example, our allograft bone tissue processing may generate waste materials that in the U.S. are classified as medical waste. In addition, we lease facilities at which hazardous materials could have been used. Because of the foregoing, we are subject to federal, state, foreign and local laws and regulations governing the use, manufacture, storage, handling, treatment, remediation and disposal of hazardous materials and certain waste products.

Although we believe that our procedures for handling and disposing of hazardous materials comply with applicable laws as currently in effect, we cannot eliminate the risk of accidental contamination or injury from these materials. In addition, under some environmental laws and regulations, we could also be held responsible for all of the costs relating to any contamination at our past or present facilities and at third-party waste disposal sites, even if such contamination was not caused by us. If an accident occurs, state or federal or other applicable authorities may curtail our use of these materials and interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines any related liability could exceed our resources. If such unexpected costs are substantial, this could significantly harm our financial condition and results of operations. We carry no insurance specifically covering environmental claims relating to the use of hazardous materials.

Risks Relating to our Intellectual Property

Our intellectual property rights may not provide meaningful commercial protection for our products, potentially enabling third parties to use our technology or very similar technology in ways that could reduce our ability to compete in the marketplace.

Our success will depend in part on our ability to, both in the U.S. and in foreign countries, obtain and maintain patent and other exclusivity with respect to our products; prevent third parties from infringing upon our proprietary rights; and maintain proprietary know-how and trade secrets. However, these legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage.

We own or have licensed patents that cover aspects of some of our product lines. Our patents, however, may not provide us with any significant competitive advantage. Others may challenge our patents and, as a result, our patents could be narrowed, invalidated or rendered unenforceable. Competitors may develop products similar to ours that our patents do not cover. In addition, our current and future patent applications may not result in the issuance of patents in the U.S. or foreign countries. Further, there is a substantial backlog of patent applications at the U.S. Patent and Trademark Office, and the approval or rejection of patent applications may take several years.

In an effort to protect our trade secrets and intellectual property rights, we require our employees, consultants and advisors to execute confidentiality and invention assignment agreements upon commencement of employment or consulting relationships with us. These agreements provide that, except in specified circumstances, all confidential information developed or made known to the individual during their relationship with us must be kept confidential. We cannot assure you, however, that these agreements will meaningfully protect our trade secrets or other proprietary information in the event of the unauthorized use or disclosure of confidential information. In addition, we cannot assure you that others will not independently develop substantially equivalent proprietary information and procedures or otherwise gain access to our trade secrets, that our trade secrets will not be disclosed or that we can otherwise protect our rights to unpatented trade secrets.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using

physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, adequately protect our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable.

In addition, we may face claims by third parties that our agreements with employees, consultants or advisors obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are unsuccessful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position. See “If we seek to protect or enforce our intellectual property rights through litigation or other proceedings, it could require us to spend significant time and money, the results of which are uncertain,” below.

Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S., if at all. Since most of our issued patents and pending patent applications are for the U.S. only, we lack a corresponding scope of patent protection in other countries. Thus, we may not be able to stop a competitor from marketing products in other countries that are similar to some of our products.

If we are unable to obtain, protect and enforce patents on our technology and to protect our trade secrets, such inability could have a material and adverse effect on our business, results of operations and financial condition.

Our success will depend partly on our ability to operate without infringing or misappropriating the proprietary rights of others.

Our success will depend in part on our ability, both in the U.S. and in foreign countries, to operate without infringing upon the patents and proprietary rights of others, and to obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur.

Significant litigation regarding patent rights occurs in our industry. Our competitors in both the U.S. and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. Generally, we do not conduct independent reviews of patents issued to third parties. In addition, patent applications in the U.S. and elsewhere can be pending for many years before issuance, so there may be applications of others now pending of which we are unaware that may later result in issued patents that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. The large number of patents, the rapid rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation increase the risk of assets and resources including management’s attention, being diverted to patent litigation. We have received, and expect to receive, communications from various industry participants alleging our infringement of their patents, trade secrets or other intellectual property rights and/or offering licenses to such intellectual property. Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

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

See “If we seek to protect or enforce our intellectual property rights through litigation or other proceedings, it could require us to spend significant time and money, the results of which are uncertain,” below.

Further, as the number of participants in the spine industry grows, the possibility of intellectual property infringement claims against us increases. If we are found to infringe the intellectual property rights of third parties, we could have to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may

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

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

If we seek to protect or enforce our intellectual property rights through litigation or other proceedings, it could require us to spend significant time and money, the results of which are uncertain.

To protect or enforce our intellectual property rights, we may have to initiate or defend litigation against or by third parties, such as infringement suits, opposition proceedings or seeking a court declaration that we do not infringe the proprietary rights of others or that their rights are invalid or unenforceable. Litigation, including defending against claims without merit is expensive and time-consuming, and could divert management attention and resources away from our business and could harm our reputation. We may not have sufficient resources to enforce our intellectual property rights or to defend our intellectual property rights against a challenge. Even if we prevail, the cost of litigation, including the diversion of management and other resources, could affect our profitability and could place a significant strain on our financial resources.

Our ability to enforce our intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. It is not unusual for parties to exchange letters surrounding allegations of intellectual property infringement and licensing arrangements. In addition, the patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims we have or may obtain cannot be predicted with certainty.

Risks Relating to Owning our Common Stock

The market price of our common stock has been and likely will continue to be volatile.

The market price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Form 10-K, these factors include:

- actual or anticipated fluctuations in our quarterly financial condition and operating performance;
- introduction of new products by us or our competitors;
- announcements by us or our competitors of significant acquisitions or dispositions;
- our ability to obtain financing as needed;
- a shift in our investor base, including sales of our shares by existing stockholders;
- any major change in our board of directors or management;
- threatened or actual litigation or governmental investigations;
- the number of shares of our common stock publicly owned and available for trading;
- the operating and stock price performance of similar companies;
- changes in earnings estimates by securities analysts or our ability to meet earnings guidance;
- publication of research reports about us or our industry or changes in recommendations or withdrawal of research coverage by securities analysts;
- changes in laws or regulations affecting our business, including tax legislation;

the success or failure of our business strategy;
investor perception of us and our industry;
changes in accounting standards, policies, guidance, interpretations or principles;
the overall performance of the equity markets;
general political and economic conditions, and other external factors.

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In addition, the stock market in general, and the stocks of medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. This could limit or prevent investors from readily selling their shares and may otherwise negatively affect the liquidity of our common stock. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in very substantial costs, divert our management's attention and resources, and harm our business, financial condition and results of operation.

Your percentage of ownership in us may be diluted and issuances of substantial amounts of our common stock, or the perception that such issuances may occur, could cause the market price of our common stock to decline significantly, even if our business is performing well.

As with any public company, your percentage ownership in us may be diluted because of equity issuances for acquisitions and investments, capital-raising transactions or otherwise, including equity awards that we have granted and we expect to grant in the future to our directors, officers and employees. As of December 31, 2018, approximately 1.0 million shares of our common stock were subject to unvested restricted stock units and approximately 1.9 million shares of our common stock were subject to exercisable stock options with a weighted average exercise price of \$14.76.

In August 2016, we entered into an equity distribution agreement with Piper Jaffray & Co. (Piper Jaffray), pursuant to which we could offer and sell shares of our common stock in "at the market" (ATM) offerings (as defined in Rule 415 of the Act) having an aggregate offering price up to \$25.0 million in gross proceeds from time to time through Piper Jaffray acting as sales agent. These shares were covered by a registration statement on Form S-3 declared effective in August 2016. During the year ended December 31, 2018, we sold 882,332 shares at an average price per share of \$10.00 and received net proceeds of approximately \$8.5 million, which consumed the remaining capacity under this distribution agreement.

In May 2018, we entered into another equity distribution agreement with Piper Jaffray (the May 2018 Distribution Agreement), pursuant to which we may offer and sell shares of our common stock in ATM offerings having an aggregate offering price up to \$50.0 million in gross proceeds from time to time through Piper Jaffray acting as sales agent. These shares are covered by a registration statement on Form S-3 declared effective in August 2016. We did not sell any shares under the May 2018 Distribution Agreement during the year ended December 31, 2018.

In October 2018, we entered into an Underwriting Agreement with Wells Fargo Securities, LLC, Piper Jaffray & Co. and Cantor Fitzgerald & Co. acting as joint bookrunning managers and as representatives of the underwriters relating to the issuance and sale of 3,250,000 shares of our common stock and an additional 487,500 shares of common stock subject to an underwriters' option. The price to the public in the offering was \$15.50 per share, before underwriting discounts and commissions. The offering closed in October 2018. We sold 3,737,500 shares and raised net proceeds of approximately \$54.1 million, after deducting underwriting discounts and commissions and estimated offering expenses.

Further, the market price of our common stock could decline as a result of the issuance, including sale, of a large number of shares of our common stock, under the May 2018 Distribution Agreement or otherwise, and the perception that these sales could occur may also depress the market price of our common stock. A decline in the price of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we are taking advantage of certain exemptions and relief from various reporting requirements applicable to public companies that are not emerging growth companies. In particular, while we are an emerging growth company: (i) we will not be required to comply with the auditor attestation requirements of Section 404(b) of SOX; (ii) we will be exempt from any rules that may be adopted

by the Public Company Accounting Oversight Board requiring mandatory audit firm rotations or a supplement to the auditor's report on financial statements; (iii) we will be subject to reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and (iv) we will not be required to hold nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments not previously approved.

In addition, as an emerging growth company we do not have to comply with any new or revised accounting standard applicable

to public companies until such date that a private company must comply with such standard. We elected not to comply with such new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies, therefore our financial statements may not be comparable to the financial statements of public companies that are not emerging growth companies.

We will remain an emerging growth company until the earliest of: (i) December 31, 2020 (the fiscal year-end following the fifth anniversary of the completion of the spin-off); (ii) the end of the fiscal year in which the market value of our common stock held by non-affiliates exceeds \$700.0 million as of the last business day of the second fiscal quarter of that year; (iii) the end of the fiscal year in which our annual revenues exceed \$1.0 billion; and (iv) the date on which we issue more than \$1.0 billion in nonconvertible debt in any three-year period.

The SEC adopted amendments to the definition of “smaller reporting company” that became effective in September 2018. Under the new definition, generally, a company qualifies as a smaller reporting company if it has a public float of less than \$250 million as of the last business day of its second fiscal quarter. If a company qualifies as a smaller reporting company on that date, it may elect to reflect that determination and use the smaller reporting company scaled disclosure accommodations in its subsequent SEC filings. Our public float as of June 30, 2018, the last business day of our most recent second fiscal quarter, was less than \$250 million, and as such, we qualify as a smaller reporting company and are following certain of the scaled disclosure accommodations, including providing audited financial statements and management discussion and analysis for our two most recent fiscal years, in contrast to other reporting companies, which must provide audited financial statements and management discussion and analysis for their three most recent fiscal years. We will measure our public float as of June 30th every year and will continue to qualify as a smaller reporting company until our public float is \$250 million or more as of such date.

Investors may find our common stock less attractive because we rely on the exemptions available to, and relief granted to, emerging growth companies by the JOBS Act and/or because we follow certain of the scaled disclosure accommodations available to smaller reporting companies, either one of which may result in a less active trading market for our common stock and our stock price may decline and/or become more volatile.

If, once we are no longer an emerging growth company, our independent registered public accounting firm cannot provide an unqualified attestation report on the effectiveness of our internal control over financial reporting, investor confidence and, in turn, the market price of our common stock, could decline.

We may issue preferred stock with terms that could dilute the voting power or reduce the value of our common stock. While we have no specific plan to issue preferred stock, our amended and restated certificate of incorporation authorizes us to issue, without stockholder approval, one or more series of preferred stock having such designation, powers, privileges, preferences, including preferences over our common stock respecting dividends and distributions, terms of redemption and relative participation, optional, or other rights, if any, of the shares of each such series of preferred stock and any qualifications, limitations or restrictions thereof, as our board of directors may determine. The terms of one or more series of preferred stock could dilute the voting power or reduce the value of our common stock. For example, the repurchase or redemption rights or liquidation preferences we could assign to holders of preferred stock could affect the residual value of the common stock.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If current or future analysts who cover us were to downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts were to stop covering us or were to stop regularly publishing reports on us, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We do not anticipate paying cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We have never declared or paid cash dividends on our common stock, and we do not currently expect to declare or pay any such cash dividends in the foreseeable future. Instead, we intend to retain our future earnings, if any, to fund the development and growth of our business. Payment of cash dividends, if any, will depend on our financial

condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we are subject to various laws and regulations that may restrict our ability to pay dividends and are subject to contractual restrictions on, or prohibitions against,

the payment of dividends. Due to the foregoing, the return on your investment in our common stock will likely depend entirely upon any future appreciation and our common stock may not appreciate. Investors seeking cash dividends should not invest in our common stock.

Certain provisions in our charter documents and Delaware law could discourage takeover attempts and lead to management entrenchment and, therefore, may depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could have the effect of delaying or preventing changes in control or changes in our management without the consent of our board of directors, including, among other things:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;

- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;

- the ability of our board of directors to determine to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;

- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or by the resignation, death or removal of a director, which prevents stockholders from filling vacancies on our board of directors;

- limitations on the removal of directors;

- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;

- the requirement that a special meeting of stockholders be called only by the chairman of our board of directors, our chief executive officer, our president (in absence of a chief executive officer) or our board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;

- advance notice procedures that stockholders must comply with to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us;

- the requirement for the affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of our voting stock, voting together as a single class, to amend or repeal the provisions of our amended and restated certificate of incorporation and of our amended and restated bylaws that relate to the matters described above, which may inhibit the ability of an acquirer from amending our amended and restated certificate of incorporation or amended and restated bylaws to facilitate a hostile acquisition; and

- the ability of our board of directors, by majority vote, to amend our amended and restated bylaws, which may allow our board of directors to take additional actions to prevent a hostile acquisition and inhibit the ability of an acquirer from amending our amended and restated bylaws to facilitate a hostile acquisition.

We believe that these provisions protect our stockholders from coercive or harmful takeover tactics by requiring potential acquirers to negotiate with our board of directors and by providing our board of directors with adequate time to assess any acquisition proposal.

We are also subject to certain anti-takeover provisions under the DGCL. Under the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, our board of directors has approved the transaction.

The provisions in our amended and restated certificate of incorporation and amended and restated bylaws and the anti-takeover provisions under the DGCL, may discourage, delay, prevent or make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including a merger, tender offer, or proxy contest involving our company. Any delay or prevention

of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. Even absent a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common stock if they are viewed as discouraging future takeover attempts.

Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or other employees or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws; or (iv) any action asserting a claim governed by the internal affairs doctrine. Our amended and restated certificate of incorporation further provides that any person or entity purchasing or acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions described above. These provisions may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

ITEM 1B. UNRESOLVED STAFF COMMENTS

As of the filing of this report, we had no unresolved comments from the SEC staff regarding our periodic or current reports under the Exchange Act that were received not less than 180 days before the end of our fiscal year to which this report relates.

ITEM 2. PROPERTIES

Our principal executive offices are located in Carlsbad, California, from which our orthobiologics and spinal implant products are designed, developed, and marketed, and from which recently launched spinal implant products are inspected, kitted and distributed. We transferred the inspection, kitting, warehousing and distribution functions for our older, legacy spinal implant products to an outsourced third party in Olive Branch, Mississippi in the fourth quarter of 2016. Our Carlsbad facility is an 82,000-square foot leased facility, where we also maintain our cadaveric training laboratory and our prototyping development and testing operation. The term of this lease expires in 2027. We also lease a 70,000-square foot manufacturing and distribution facility located in Irvine, California, from which most of our orthobiologics products are manufactured and all are distributed. The term of this lease expires in 2023. We also lease a 4,000-square foot office in Wayne, Pennsylvania, where we design spinal implants and which facilitates our interactions with customers on the East Coast. We also lease a 2,600-square foot office in Lyon, France to facilitate our international sales and marketing. We believe that our facilities are sufficient to meet our current needs and that we will be available to renew these leases when needed on acceptable terms.

Our manufacturing facilities are registered with the FDA. Our facilities are subject to FDA inspection to ensure compliance with its Quality System Regulations. For further information regarding the status of FDA inspections, see the "Item 1. Business- Regulation." above.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are subject to legal proceedings and claims in the ordinary course of business. While management presently believes that the ultimate outcome of these proceedings, individually and in the aggregate, will not materially harm our financial position, cash flows, or overall trends in results of operations, legal proceedings are subject to inherent uncertainties, and unfavorable rulings or outcomes could occur that have individually or in aggregate, a material adverse effect on our business, financial condition or operating results. We are not currently subject to any pending material litigation, other than ordinary routine litigation incidental to our business, as described above.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND

5. ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our common stock is listed on the Nasdaq Global Select Market under the symbol "SPNE." As of February 25, 2019, we had 334 stockholders of record.

Equity Compensation Plan Information

Information about our equity compensation plan is incorporated herein by reference to Part III, Item 12 of this report.

Recent Sales of Unregistered Securities

During the fourth quarter of 2018, we did not issue any securities that were not registered under the Securities Act of 1933, as amended (the Securities Act).

Purchases of Equity Securities by the Issuer

The table below is a summary of our purchases of our common stock for the months with purchase activities during the quarter ended December 31, 2018.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number of Shares That May Yet be Purchased Under the Plans or Programs
October 1 - October 31	1,164	\$ 16.61	—	—
November 1 - November 30	476	\$ 17.75	—	—
December 1 - December 31	27	\$ 19.66	—	—

(1) These shares were surrendered to the Company to satisfy tax withholdings obligations in connection with the vesting of restricted stock awards.

ITEM 6. SELECTED FINANCIAL DATA

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide this information.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The terms "we," "us," "our," "SeaSpine" or the "Company" refer collectively to SeaSpine Holdings Corporation and its wholly-owned subsidiaries, unless otherwise stated. All information presented in this report is based on our fiscal year. Unless otherwise stated, references to particular years, quarters, months or periods refer to our fiscal years ending December 31 and the associated quarters, months and periods of those fiscal years.

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. The matters discussed in these forward-looking statements are subject to risk and uncertainties that could cause actual results to differ materially from those made, projected or implied in the forward-looking statements. Such risks and uncertainties may also give rise to future claims and increase exposure to contingent liabilities. Please see the "Risk Factors" section for a discussion of the uncertainties, risks and assumptions associated with these statements. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.

You can identify these forward-looking statements by forward-looking words such as "believe," "may," "could," "will," "estimate," "continue," "anticipate," "intend," "seek," "plan," "expect," "should," "would" and similar expressions.

These risks and uncertainties arise from (among other factors) the following:

- our expectations and estimates concerning future financial performance, financing plans and the impact of competition;

- our ability to successfully develop new and next-generation products and the costs associated with designing and developing those new and next-generation products;

- physicians' willingness to adopt our recently launched and planned products, customers' continued willingness to pay for our products and third-party payors' willingness to provide or continue coverage and appropriate reimbursement for any of our products and our ability to secure regulatory approval for products in development;

- our ability to attract and retain new, high-quality independent sales agents, whether as a result of inability to reach agreement on financial or other contractual terms or otherwise, disruption to our existing distribution network as new independent sales agents are added, and the ability of new independent sales agents to generate growth or offset disruption to existing independent sales agents;

- anticipated demand for our products and our ability to purchase or produce our products in sufficient quantities to meet customer demand;

- anticipated trends in our business, including healthcare reform in the United States, increased pricing pressure from our competitors or hospitals, exclusion from major healthcare systems, whether as a result of unwillingness to provide required pricing or otherwise, and changes in third-party payment systems;

- the risk of supply shortages, including our dependence on a limited number of third-party suppliers for components and raw materials;

our ability to manage timelines and costs related to manufacturing our products;

our ability to obtain additional debt and equity financing to fund capital expenditures and working capital requirements and acquisitions;

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our ability to complete acquisitions, integrate operations post-acquisition and maintain relationships with customers of acquired entities; and

our ability to support the safety and efficacy of our products with long-term clinical data;

existing and future regulations affecting our business, both in the United States and internationally, and enforcement of those regulations;

our ability to protect our intellectual property, including unpatented trade secrets, and to operate without infringing or misappropriating the proprietary rights of others;

general economic and business conditions, in both domestic and international markets;

other risk factors described in the section entitled “Risk Factors.”

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this report.

Spin-off from Integra

SeaSpine was incorporated in Delaware on February 12, 2015 in connection with the spin-off of the orthobiologics and

spinal implant business of Integra. The spin-off occurred on July 1, 2015. Subsequent to the spin-off, our financial statements are presented on a consolidated basis, as we became a separate publicly-traded company on July 1, 2015.

Overview

We are 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 implant 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. We believe this broad combined portfolio of orthobiologics and spinal implant products is essential to meet the “complete solution” requirements of such surgeons.

We report revenue in two product categories: orthobiologics and spinal implants. Our orthobiologics products consist of a broad range of advanced and traditional bone graft substitutes designed to improve bone fusion rates following a wide range of orthopedic surgeries, including spine, hip, and extremities procedures. Our spinal implant portfolio consists of an extensive line of products to facilitate spinal fusion in degenerative, MIS, and complex spinal deformity procedures.

Our U.S. sales organization consists of regional and territory managers who oversee a broad network of independent orthobiologics and spinal implant sales agents. We pay these sales agents commissions based on the sales of our products. Our international sales organization consists of a sales management team that oversees a network of independent orthobiologics and spinal implant stocking distributors that purchase products directly from us and independently sell them. For the years ended December 31, 2018 and 2017, international sales accounted for approximately 11% and 10% of our revenue, respectively. Our policy is not to sell our products through or to participate in physician-owned distributorships.

For the year ended December 31, 2018, our total revenue, net was \$143.4 million and our net loss was \$33.5 million. For the same period, revenue from sales of orthobiologics and spinal implants totaled \$75.3 million and \$68.1 million, respectively. We will continue to invest in the expansion of our business, primarily in sales, marketing and research and development, and we expect to continue to incur losses. As of December 31, 2018, our cash, cash equivalents and investments totaled \$54.0 million.

As of February 25, 2019, we had 361 regular employees.
Components of Our Results of Operations
Revenue

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Our net revenue is derived primarily from the sale of orthobiologics and spinal implant products across North America, Europe, Asia Pacific and Latin America. Sales are reported net of returns, rebates, group purchasing organization fees and other customer allowances.

In the United States, we generate most of our revenue by consigning our orthobiologics products and by consigning or loaning our spinal implant sets to hospitals and independent sales agents, who in turn either deliver them to hospitals for a single surgical procedure, after which they are returned to us, or leave them with hospitals that are high volume users for multiple procedures. The spinal implant sets typically contain the instruments, disposables, and spinal implants required to complete a surgery. We ship replacement inventory to independent sales agents to replace the consigned inventory used in surgeries. We maintain and replenish loaned sets at our kitting and distribution centers and return replenished sets to a hospital or independent sales agent for the next procedure. We recognize revenue on these consigned or loaned products when they have been used or implanted in a surgical procedure.

For all other sales transactions, including sales to international stocking distributors and private label partners, we generally recognize revenue when the products are shipped to the customer or stocking distributor and the transfer of title and risk of loss occurs. There is generally no customer acceptance or other condition that prevents us from recognizing revenue in accordance with the delivery terms for these sales transactions.

Cost of Goods Sold

Cost of goods sold primarily consists of the costs of finished goods purchased directly from third parties and raw materials used in the manufacturing of our products, plant and equipment overhead, labor costs and packaging costs. The majority of our orthobiologics products are designed and manufactured internally. The cost of human tissue and fixed manufacturing overhead costs are significant drivers of the cost of goods sold and consequently our orthobiologics products, at current production volumes, generate lower gross margin than our spinal implant products. We rely on third-party suppliers to manufacture our spinal implant products, and we assemble them into surgical sets at our kitting and distribution centers. The cost to inspect incoming finished goods is included in the cost of goods sold. Other costs included in cost of goods sold include amortization of product technology intangible assets, royalties, scrap and consignment losses, and charges for expired, excess and obsolete inventory.

Selling, General and Administrative Expense

Our selling, general and administrative (SG&A) expenses consist primarily of sales commissions to independent sales agents, cost of medical education and training, payroll and other headcount related expenses, depreciation of instrument sets, instrument replacement expense, stock-based compensation, marketing expenses, supply chain and distribution expenses, including costs to ship our spinal implants to and from hospitals and independent sales agents, expenses for information technology, legal, human resources, insurance, finance, facilities, and management. We also record gains or losses associated with changes in the fair value of contingent consideration liabilities in SG&A expenses.

Research and Development Expense

Our research and development (R&D) expenses primarily consist of expenses related to the headcount for engineering, product development, clinical affairs and regulatory functions as well as consulting services, third-party prototyping services, outside research and clinical studies activities, and materials, production and other costs

associated with development of our products. We expense R&D costs as they are incurred.

While our R&D expenses fluctuate from period to period based on the timing of specific initiatives, we expect these costs will increase over time as we continue to design and commercialize new products and expand our product portfolio, add related personnel and conduct additional clinical activities.

Intangible Amortization

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Our intangible amortization, including the amounts reported in cost of goods sold, consists of acquisition-related amortization. We expect total annual amortization expense (including amounts reported in cost of goods sold) to be approximately \$5.8 million in 2019, \$4.9 million in 2020, \$4.9 million in 2021, \$4.8 million in 2022, and \$4.2 million in 2023.

RESULTS OF OPERATIONS

	Year Ended December 31,		2018 vs. 2017	
(In thousands, except percentages)	2018	2017	%	
			Change	
Total revenue, net	\$143,443	\$131,814	9	%
Cost of goods sold	55,969	51,826	8	%
Gross profit	87,474	79,988	9	%
Gross margin	61	% 61	% —	%
Operating expenses:				
Selling, general and administrative	105,387	97,303	8	%
Research and development	12,058	12,180	(1)	%
Intangible amortization	3,168	3,168	—	%
Total operating expenses	120,613	112,651	7	%
Operating loss	(33,139)	(32,663)	1	%
Other expense (income), net	256	(430)	(160)	%
Loss before income taxes	(33,395)	(32,233)	4	%
Provision (benefit) for income taxes	129	(118)	(209)	%
Net loss	\$(33,524)	\$(32,115)	4	%

Year Ended December 31, 2018 Compared to Year Ended December 31, 2017

Revenue

Total revenue, net increased in 2018 by \$11.6 million, or 8.8%, to \$143.4 million compared to \$131.8 million for the prior year.

	Year Ended December 31,		2018 vs. 2017	
(In thousands)	2018	2017	%	
			Change	
Orthobiologics	\$75,339	\$69,128	9.0	%
United States	67,363	62,533	7.7	%
International	7,976	6,595	20.9	%
% of total revenue, net	53	% 52	%	
Spinal Implants	\$68,104	\$62,686	8.6	%
United States	60,520	55,872	8.3	%
International	7,584	6,814	11.3	%
% of total revenue, net	47	% 48	%	
Total revenue, net	\$143,443	\$131,814	8.8	%
	Year Ended	2018 vs.		
	December 31,	December 31,		
	2018	2017		

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			%	
			Change	
	(In thousands)			
United States	127,883	18,405	8.0	%
% of total revenue, net	89	90		
International	15,560	13,409	16.0	%
% of total revenue, net	11	10		

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Total revenue, net \$143,443 \$131,814 8.8%

Revenue from orthobiologics sales in the United States increased \$4.8 million in 2018 compared to 2017 and was driven primarily by recently launched products and growth in our legacy DBM product portfolio. This growth was partially offset by continuing sales declines in our collagen ceramic matrix product line. Revenue from international sales of our orthobiologics products increased \$1.4 million in 2018 compared to 2017, which was primarily attributable to increased sales in Latin America and Europe.

Revenue from spinal implant sales in the United States increased \$4.6 million in 2018 compared to 2017, primarily due to the revenue growth contributed by recently launched products. We continue to experience low to mid-single digit pricing pressure in the U.S. spinal implant market. Revenue from international sales of spinal implants increased \$0.8 million in 2018 compared to 2017, primarily due to revenue growth from sales to a new distributor in Australia that was partially offset by a decline in Europe and Latin America sales.

Cost of Goods Sold and Gross Margin

Cost of goods sold in 2018 increased \$4.1 million from 2017 to \$56.0 million. Gross margin remained consistent from 2017 at 61% in 2018.

Cost of goods sold included \$3.3 million and \$3.6 million of amortization for technology-based intangible assets for 2018 and 2017, respectively, and \$0.8 million of depreciation expense for each of 2018 and 2017.

Selling, General and Administrative

SG&A expenses increased \$8.1 million to \$105.4 million in 2018. The increase was mainly driven by higher sales commission expense, increased headcount and compensation expenses, the majority of which related to the expansion of our medical education and training organization, the hiring of additional product managers to support the successful launch of new products, and higher costs associated with tradeshow and meetings. The increase was partially offset by an increase in non-cash gains from decreases in the fair value of contingent consideration liabilities related to our acquisition in 2016 of certain medical device assets from N.L.T. Spine Ltd. (NLT), and NLT Spine, Inc., a wholly owned subsidiary of NLT.

Research and Development

R&D expenses stayed relatively consistent from 2017 at approximately \$12.1 million in 2018, representing 8% of revenue in 2018.

Intangible Amortization

Intangible amortization expense, excluding the amounts reported in cost of goods sold for product technology intangible assets, remained consistent at \$3.2 million in 2018 compared to 2017.

Income Taxes

	Year Ended December	
	31,	
	2018	2017
	(In thousands)	
Loss before income taxes	\$(33,395)	\$(32,233)
Provision (benefit) for income taxes	129	(118)
Effective tax rate	(0.4)	0.4
)%	%

The primary driver of the effective tax rate in 2018 was expenses related to current state income taxes, current foreign income taxes and the reduction of foreign deferred tax assets. These expenses were partially offset by a benefit related to the release of uncertain tax positions due to the lapse of the statute of limitations. In 2017 we reported an income tax benefit based on the release of uncertain tax positions following the lapse of the applicable statute of limitations.

In addition, for any pretax losses incurred subsequent to the spin-off by the consolidated U.S. tax group, we recorded no corresponding tax benefit because we have concluded that it is more-likely-than-not that we will be unable to realize the benefit

from any resulting deferred tax assets. We will continue to assess our position in future periods to determine if it is appropriate to reduce a portion of our valuation allowance in the future.

On December 22, 2017, the Tax Cuts and Jobs Act (2017 Tax Act) was signed into law and has resulted in significant change to the U.S corporate income tax system. The 2017 Tax Act includes a federal statutory rate reduction from 35% to 21%. Since our U.S. net deferred tax assets are currently offset by a full valuations allowance, the change in tax rate has not impacted our effective tax rate for the period ending December 31, 2018. We are not subject to the new transition tax on accumulated foreign earnings enacted by the 2017 Tax Act because our foreign operations have been included in our US tax filings pursuant to an election to disregard our foreign subsidiaries for federal income tax purposes.

Business Factors Affecting the Results of Operations

Special Charges and Gains

We define special charges and gains as expenses and gains for which the amount or timing can vary significantly from period to period, and for which the amounts are non-cash in nature, or the amounts are not expected to recur at the same magnitude.

We believe that identification of these special charges and gains provides important supplemental information to investors regarding financial and business trends relating to our financial condition and results of operations. Investors may find this information useful in assessing comparability of our operating performance from period to period, against the business model objectives that management has established, and against other companies in our industry.

We provide this information to investors so that they can analyze our operating results in the same way that management does and use this information in their assessment of our core business and valuation.

Loss before income taxes includes the following special gains for the years ended December 31, 2018 and 2017:

	Year Ended December 31, 2018 2017 (In thousands)	
Special Gains:		
Non-cash gain from change in fair value of contingent consideration liabilities	\$(1,802)	\$(975)
Non-cash gain from release of a foreign non-income tax liability	—	(1,512)
Total Special Gains	\$(1,802)	\$(2,487)

The items reported above are reflected in the consolidated statements of operations as follows:

	Year Ended December 31, 2018 2017 (In thousands)	
Selling, general and administrative	\$(1,802)	\$(2,375)
Other income	—	(112)
Total Special Gains	\$(1,802)	\$(2,487)

These special gains consist of the following items:

• A gain from change in fair value of contingent consideration that relates to the decrease in the fair value of contingent milestone and royalty payments associated with the 2016 NLT acquisition.

• A gain from the release of a foreign non-income tax liability following the lapse of the applicable statute of limitations.

Liquidity and Capital Resources

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Overview

As of December 31, 2018, we had cash, cash equivalents and investments totaling approximately \$54.0 million, and \$23.4 million of current borrowing capacity was available under our credit facility. We believe that our cash, cash equivalents and investments on hand and the amount currently available to us under our credit facility will be sufficient to fund our operations for at least the next twelve months.

Credit Facility

We have a \$30.0 million credit facility with Wells Fargo Bank, National Association which matures in July 2021, subject to a one-time, one-year extension at our election. In addition, at any time through July 27, 2020, we may increase the borrowing limit by up to an additional \$10.0 million, subject to us having sufficient amounts of eligible accounts receivable and inventory and to customary conditions precedent, including obtaining the commitment of lenders to provide such additional amount.

At December 31, 2018, we had no outstanding borrowings under the credit facility. The borrowing capacity under the credit facility is determined monthly and is based on the amount of our eligible accounts receivable and inventory balances and qualified cash (as defined in the credit facility). Depending on the extent to which our eligible accounts receivable and inventory balances increase, our borrowing capacity could increase by as much as an additional \$3.1 million from the \$23.4 million available as of December 31, 2018 before we are required to maintain the minimum fixed charge coverage ratio as discussed below. The credit facility contains various customary affirmative and negative covenants, including prohibiting us from incurring indebtedness without the lender's consent. Under the terms of the credit facility, if our Total Liquidity (as defined in the credit facility) is less than \$5.0 million, we are required to maintain a minimum fixed charge coverage ratio of 1.10 to 1.00 for the applicable measurement period. Our Total Liquidity was \$74.9 million at December 31, 2018, and therefore that financial covenant was not applicable at that time.

Business Combinations

In August 2016, we entered into an asset purchase agreement with NLT to acquire certain of the assets of NLT's medical device business related to the expandable interbody medical devices. We made an up-front cash payment of \$1.0 million in connection with the initial closing in September 2016 and issued 350,000 shares of our common stock in January 2017 as contingent closing consideration. At December 31, 2018, we recorded a \$1.6 million liability representing the estimated fair value of future contingent milestone payments related to the achievement of certain commercial milestones, which we anticipate will become payable at varying times between 2020 and 2025, and a \$0.9 million liability representing the estimated fair value of future contingent royalty payments based on percentages of our future net sales of certain of the products and technology we acquired, which we anticipate will become payable at varying times between 2019 and 2030. The contingent milestone payments, if any, are payable in cash or in shares of our common stock, at our election. The contingent royalty payments are payable in cash.

At the Market Program

In August 2016, we entered into an equity distribution agreement with Piper Jaffray & Co. (Piper Jaffray), pursuant to which we may offer and sell shares of our common stock in "at the market" (ATM) offerings (as defined in Rule 415 of the Securities Act) having an aggregate offering price up to \$25.0 million in gross proceeds from time to time through Piper Jaffray acting as sales agent. During the year ended December 31, 2017, we received net proceeds of approximately \$15.6 million, net of \$0.6 million of offering costs, from the sale of 1,500,000 shares of our common stock. In February 2018, we received net proceeds of approximately \$8.5 million, net of \$0.3 million of offering costs, from the sale of 882,332 shares of our common stock and which consumed the remaining capacity under this equity

distribution agreement.

In May 2018, we entered into another equity distribution agreement with Piper Jaffray, pursuant to which we may offer and sell shares of our common stock in ATM offerings having an aggregate offering price up to \$50.0 million in gross proceeds from time to time through Piper Jaffray acting as sales agent. We did not sell any shares of common stock under this distribution agreement during the year ended December 31, 2018. Future sales, if any, will depend on a variety of factors including, but not limited to, market conditions, the trading price of our common stock and our capital needs. We intend to use any net proceeds for general corporate purposes, including sales and marketing expenditures aimed at growing our business, research and development expenditures focused on product development, and investments in inventory and spinal instruments and sets.

Underwritten Offering

On October 11, 2018, we entered into an Underwriting Agreement with Wells Fargo Securities, LLC, Piper Jaffray & Co. and Cantor Fitzgerald & Co. acting as joint bookrunning managers and as representatives of the underwriters relating to the

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issuance and sale of 3,250,000 shares of our common stock. The price to the public in the offering was \$15.50 per share, before underwriting discounts and commissions. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 487,500 shares of common stock. The underwriters exercised this option and the offering closed on October 15, 2018 with the sale of 3,737,500 shares of our common stock. The net proceeds from the offering were approximately \$54.1 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We used a portion of the net proceeds from this offering to repay all of our then-outstanding borrowings under our Wells Fargo credit facility, and we intend to use the remaining proceeds for general corporate purposes, including general and administrative expenses, capital expenditures and general working capital purposes.

Cash and Cash Equivalents

We had cash and cash equivalents totaling approximately \$24.2 million and \$10.8 million at December 31, 2018 and December 31, 2017, respectively.

Cash Flows

	Year Ended	
	December 31,	
	2018	2017
	(In thousands)	
Net cash used in operating activities	\$(12,558)	\$(8,622)
Net cash used in investing activities	(38,104)	(7,646)
Net cash provided by financing activities	64,197	12,040
Effect of exchange rate fluctuations on cash	(90)	450
Net increase (decrease) in cash and cash equivalents	\$13,445	\$(3,778)

Net Cash Flows Used in Operating Activities

We used \$12.6 million and \$8.6 million in operating activities during 2018 and 2017, respectively.

Operating cash outflows during 2018 increased by \$3.9 million compared to 2017. The increase was primarily due to 2017 performance incentive bonuses for the executive management team being paid in cash in 2018, whereas 2016 performance incentive bonuses for the executive management team were paid with equity in lieu of cash in 2017, increased sales commission payments during 2018 compared to 2017 and increased inventory purchases and settlement of accrued expenses which increased operating cash outflows compared to 2017. These changes were partially offset by increases in accounts payable which reduced cash outflows due to timing of payments to suppliers.

Net Cash Flows Used in Investing Activities

Net cash used in investing activities was \$38.1 million in 2018 compared to \$7.6 million in 2017. The \$30.5 million increase was primarily due to \$29.8 million of purchases of U.S. Treasury Bills and \$0.9 million increase in investments in spinal instruments and sets to support recent spinal implant product launches.

Net Cash Flows Provided by Financing Activities

Net cash provided by financing activities was \$64.2 million in 2018 compared to \$12.0 million in 2017. Financing cash flows for 2018 were comprised primarily of \$54.1 million of net proceeds from the sale of shares of our common stock in our underwritten offering and \$8.5 million of net proceeds from the sale of shares of our common stock under our ATM equity offering program. We used \$7.3 million of cash to repay all of the then-outstanding borrowings under our Wells Fargo credit facility. Financing cash flows for 2017 were comprised primarily of \$15.6 million of net proceeds from the sale of shares of our common stock under our ATM equity offering program and \$1.0 million of proceeds from the sale of shares of our common stock under our 2015 Employee Stock Purchase Plan. We used \$4.0 million of cash to repay all of the then-outstanding borrowings under our Wells Fargo credit facility and \$0.4 million

of cash to repay the remaining short-term debt related to our insurance premium finance agreements (see Note 4 "Debt and Interest" to the Notes to Consolidated Financial Statements included in Part I, Item 1 of this report).

Off-Balance Sheet Arrangements

There were no off-balance sheet arrangements as of December 31, 2018 that have or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to our business.

Contractual Obligations and Commitments

As of December 31, 2018, we were obligated to pay the following amounts under various agreements:

	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
	(In millions)				
Employment Agreements	\$0.7	\$0.5	\$ 0.2	\$ —	\$ —
Operating Leases	15.0	2.2	4.4	3.8	4.6
Purchase Obligations	13.8	13.8	—	—	—
Credit Facility	—	—	—	—	—
Other	0.9	0.4	0.5	—	—
Total	\$30.4	\$16.9	\$ 5.1	\$ 3.8	\$ 4.6

The "Other" line item includes minimum royalties and milestone payments under certain license agreements. The table above excludes the following liabilities because we cannot reliably estimate the timing of when they may become payable, if ever:

- an estimated \$0.3 million liability, including interest and penalties for uncertain tax benefits;
- contingent milestone and royalty payments related to the NLT asset acquisition; and
- up to \$2.4 million in the aggregate of potential royalty and milestone payments under a license agreement that may be payable at various stages of developing the licensed technology and sales of products using the licensed technology.

Critical Accounting Policies and the Use of Estimates

Our discussion and analysis of financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities, and the reported amounts of revenues and expenses. Significant estimates affecting amounts reported or disclosed in the consolidated financial statements include revenue recognition, allowances for doubtful accounts receivable and sales return and other credits, net realizable value of inventories, amortization periods for acquired intangible assets, estimates of projected cash flows and discount rates used to value intangible assets and test them for impairment, estimates of projected cash flows and assumptions related to the timing and probability of the product launch dates, discount rates matched to the timing of payments, and probability of success rates used to value contingent consideration liabilities from business combinations, estimates of projected cash flows and depreciation and amortization periods for long-lived assets, valuation of stock-based compensation, computation of taxes and valuation allowances recorded against deferred tax assets, and loss contingencies. These estimates are based on historical experience and on various other assumptions believed to be reasonable under the current circumstances. Actual results could differ from these estimates.

We believe that the following accounting policies, which form the basis for developing these estimates, are those that are most critical to the presentation of our consolidated financial statements and require the more difficult subjective and complex judgments:

Revenue Recognition

Our net sales are derived primarily from the sale of orthobiologics and spinal implant products globally. Sales are reported net of returns, rebates, group purchasing organization fees and other customer allowances.

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Revenue is recognized when persuasive evidence of an arrangement exists, delivery has occurred, title and risk of loss have passed to the customer, there is a fixed or determinable sales price and collectability of that sales price is reasonably assured.

In the United States, we generate most of our revenue by consigning our orthobiologics products and consigning or loaning our spinal implant 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 implant sets typically contain the instruments, including disposables, and spinal implants required to complete a surgery. We ship replacement inventory to independent sales agents to replace the consigned inventory used in surgeries and maintain and replenish the loaned sets and return them to a hospital or independent sales agent for the next procedure. We recognize revenue on these consigned or loaned products when they have been used or implanted in a surgical procedure.

For all other transactions, including sales to international stocking distributors, we recognize revenue when the products are shipped to the customer or stocking distributor and the transfer of title and risk of loss occurs. There are generally no customer acceptance or other conditions that prevent us from recognizing revenue in accordance with the delivery terms.

Product royalties are estimated and recognized in the same period that the royalty-based products are sold by licensees. We estimate and recognize royalty revenue based upon communication with licensees, historical information and expected sales trends. Differences between actual revenues and estimated royalty revenues are adjusted in the period in which they become known, which is typically the following quarter. Historically, such adjustments have not been significant.

Allowance for Doubtful Accounts Receivable

We evaluate the collectability of accounts receivable based on a combination of factors. In circumstances where a specific customer is unable to meet its financial obligations to us, we record an allowance to reduce the net recognized receivable to the amount we reasonably expect to collect. For all other customers, we record allowances for doubtful accounts based on the length of time the receivables are past due, the current business environment and our historical experience. If the financial condition of customers or the length of time that receivables are past due were to change, we may incur bad debt expense in SG&A.

Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost, the value determined by the first-in, first-out method, or the market methods. At each balance sheet date, we evaluate ending inventories for excess quantities, obsolescence or shelf-life expiration. Our evaluation includes an analysis of our current and future strategic plans, historical sales levels by product, projections of future demand by product, the risk of technological or competitive obsolescence for our products, general market conditions, a review of the shelf-life expiration dates for our products, and the feasibility of reworking or using excess or obsolete products or components in the production or assembly of other products that are not obsolete or for which we do not have excess quantities in inventory. To the extent that we determine there are excess or obsolete quantities or quantities with a shelf life that is too near its expiration for us to reasonably expect that we can sell those products prior to their expiration, we adjust their carrying value to estimated net realizable value. If future demand or market conditions are lower than our projections or if we are unable to rework excess or obsolete quantities into other products, we may record further adjustments to the carrying value of inventory through a charge to cost of goods sold in the period the

revision is made. In addition, we capitalize inventory costs associated with certain products prior to regulatory approval, based on management's judgment of probable economic benefit. We could be required to expense previously capitalized costs related to pre-approval inventory upon a change in such judgment, due to, among other potential factors, a denial or delay of approval by necessary regulatory bodies or a decision by management to discontinue the related development program.

Property, Plant and Equipment

Property, plant and equipment is carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method based on an asset's estimated useful life. Maintenance and repairs on all property and equipment are expensed as incurred. Depreciation of spinal instrument sets and instrument replacement expense is recorded in SG&A.

Valuation of Identifiable Intangible Assets

Our intangible assets are comprised primarily of product technology, customer relationships, and trade name and trademarks. We make significant judgments in relation to the valuation of intangible assets resulting from business combinations and asset acquisitions. Significant estimates include, but are not limited to, measurements estimating cash flows and determining the appropriate discount rate.

Intangible assets are amortized on a straight-line basis over their estimated useful lives of 1 to 20 years. We base the useful lives and related amortization expense on the period of time we estimate the assets will generate revenues or otherwise be used by the Company. We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the technologies. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

We review identifiable intangible assets with definite lives for impairment quarterly or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider in determining whether a triggering event has occurred include a significant change in the business climate, legal factors, operating performance indicators, competition, sale or disposition of significant assets or products. Application of these impairment tests requires significant judgments, including estimation of future cash flows, which depends on internal forecasts, estimation of the long-term rate of growth for our business, the useful life over which cash flows will occur and determination of our weighted-average cost of capital.

Should a triggering event be deemed to occur, we are required to estimate the expected net cash flows to be realized over the life of the asset and/or the asset's fair value. Fair values are determined by a discounted cash flow model. These estimates are also subject to significant management judgment including the determination of many factors such as revenue growth rates, cost growth rates, terminal value assumptions and discount rates. Changes in these estimates can have a significant impact on the determination of cash flows and fair value and could result in future material impairments.

Due to market trend factors, new features necessary to be competitive, and changing pricing dynamics, there are shifts in the commercialization strategy of some of the acquired product technologies and the estimated net sales associated with the 2016 NLT acquisition. We performed a recoverability test and determined that the expected net cash flows to be realized over the life of the related intangible assets exceeds their carrying value as of December 31, 2018. As such, we determined that the related intangible assets are not impaired; however, if estimates of expected cash flows continue to decline, we may record impairment charges on the related intangible assets in the future.

Valuation of Stock-Based Compensation

The estimated fair value of stock-based awards exchanged for employee and non-employee director services are expensed over the requisite service period.

For purposes of calculating stock-based compensation, we estimate the fair value of stock options using a Black-Scholes option-pricing model. The determination of the fair value of stock-based payment awards utilizing the Black-Scholes model is affected by our stock price and several assumptions, including expected volatility, expected term, risk-free interest rate and expected dividends. Due to our limited historical data as a separate public company, the expected volatility is calculated based upon the historical volatility of comparable companies in the medical device industry whose share prices are publicly available for a sufficient period of time. The expected term of "plain vanilla" options is calculated using the simplified method as prescribed by accounting guidance for stock-based compensation.

A "plain vanilla" option is an option with these characteristics: (1) the option is granted at-the-money; (2) exercisability is conditional only on satisfaction of a service condition through the vesting date; (3) employees who terminate their service prior to vesting forfeit the options; (4) employees who terminate their service after vesting are granted limited time to exercise their stock options; and (5) the options are nontransferable and nonhedgeable. The expected term of any other option is based on disclosures from similar companies with similar grants. The risk-free interest rates are derived from the U.S. Treasury yield curve in effect on the date of grant for instruments with a remaining term similar to the expected term of the options. We considered that we have never paid cash dividends and do not currently intend to pay cash dividends. The fair value of restricted stock awards granted is based on the market price of our common stock on the date of grant. In addition, we apply an expected forfeiture rate when amortizing stock-based compensation expense. The expected forfeiture rate is based on historical experience of pre-vesting forfeitures on awards by each homogenous group of shareowners and is estimated to be 13% and 15% annually for all non-executive employees for the years ended December 31, 2018 and 2017, respectively. No forfeiture rate is applied for non-employee directors and

executive employees as their pre-vesting forfeitures are anticipated to be highly unlikely. As individual grant awards become fully vested, stock-based compensation expense is adjusted to recognize actual forfeitures.

If factors change and we employ different assumptions, stock-based compensation expense may differ significantly from what we have recorded in the past. If there is a difference between the assumptions used in determining stock-based compensation expense and the actual factors which become known over time, specifically with respect to anticipated forfeitures, we may change the input factors used in determining stock-based compensation costs for future grants. These changes, if any, may materially impact our results of operations in the period such changes are made.

Income Taxes

The income tax provision in the consolidated statements of operations for periods prior to the spin-off was calculated using the separate return method, as if we filed a separate tax return and operated as a stand-alone business. Therefore, cash tax payments and items of current and deferred taxes may not reflect our actual tax balances included in Integra's historical consolidated income tax return. More specifically, the presentation of substantial net operating losses, and any related valuation allowances, presented herein prior to the spin-off do not represent actual net operating losses incurred by us or that are available for carryforward to a future tax year.

Changes in the tax rates of the various jurisdictions in which we operate affect our profits. In addition, we maintain a reserve for uncertain tax benefits, changes to which could impact our effective tax rate in the period such changes are made. The effective tax rate can also be impacted by changes in valuation allowances of deferred tax assets, and tax law changes.

Our provision for income taxes may change period-to-period based on specific events, such as the settlement of income tax audits and changes in tax laws, as well as general factors, including the geographic mix of income before taxes, state and local taxes.

We recognize a tax benefit from an uncertain tax position only if it is more likely than not to be sustained upon examination based on the technical merits of the position. The amount of the accrual for which an exposure exists is not material for any period presented.

We believe that we have identified all reasonably identifiable exposures and the reserve we have established for identifiable exposures is appropriate under the circumstances; however, it is possible that additional exposures exist and that exposures will be settled at amounts different than the amounts reserved. It is also possible that changes in facts and circumstances could cause us to either materially increase or reduce the carrying amount of our tax reserves.

Our deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and their basis for income tax purposes, and also the temporary differences created by the tax effects of capital loss, net operating loss and tax credit carryforwards. We record valuation allowances to reduce deferred tax assets to the amounts that are more likely than not to be realized. We could recognize no benefit from our deferred tax assets or we could recognize some or all of the future benefit depending on the amount and timing of taxable income we generate in the future.

The Tax Cuts and Jobs Act enacted on December 22, 2017 reduces the U.S federal corporate tax rate from 35% to 21%. Accordingly, we modified the value of the deferred tax assets and liabilities including the net operating loss carryover at December 31, 2017. We are not subject to the new transition tax on accumulated foreign earnings enacted by the 2017 Tax Act because our foreign operations have been included in our US tax filings pursuant to an election to

disregard our foreign subsidiaries for federal income tax purposes.

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Loss Contingencies

We are subject to claims and lawsuits in the ordinary course of our business, with respect to our products, our current or former employees, and involving commercial disputes. We accrue for loss contingencies when it is deemed probable that a loss has been incurred and that loss is estimable. The amounts accrued are based on the full amount of the estimated loss before considering insurance proceeds, if applicable, and do not include an estimate for legal fees expected to be incurred in connection with the loss contingency. We accrue legal fees expected to be incurred in connection with loss contingencies as those fees are incurred by outside counsel as a period cost. Our financial statements do not reflect any material amounts related to possible unfavorable outcomes of claims and lawsuits to which we are currently a party because we currently believe that such claims and lawsuits are not expected, individually or in the aggregate, to result in a material and adverse effect on our financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a "smaller reporting company" as defined by Item 10 of Regulation S-K, the Company is not required to provide this information.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial statements and the financial statement schedules specified by this Item, together with the report thereon of RSM US LLP, are presented following the signature page to this report.

Information on quarterly results of operations is set forth in our financial statements under Note 13, "Selected Quarterly Information — Unaudited," to our consolidated financial statements.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of our management, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act were effective as of the end of the period covered by this report to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. Management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework (2013 Framework). Based on

this assessment, our management concluded that, as of December 31, 2018, our internal control over financial reporting was effective based on those criteria.

Attestation Report on Internal Control over Financial Reporting

As an emerging growth company, under Section 103 of the JOBS Act, we are not required to provide, and this report does not include, an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) under the Exchange Act that occurred during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent or detect all error and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

ITEM 9B. OTHER INFORMATION

None.

Part III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

Information required by this item will be set forth under the headings “PROPOSAL 1: ELECTION OF DIRECTORS,” “EXECUTIVE COMPENSATION AND OTHER INFORMATION,” and “SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE” in our definitive proxy statement to be filed with the SEC in connection with our 2019 Annual Meeting of Stockholders, or the Definitive Proxy Statement, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2018, and is incorporated in this report by reference.

Item 11. EXECUTIVE COMPENSATION.

The information required by this item will be set forth under the heading "EXECUTIVE COMPENSATION AND OTHER INFORMATION" in the Definitive Proxy Statement and is incorporated in this report by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this item will be set forth under the headings “SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT” and “EXECUTIVE COMPENSATION AND OTHER INFORMATION” in the Definitive Proxy Statement and is incorporated in this report by reference.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item will be set forth under the headings “CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS” and “PROPOSAL 1: ELECTION OF DIRECTORS” in the Definitive Proxy Statement and is incorporated in this report by reference.

Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this item will be set forth under the headings “PROPOSAL 2: RATIFICATION OF SELECTION OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM” in the Definitive Proxy Statement and is incorporated in this report by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as a part of this report.

1. Financial Statements.

The following financial statements and financial statement schedules are filed as a part of this report:

<u>Report of Independent Registered Public Accounting Firm</u>	<u>F- 1</u>
<u>Consolidated Statements of Operations for the years ended December 31, 2018 and 2017</u>	<u>F- 3</u>
<u>Consolidated Statements of Comprehensive Loss for the years ended December 31, 2018 and 2017</u>	<u>F- 4</u>
<u>Consolidated Balance Sheets as of December 31, 2018 and 2017</u>	<u>F- 5</u>
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017</u>	<u>F- 6</u>
<u>Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018 and 2017</u>	<u>F- 8</u>
<u>Notes to Consolidated Financial Statements</u>	<u>F- 9</u>

2. Financial Statement Schedules.

<u>Schedule II — Valuation and Qualifying Accounts</u>	<u>F- 28</u>
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All other schedules not listed above have been omitted, because they are not applicable or are not required, or because the required information is included in the consolidated financial statements or notes thereto.

3. Exhibits required to be filed by Item 601 of Regulation S-K.

EXHIBIT INDEX

Exhibit No.	Description	Filed or Furnished Herewith	Incorporated by Reference		
			Form	File/Film No.	Date Filed
2.1(a)*#	<u>Asset Purchase Agreement among SeaSpine Holdings Corporation, N.L.T Spine Ltd. and NLT Spine, Inc., dated August 17, 2016</u>		Form 10-Q	001-36905-161987764	11/10/2016
2.1(b)	<u>Amendment to the Asset Purchase Agreement among SeaSpine Holdings Corporation, N.L.T Spine Ltd. and NLT Spine, Inc., dated September 26, 2016</u>		Form 10-Q	001-36905-161987764	11/10/2016
2.1(c)	<u>Amendment No. 2 to Asset Purchase Agreement among SeaSpine Holdings Corporation, N.L.T Spine Ltd. and NLT Spine, Inc., dated January 31, 2017</u>		Form 10-K	001-36905-17665133	3/3/2017
3.1	<u>Amended and Restated Certificate of Incorporation of SeaSpine Holdings Corporation</u>		Form 8-K	001-36905-15966132	7/1/2015
3.2	<u>Amended and Restated Bylaws of SeaSpine Holdings Corporation</u>	X			
4.1	<u>Form of Common Stock Certificate of SeaSpine Holdings Corporation</u>		Form 10	001-36905-15904590	6/1/2015
4.2	<u>Form of Indenture</u>		Form S-3	333-213089-161825462	8/11/2016
10.1	<u>Microfibrillar Collagen Supply Agreement between Integra LifeSciences Holdings Corporation and SeaSpine Holdings Corporation, dated as of July 1, 2015</u>		Form 8-K	001-36905-15966132	7/1/2015
10.2	<u>Collagen Ceramic Supply Agreement between Integra LifeSciences Holdings Corporation and SeaSpine Holdings Corporation, dated as of July 1, 2015</u>		Form 8-K	001-36905-15966132	7/1/2015
10.3	<u>Demineralized Bone Matrix and Collagen Ceramic Products Supply Agreement between Integra LifeSciences Holdings Corporation and SeaSpine Holdings Corporation, dated as of July 1, 2015</u>		Form 8-K	001-36905-15966132	7/1/2015
10.4**	<u>Form of Indemnification Agreement entered into between SeaSpine Holdings Corporation</u>		Form 10	001-36905-15904590	6/1/2015

and each of its directors and executive officers

10.5** SeaSpine Holdings Corporation 2015 Employee
Stock Purchase Plan

Form 001-36905-15904590 6/1/2015
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10.6**	<u>Employment Agreement, by and between SeaSpine Holdings Corporation, SeaSpine Orthopedics Corporation and Keith Valentine, dated April 28, 2015</u>	Form 10	001-36905-15904590	6/1/2015
10.7**	<u>John Bostjancic Letter Agreement, dated March 30, 2015</u>	Form 10	001-36905-15904590	6/1/2015
10.8**	<u>John Winge Letter Agreement, dated January 22, 2015</u>	Form 10	001-36905-15904590	6/1/2015
10.9	<u>Amended and Restated Lease between Monarch RRC Properties, LLC (assignee of original landlord, New Goodyear LTD) and IsoTis Orthobiologics, Inc., dated as of February 23, 2006, for property at 2 Goodyear, Irvine, CA (the "Irvine Industrial Real Estate Lease")</u>	Form 10	001-36905-15904590	6/1/2015
10.10(a)	<u>Amendment No. 1 to Irvine Industrial Real Estate Lease, dated as of May 26, 2011</u>	Form 10	001-36905-15904590	6/1/2015
10.10(b)	<u>Amendment No. 2 to Irvine Industrial Real Estate Lease, dated as of May 14, 2013</u>	Form 10	001-36905-15904590	6/1/2015
10.11	<u>Sublease Agreement between SeaSpine Orthopedics Corporation, and SkinMedica, Inc., dated as of July 8, 2015</u>	Form 8-K	001-36905-151103433	9/11/2015
10.12**	<u>SeaSpine Holdings Corporation Senior Leadership Retention and Severance Plan, effective January 27, 2016</u>	Form 8-K	001-36905-161378936	2/2/2016
10.13(a)	<u>Credit Agreement between SeaSpine Holdings Corporation, SeaSpine Orthopedics Corporation, SeaSpine, Inc., SeaSpine Sales LLC, Theken Spine, LLC, ISOTIS Orthobiologics, Inc. and Wells Fargo Bank, National Association, as administrative agent for each member of the lender group and the bank product providers, entered into as of December 24, 2015</u>	Form 10-K	001-36905-161510399	3/16/2016
10.13(b)	<u>First Amendment to Credit Agreement and Waiver among SeaSpine Holdings Corporation, SeaSpine Orthopedics Corporation, SeaSpine, Inc., SeaSpine Sales LLC, Theken Spine, LLC, ISOTIS Orthobiologics, Inc. and Wells Fargo Bank, National Association, as administrative agent for each member of the lender group and the bank product providers, made as of October 14, 2016</u>	Form 10-K	001-36905-17665133	3/3/2017

10.13(c)	<u>Amended and Restated Credit Agreement between SeaSpine Holdings Corporation, SeaSpine Orthopedics Corporation, SeaSpine, Inc., SeaSpine Sales LLC, Theken Spine, LLC, ISOTIS Orthobiologics, Inc. and Wells Fargo Bank, National Association, as administrative agent for each member of the lender group and the bank product providers, entered into as of July 27, 2018</u>	Form 10-Q	001-36905-181164006	11/6/2018
10.14(a)**	<u>SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan (As Amended and Restated as of March 30, 2016)</u>	Form S-8	333-211887-161700155	6/7/2016
10.14(b)**	<u>First Amendment to the SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan</u>	Form 8-K	001-36905-161841057	8/18/2016
10.14(c)**	<u>Second Amendment to the SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan</u>	Form S-8	333-223435-18663875	3/5/2018
10.14(d)**	<u>SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan- Form of Stock Option Grant Notice (including Stock Option Agreement)</u>	Form S-8	333-211887-161700155	6/7/2016
10.14(e)**	<u>SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan - Form of Stock Option Grant Notice (including Stock Option Agreement)</u>	Form 10	001-36905-15904590	6/1/2015
10.14(f)**	<u>SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan- Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement</u>	Form S-8	333-211887-161700155	6/7/2016
10.14(g)**	<u>SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan - Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement.</u>	Form 10-K	001-36905-17665133	3/3/2017
10.14(h)**	<u>SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan - Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement. (used for grants on and after February 1, 2018)</u>	Form 10-K	001-36905-18663242	3/2/2018

10.14(i)**	<u>SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan - Form of Stock Option Grant Notice and Stock Option Agreement. (used for grants on and after June 6, 2018 for Senior Leadership Team Members)</u>	Form 10-Q	001-36905-18979117	7/31/2018
10.14(j)**	<u>SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan - Form of Stock Option Grant Notice and Stock Option Agreement. (used for grants on and after June 6, 2018 for Non-Senior Leadership Team Members)</u>	Form 10-Q	001-36905-18979117	7/31/2018
10.15(a)**	<u>SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan</u>	Form 10-Q	001-36905-18979117	7/31/2018
10.15(b)**	<u>Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan</u>	Form 10-Q	001-36905-18979117	7/31/2018
10.15(c)**	<u>Form of Stock Option Grant Notice and Stock Option Agreement under the SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan (for Senior Leadership Team Members)</u>	Form 10-Q	001-36905-18979117	7/31/2018
10.16(d)**	<u>Form of Stock Option Grant Notice and Stock Option Agreement under the SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan (for Non-Senior Leadership Team Members)</u>	Form 10-Q	001-36905-18979117	7/31/2018
10.17**	<u>Amended and Restated Non-Employee Director Compensation Program, effective May 30, 2018</u>	Form 10-Q	001-36905-18979117	7/31/2018
10.18**	<u>Patrick Keran Letter Agreement, dated October 1, 2015</u>	Form 10-Q	001-36905-17818719	5/5/2017
10.19*	<u>Supply Agreement, dated May 15, 2013, by and between Integra LifeSciences Corporation and PcoMed, LLC, and subsequent assignment to SeaSpine Holdings Corporation on May 21, 2015</u>	Form 8-K	001-36905-181116276	10/10/2018
21.1	<u>Subsidiaries of the Registrant</u>	Form 10-K	001-36905-161510399	3/16/2016

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23.1	<u>Consent of RSM, Independent Registered Public Accounting Firm</u>	X
24.1	Power of Attorney (included on the signatures page)	X
31.1	<u>Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	X
31.2	<u>Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	X
32.1***	<u>Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>	X
32.2***	<u>Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>	X
†101.INS	XBRL Instance Document	X
†101.SCH	XBRL Taxonomy Extension Schema Document	X
†101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X
†101.DEF	XBRL Definition Linkbase Document	X
†101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	X
†101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	X

Confidential treatment has been requested or granted to certain confidential information contained in this exhibit.

* Such information was omitted from this exhibit by means of redacting a portion of the text and replacing it with an asterisk. We have filed separately with the SEC an unredacted copy of the exhibit.

Certain schedules and attachments referenced in this agreement have been omitted in accordance with Item #601(b)(2) of Regulation S-K. A copy of any omitted schedule and attachment will be furnished supplementally to the SEC upon request.

** Indicates management contract or compensatory plan or arrangement.

These certifications are being furnished solely to accompany this report pursuant to 18 U.S.C. 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation by reference language in such filing.

The financial information of SeaSpine Holdings Corporation Annual Report on Form 10-K for the year ended December 31, 2018 filed on March 1, 2019 formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Statements of Operations, (ii) the Consolidated Statements of Comprehensive Loss, (iii) the Consolidated Balance Sheets, (iv) Parenthetical Data to the Consolidated Balance Sheets, (v) the Consolidated Statements of Cash Flows, (vi) the Consolidated Statements of Equity, and (vii) Notes to Consolidated Financial Statements, is furnished electronically herewith.

ITEM 16. FORM 10-K SUMMARY

None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SEASPINE HOLDINGS CORPORATION

Date: March 1, 2019 /s/ Keith C. Valentine
Keith C. Valentine
President and Chief Executive Officer

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Keith C. Valentine and John J. Bostjancic, jointly and severally, his or her attorneys-in-fact, each with the power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Keith C. Valentine Keith C. Valentine	President, Chief Executive Officer and Director (Principal Executive Officer)	March 1, 2019
/s/ John J. Bostjancic John J. Bostjancic	Chief Financial Officer (Principal Financial and Accounting Officer)	March 1, 2019
/s/ Kirtley C. Stephenson Kirtley C. Stephenson	Chair of the Board	March 1, 2019
/s/ Stuart M. Essig Stuart M. Essig	Lead Independent Director	March 1, 2019
/s/ Cheryl R. Blanchard Cheryl R. Blanchard	Director	March 1, 2019
/s/ Keith Bradley Keith Bradley	Director	March 1, 2019
/s/ Kimberly Commins-Tzoumakas Kimberly Commins-Tzoumakas	Director	March 1, 2019
/s/ Michael Fekete Michael Fekete	Director	March 1, 2019
/s/ Renee M. Gaeta Renee M. Gaeta	Director	March 1, 2019
/s/ John B. Henneman, III John B. Henneman, III	Director	March 1, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of SeaSpine Holdings Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of SeaSpine Holdings Corporation and its subsidiaries (the Company) as of December 31, 2018, and 2017, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for the years then ended, and the related notes to the consolidated financial statements and schedule (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ RSM US LLP

We have served as the Company's auditor since 2017.

Los Angeles, California
March 1, 2019

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SEASPINE HOLDINGS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)

	Year Ended	
	December 31,	
	2018	2017
Total revenue, net	\$143,443	\$131,814
Cost of goods sold	55,969	51,826
Gross profit	87,474	79,988
Operating expenses:		
Selling, general and administrative	105,387	97,303
Research and development	12,058	12,180
Intangible amortization	3,168	3,168
Total operating expenses	120,613	112,651
Operating loss	(33,139)	(32,663)
Other expense (income), net	256	(430)
Loss before income taxes	(33,395)	(32,233)
Provision (benefit) for income taxes	129	(118)
Net loss	\$(33,524)	\$(32,115)
Net loss per share, basic and diluted	\$(2.18)	\$(2.58)
Weighted average shares used to compute basic and diluted net loss per share	15,358	12,426

The accompanying notes are an integral part of these consolidated financial statements.

SEASPINE HOLDINGS CORPORATION
 CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
 (In thousands)

	Year Ended	
	December 31,	
	2018	2017
Net loss	\$(33,524)	\$(32,115)
Other comprehensive (loss) income		
Change in foreign currency translation adjustments	(345)	678
Unrealized loss on investments	(3)	—
Comprehensive loss	\$(33,872)	\$(31,437)

The accompanying notes are an integral part of these consolidated financial statements.

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SEASPINE HOLDINGS CORPORATION
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value data)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 24,233	\$ 10,788
Short-term investments	29,800	—
Trade accounts receivable, net of allowances of \$850 and \$466	20,335	21,872
Inventories	42,742	41,721
Prepaid expenses and other current assets	2,948	2,037
Total current assets	120,058	76,418
Property, plant and equipment, net	22,623	22,063
Intangible assets, net	28,712	35,207
Other assets	949	786
Total assets	\$ 172,342	\$ 134,474
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable, trade	9,214	7,385
Accrued compensation	7,900	5,833
Accrued commissions	5,451	5,793
Contingent consideration liabilities	129	207
Other accrued expenses and current liabilities	3,852	3,939
Total current liabilities	26,546	23,157
Contingent consideration liabilities	2,367	4,228
Other liabilities	1,344	1,436
Total liabilities	30,257	28,821
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 15,000 authorized; no shares issued and outstanding at December 31, 2018 and December 31, 2017	—	—
Common stock, \$0.01 par value; 60,000 authorized; 18,669 and 13,508 shares issued and outstanding at December 31, 2018 and 2017, respectively	187	135
Additional paid-in capital	277,096	206,844
Accumulated other comprehensive income	1,602	1,950
Accumulated deficit	(136,800)	(103,276)
Total stockholders' equity	142,085	105,653
Total liabilities and stockholders' equity	\$ 172,342	\$ 134,474

The accompanying notes are an integral part of these consolidated financial statements.

SEASPINE HOLDINGS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2018	2017
OPERATING ACTIVITIES:		
Net loss	\$(33,524)	\$(32,115)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	10,695	10,871
Instrument replacement expense	1,818	1,848
Impairment of spinal instruments	527	—
Provision for excess and obsolete inventories	3,430	4,399
Amortization of debt issuance costs	113	139
Deferred income tax benefit	126	(78)
Stock-based compensation	5,800	6,067
Gain from change in fair value of contingent consideration liabilities	(1,802)	(975)
Gain from release of a foreign non-income tax liability	—	(1,512)
Changes in assets and liabilities		
Accounts receivable	1,383	(612)
Inventories	(3,454)	1,206
Prepaid expenses and other current assets	(963)	(211)
Other non-current assets	(249)	72
Accounts payable	1,860	(2,080)
Income taxes payable	16	—
Accrued commissions	(341)	1,394
Other accrued expenses and current liabilities	2,297	2,630
Other non-current liabilities	(290)	335
Net cash used in operating activities	(12,558)	(8,622)
INVESTING ACTIVITIES:		
Purchases of investments	(29,756)	—
Purchases of property and equipment	(8,348)	(7,446)
Additions to technology assets	—	(200)
Net cash used in investing activities	(38,104)	(7,646)
FINANCING ACTIVITIES:		
Borrowings under credit facility	7,000	—
Repayments of credit facility	(7,000)	(4,020)
Repayments of short term debt	—	(445)
Proceeds from issuance of common stock- employee stock purchase plan and exercise of stock options	2,520	1,021
Proceeds from issuance of common stock, net of offering costs	62,611	15,557
Repurchases of common stock for income tax withheld upon vesting of restricted stock	(627)	(50)
Payment of contingent royalty consideration liabilities in connection with acquisition of business	(137)	(23)
Debt issuance costs	(170)	—
Net cash provided by financing activities	64,197	12,040
Effect of exchange rate changes on cash and cash equivalents	(90)	450
Net change in cash and cash equivalents	13,445	(3,778)
Cash and cash equivalents at beginning of period	10,788	14,566

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Cash and cash equivalents at end of period	\$24,233	\$10,788
Non-cash investing activities:		
Property and equipment in liabilities	\$973	\$925
Supplemental cash flow information:		
Interest paid	\$441	\$373

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SEASPINE HOLDINGS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)
(In thousands)

Income taxes paid \$ 130 \$ 89

The accompanying notes are an integral part of these consolidated financial statements.

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SEASPINE HOLDINGS CORPORATION
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Additional	Accumulated	Total	
	Number	Amount	Paid-In	Other	Accumulated	Stockholders'
	of		Capital	Comprehensive	Deficit	Equity
	Shares			Income		
				(Loss)		
Balance December 31, 2016	11,258	\$ 113	\$ 180,753	\$ 1,272	\$(71,161)	\$ 110,977
Net loss	—	—	—	—	(32,115)	(32,115)
Foreign currency translation adjustment	—	—	—	678	—	678
Restricted stock issued	253	2	968	—	—	970
Issuance of common stock under employee stock purchase plan	150	2	984	—	—	986
Issuance of common stock- NLT Spine Ltd contingent closing consideration	350	3	2,545	—	—	2,548
Issuance of common stock- ATM transactions	1,500	15	15,542	—	—	15,557
Issuance of common stock- exercise of stock options	5	—	35	—	—	35
Restricted stock awards forfeited	(1)	—	—	—	—	—
Repurchases of common stock for income tax withheld upon vesting of restricted stock	(7)	—	(50)	—	—	(50)
Stock-based compensation	—	—	6,067	—	—	6,067
Balance December 31, 2017	13,508	\$ 135	\$ 206,844	\$ 1,950	\$(103,276)	\$ 105,653
Net loss	—	—	—	—	(33,524)	(33,524)
Foreign currency translation adjustment	—	—	—	(345)	—	(345)
Unrealized loss on short-term investments	—	—	—	(3)	—	(3)
Restricted stock issued	259	3	(1)	—	—	2
Issuance of common stock under employee stock purchase plan	160	2	1,107	—	—	1,109
Issuance of common stock- ATM transactions	882	9	8,505	—	—	8,514
Issuance of common stock- public offering	3,738	37	54,060	—	—	54,097
Issuance of common stock- exercise of stock options	124	1	1,410	—	—	1,411
Repurchases of common stock for income tax withheld upon vesting of restricted stock	(2)	—	(629)	—	—	(629)