

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-K

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

For the fiscal year ended December 31, 2019
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)

92008

(ZIP CODE)

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

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

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Exchange on Which Registered</u>
Common Stock, Par Value \$.01 Per Share	SPNE	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 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 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	<input type="radio"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="radio"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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 the last business day of the registrant's most recently completed second fiscal quarter (June 28, 2019), the aggregate market value of the registrant's common stock held by non-affiliates was approximately \$208,280,116 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 21, 2020 was 27,236,503.

DOCUMENTS INCORPORATED BY REFERENCE:

Certain portions of the registrant's definitive proxy statement relating to its 2020 Annual Meeting of Stockholders (scheduled for June 3, 2020) 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

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 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. Our orthobiologics products consist of a broad range of advanced and traditional bone graft substitutes that are designed to improve bone fusion rates following a wide range of orthopedic surgeries, including spine, hip, and extremities procedures. Our 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 us to offer surgeon customers a differentiated portfolio and a complete solution to meet their patients' fusion requirements. We currently market our products in the United States and in approximately 30 countries worldwide.

We were 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:



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, which may be made out of machined bone, titanium, or polyetheretherketone (PEEK) 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.

- **Our integrated orthobiologics business designs and processes 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 combined with traditional demineralized bone matrix (DBM) forms designed to provide both immediate and sustained availability of the natural array of osteoinductive bone proteins. Similarly, our research and development team developed our proprietary demineralized fiber technology by testing various geometries in an effort to optimize the combination of inductivity, conductivity, handling, and expansion properties. We believe that we have the number two market position in the United States DBM market with an estimated 18% market share.
- **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 is a proprietary surface technology for interbody implants that incorporates 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 expanded the use of NanoMetalene with the launch of five interbody products featuring Reef Topography™. Reef Topography™ describes machined macrostructures and undercut features that are designed to act as an integrated fusion scaffolding that enhances our NanoMetalene technology and provides an innovative structure with increased surface area for new bone to grow onto and into the interbody device. We have exclusive rights to NanoMetalene and Reef Topography technologies within the spine market.

- **A synergistic channel strategy for orthobiologics products.** Our dual branding strategy allows us to market our orthobiologics products through independent sales agents who carry competitive spinal implant products. Specifically, we market our orthobiologics under the SeaSpine and Isotis brands, 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 design and 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 and Reef Topography technologies may have advantages over many existing implant materials and surface options, and that our fibers-based OsteoStrand® and OsteoStrand Plus tissue products are more efficacious and 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. For example, in September 2019, we announced a development and licensing agreement with restor3D, a privately-held medical device company co-founded by Ken Gall, Professor of Mechanical Engineering at Duke University, to co-develop 3D-printed titanium implants with enhanced anatomical fit and superior integrative properties, and in January 2020, we announced a strategic alliance agreement with 7D Surgical, Inc., a privately-held Toronto-based company developing advanced image guidance technologies and machine-vision-based registration algorithms to improve surgical workflow and patient care, under which we will seek to offer a customized, best-in-class navigational solution and enabling technology to our hospital and surgeon customers on a non-exclusive basis.

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, 2019 Compared to Year Ended December 31, 2018—Revenue” and in [Part II, Item 8](#) of this report in the Notes to Consolidated Financial Statements in [Note 10, “Segment and Geographic Information.”](#)

Orthobiologics

Our orthobiologics products are used in orthopedic and dental procedures and consist of a broad range of bone graft substitutes intended to address the key elements of bone regeneration.

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 fibers-based and particulate 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.

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, provide 100% demineralized bone fibers 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.

Our OsteoBallast® and Ballast® Demineralized Bone Matrix in Resorbable Mesh product lines are 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.

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 used in open and MIS 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 composite PEEK interbody devices featuring NanoMetalene surface technology and 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 devices 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 is a comprehensive lateral lumbar interbody system that can be used to fuse the spine through a lateral approach. Our Cambria NanoMetalene interbody device can be used to fuse the cervical spine through an anterior approach. Our Shoreline® Anterior Cervical Standalone System, featuring the NanoMetalene with Reef Topography technologies, 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 fusions. In 2020, we plan to alpha launch additional NanoMetalene with Reef Topography interbody devices for transforaminal lumbar interbody fusion, posterior lumbar interbody fusion and anterior lumbar interbody fusion procedures. In addition to the novel 3D-printed titanium interbody devices we expect to alpha launch in 2020, we plan on a limited launch of our Explorer TO™ expandable interbody device system with complementary lordotic and parallel expanding implant options.

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 for open and MIS procedures 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 Mariner MIS Posterior Fixation System and NewPort MIS solutions. Launched in 2019, the Mariner MIS Posterior Fixation System features low-profile, robust towers for rod introduction and reduction as well as ultra-tough modular extended tab heads, capable of providing powerful instrumented compression and distraction of the spine. 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 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 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. Initially released in 2019 with full commercial launch in 2020, the Mariner Outrigger Revision System is an adjunct to the Mariner Posterior Fixation System designed to effectively revise and extend previous fusions. Our complex spinal implant portfolio allows surgeons to combine various product lines and approaches, offering several treatment options for the most difficult cases. In 2020, we plan to continue to extend the Mariner modular platform to address complex spine adult deformity pathologies.

Product Pipeline

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 with Reef Topography, 3D-printed titanium and expandable interbody platforms technology and provide next generation solutions for our existing products or extend the range of solutions that we provide. We aim to further build upon our foundation of static and expandable interbodies through hyperlordotic and alternative approach options within the interbody space. We are also committed to providing products, such as additional hyperlordotic cage options 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 2019, 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 10, "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 2018 and 2019, 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 2020. 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 and/or DBM products 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 5% of our total revenue in 2019.

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 Spine, XTANT Medical, Baxter, Bioventus, Cerapedics 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, 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 European 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 for most products. 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. ISO 13485 is a recognized international quality standard 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 21, 2020, we had 386 regular employees, 61 of whom were engaged in research and development, 110 in manufacturing, 115 in sales and marketing and 100 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 2019.

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) invest in our Irvine manufacturing facility; (vii) 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 Spine, XTANT Medical, Baxter, Bioventus, Cerapedics 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 clearance and/or 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, including risks inherent in newly initiated collaborations, such as with restor3d, Inc. and 7D Surgical, Inc., or use of nascent manufacturing or imaging techniques, such as additive processing (more commonly known as 3D printing) or advanced optical technologies and machine version-based registration algorithms. Some of these risks 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 continue to invest in medical education and training and, 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, in the past, a major national third-party insurer in the U.S. 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. In particular, certain of our DBM products are priced at a premium to competitors' DBM products and a significant price reduction could result in a material adverse effect on our profitability.
- 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.
- 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 sunset legacy systems while introducing 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 clearance and/or 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 regulatory clearance and/or approvals for new products or product enhancements or modifications in a timely manner;
- achieve timely alpha and/or full commercial launches of new products;
- 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. 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. This could be due to a number of factors, including, but not limited to, perceived deficiencies, or gaps, in our existing product portfolio, intense competition for independent sales agents' services, or because of the disruption associated with restrictive covenants to which distributors may be subject and potential litigation and expense associated therewith. We may also experience unforeseen disengagement from independent sales agents who have worked with us for many years. 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 or 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. However, the EU Medical Device Regulations, which will replace the existing medical device directives in May 2020, require submission of certain post-market data to maintain our CE marks. Additionally, we recently completed an analysis of which of our product systems will require submission of clinical data pursuant to MEDDEV 2.7.1 rev 4, which sets forth the European Commission's guidance on the clinical evaluation of medical devices. Accordingly, and in line with our vision to deliver clinical value, we have commenced clinical data collection activities for certain of our marketed products as more fully described elsewhere in this "Risk Factors" section.

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 (such as the result of COVID-19, more commonly referred to as coronavirus), 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. Notably, disruptions to our business operations may result from any of the foregoing events that disrupt our suppliers. For example, if we are unable to obtain disposables or other materials required to maintain "clean room" sterility in our Irvine, California facility, we may be unable to continue to manufacture products at that facility, which products account for approximately 50% of our total revenue. 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") to incorporate certain surface technology into our NanoMetalene products. The termination of, or loss of exclusivity under, this license agreement could harm sales of certain of our products if we are unable to timely develop, or negotiate an exclusive license to, a comparable alternative surface technology.

We have an exclusive license and supply agreement with PcoMed allowing the incorporation of its surface technology into our NanoMetalene products, the net sales of which represent approximately 12% of our revenue for the year ended December 31, 2019. 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 and we were unable to successfully develop or license comparable surface technology, whether on exclusive terms, or at all, we could lose rights to surface technology that is important to our products and 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 or as a result of any of the disruptions described above under the risk factor titled "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." 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, fire, flood (and other natural disasters), 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.

The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. A number of states have adopted laws and regulations that may affect our privacy and data security practices regarding the use, disclosure and protection of personally identifiable information. For example, the California Consumer Privacy Act (the CCPA), which goes into effect on January 1, 2020, will, among other things, create new individual privacy rights and impose increased obligations on companies handling personally identifiable information. 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 the CCPA, 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, cyber, 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, 2019, 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;
- complex data privacy requirements, including, but not limited to, the EU General Data Protection Regulation;
- 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 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, or encouraged/assisted an independent sales agent, 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;
- accurate predictions of product demand and production capabilities sufficient to meet that demand;
- our ability to realize expected yield improvements and scrap reduction initiatives that we have undertaken at our Irvine facility;
- higher than anticipated independent sales agent commissions;
- 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. Further, as we increasingly launch new products and product systems, we may cannibalize older products and product systems, which could exacerbate excess and obsolete charges.

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, 2019, we had \$19.2 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, including increased costs associated with the United Kingdom's exit from the European Union and the European Union's new Medical Device 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 increased its scrutiny of the medical device industry in recent years 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.

The European Union adopted the EU Medical Device Regulation (“MDR”) in 2017, which will replace the existing medical device directives in May 2020. Devices with valid CE certificates issued under the directive before May 2020 may remain on the market until their certificates expire (but no later than May 2024). The MDR will change many aspects of the existing regulatory framework, imposing stricter pre-market and post-market requirements for medical devices such as ours. Penalties may be severe, including fines and criminal sanctions. Compliance with the new regulations may require us to incur significant costs, and failure to meet the requirements could limit our ability to distribute products in the European Union.

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 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. In past years, public scrutiny was particularly acute in 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. 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 2019. 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.

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, 2019, approximately 0.9 million shares of our common stock were subject to unvested restricted stock units and approximately 2.2 million shares of our common stock were subject to exercisable stock options with a weighted average exercise price of \$14.68.

Since July 1, 2015, we have issued an aggregate of 13.9 million shares of our common stock for capital-raising purposes. Most recently, we issued an aggregate of 7,820,000 shares of our common stock (including 1,020,000 shares sold to the underwriter upon exercise of an underwriter option) in an underwritten offering completed in January 2020 at price to the public of \$12.50 per share, before underwriting discounts and commissions.

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, 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 or equity-linked 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 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 the last business day of our most recent second fiscal quarter 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

We lease real property to support our business. The following lists those leased properties that we believe are material to our business. We believe that our facilities meet our current needs and that we will be able to renew these leases when needed on acceptable terms or find alternative facilities.

Location	Approx. Square Feet	Purpose
Carlsbad, California	82,000	Design, development, marketing, and inspection of our orthobiologics and spinal implant products and distribution of certain of our spinal implant products. Also serves as our principal executive offices and houses our cadaveric training laboratory and our prototyping development and testing operations.
Irvine, California	70,000	Manufacture and distribution of our orthobiologics products
Wayne, Pennsylvania	3,700	Design of our spinal implants
Lyon, France	2,600	International sales and marketing

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 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND 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 21, 2020, we had 323 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 2019, 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, 2019.

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	3,287	\$ 11.56	—	—
November 1 - November 30	821	\$ 13.51	—	—
December 1 - December 31	625	\$ 13.12	—	—

(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 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 Securities Exchange Act of 1934, as amended (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):

- 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, including risks inherent in newly initiated collaborations, such as with restor3d, Inc. and 7D Surgical, or use of nascent manufacturing techniques, such as additive processing/3D printing;
- 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 clearance and/or approval for products in development;
- our ability to attract and retain new, high-quality distributors, whether as a result of perceived deficiencies, or gaps, in our existing product portfolio, inability to reach agreement on financial or other contractual terms or otherwise, as well as disruption associated with restrictive covenants to, which distributors may be subject and potential litigation and expense associate therewith;
- our ability to continue to invest in medical education and training, product development, and/or sales and commercial marketing initiatives at levels sufficient to drive future revenue growth;
- anticipated trends in our business, including consolidation among hospital systems, 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, and the associated potentially long-term disruption to product sales, including as a result of our dependence on PcoMed to supply products incorporating NanoMetalene technology and a limited number of third-party suppliers for components and raw materials and certain processing services;
- unexpected expenses and delay and our ability to manage timelines and costs related to manufacturing our products including as a result of litigation or developing and supporting the full commercial launch of new products;

- our ability to obtain additional debt and equity financing to fund capital expenditures and working capital requirements and acquisitions;
- our ability to complete acquisitions, integrate operations post-acquisition and maintain relationships with customers of acquired entities;
- 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; and
- 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 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, minimally invasive surgery (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 each of the years ended December 31, 2019 and 2018, international sales accounted for approximately 11% of our revenue. Our policy is not to sell our products through or to participate in physician-owned distributorships.

For the year ended December 31, 2019, our total revenue, net was \$159.1 million and our net loss was \$39.3 million. For the same period, revenue from sales of orthobiologics and spinal implants totaled \$81.3 million and \$77.8 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, 2019, our cash and cash equivalents totaled \$20.2 million. In January 2020, we completed an underwritten offering of our common stock that raised net proceeds of approximately \$91.5 million, after deducting underwriting discounts and commissions and estimated offering expenses.

As of February 21, 2020, we had 386 regular employees.

Components of Our Results of Operations

Revenue

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 and Marketing Expense

Our selling and marketing expenses consist primarily of sales commissions to independent sales agents, payroll and other headcount related expenses, marketing expenses, depreciation of instrument sets, instrument replacement expense, and cost of medical education and training.

General and Administrative Expense

Our general and administrative expenses consist primarily of payroll and other headcount related expenses, stock-based compensation, and 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 general and administrative 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

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 \$4.3 million in 2020, \$4.3 million in 2021, \$4.2 million in 2022, \$3.6 million in 2023, and \$1.7 million in 2024. See "RESULTS OF OPERATIONS-Year Ended December 31, 2019 Compared to Year Ended December 31, 2018-Impairment of Intangible Assets," below.

RESULTS OF OPERATIONS

(In thousands, except percentages)	Year Ended December 31,	
	2019	2018
Total revenue, net	\$ 159,083	\$ 143,443
Cost of goods sold	57,979	55,969
Gross profit	101,104	87,474
Gross margin	64%	61%
Operating expenses:		
Selling and marketing	83,445	75,156
General and administrative	33,594	30,231
Research and development	15,125	12,058
Impairment of intangible assets	4,993	—
Intangible amortization	3,169	3,168
Total operating expenses	140,326	120,613
Operating loss	(39,222)	(33,139)
Other (income) expense, net	(302)	256
Loss before income taxes	(38,920)	(33,395)
Provision for income taxes	356	129
Net loss	\$ (39,276)	\$ (33,524)

Year Ended December 31, 2019 Compared to Year Ended December 31, 2018

Revenue

Total revenue, net for the year ended 2019 increased by \$15.6 million, or 11%, to \$159.1 million compared to \$143.4 million for the prior year.

	Year Ended December 31,		2019 vs. 2018
	2019	2018	
	(In thousands)		% Change
Orthobiologics	\$ 81,299	\$ 75,339	8 %
United States	73,543	67,363	9 %
International	7,756	7,976	(3)%
% of total revenue, net	51%	53%	
Spinal Implants	\$ 77,784	\$ 68,104	14 %
United States	68,308	60,520	13 %
International	9,476	7,584	25 %
% of total revenue, net	49%	47%	
Total revenue, net	\$ 159,083	\$ 143,443	11 %

	Year Ended December 31,		2019 vs. 2018
	2019	2018	
	(In thousands)		% Change
United States	141,851	127,883	11%
% of total revenue, net	89%	89%	
International	17,232	15,560	11%
% of total revenue, net	11%	11%	
Total revenue, net	\$ 159,083	\$ 143,443	11%

Revenue from orthobiologics sales in the United States increased \$6.2 million in 2019 compared to 2018. This growth was driven primarily by sales of recently launched DBM products, which was somewhat offset by expected cannibalization of legacy DBM products. Revenue from orthobiologics sales internationally decreased \$0.2 million in 2019 compared to 2018, which was primarily attributable to currency declines.

Revenue from spinal implant sales in the United States increased \$7.8 million in 2019 compared to 2018, primarily due to the revenue growth contributed by recently launched products. We continue to experience low single digit pricing declines in the U.S. spinal implant market. Revenue from international sales of spinal implants increased \$1.9 million in 2019 compared to 2018, primarily due to higher sales of our newer products to existing distributors and revenue growth from sales to a new distributor in Mexico.

Cost of Goods Sold and Gross Margin

Cost of goods sold in 2019 increased \$2.0 million from 2018 to \$58.0 million. Gross margin was 64% in 2019 compared to 61% for 2018. The increase in gross margin was due to a shift in product mix, with the higher margin spinal implant product revenue growing faster than orthobiologics product revenue. Additionally, orthobiologics manufacturing scrap and technology-related intangible amortization were lower in the current period compared to the prior year period.

Cost of goods sold included \$2.2 million and \$3.3 million of amortization for product technology intangible assets for 2019 and 2018, respectively, and \$0.9 million and \$0.8 million of depreciation expense for 2019 and 2018, respectively.

Selling and Marketing

Selling and marketing expenses increased \$8.3 million to \$83.4 million in 2019. The increase was mainly driven by higher sales commission expense, higher instrument set depreciation and instrument replacement expense due to new product launches and higher volume related shipping and third-party logistics expenses.

General and Administrative

General and administrative expenses increased \$3.4 million to \$33.6 million in 2019. The increase was driven by higher salaries and wages and stock compensation expense in 2019 compared to 2018 due to increased headcount. Additionally, the increase included a \$1.5 million decrease in 2019 of non-cash gains from changes 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 increased \$3.1 million to \$15.1 million, or 10% of revenue, in 2019. The increase was primarily driven by increased salaries and wages, a \$0.5 million fee paid in connection with our recently announced development and license agreement for 3D-printed implants, higher clinical study expenses, and increased program and related external costs as we develop and launch new products and enter into new geographic markets.

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 2019 compared to 2018.

Impairment of Intangible Assets

We recorded a \$5.0 million intangible asset impairment charge in 2019 related to a shift in our commercialization strategy with respect to the product technologies we acquired from NLT due to market trend factors, new features necessary to be competitive, and more cost-effective internal development initiatives. Accordingly, we evaluated the ongoing value of the product technology intangible assets associated with the acquisition of these assets. Based on this evaluation, we determined that intangible assets with a carrying amount of \$6.8 million were no longer recoverable and were impaired, and we wrote those intangible assets down to their estimated fair value of \$1.8 million.

Income Taxes

	Year Ended December 31,	
	2019	2018
	(In thousands)	
Loss before income taxes	\$ (38,920)	\$ (33,395)
Provision for income taxes	356	129
Effective tax rate	(0.9)%	(0.4)%

The primary drivers of the effective tax rate in 2019 and 2018 were 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 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.

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 charges/(gains) for the years ended December 31, 2019 and 2018:

	Year Ended December 31,	
	2019	2018
Special Charges/(Gains):	(In thousands)	
Impairment of intangible assets ⁽¹⁾	4,993	—
Gain from change in fair value of contingent consideration liabilities ⁽²⁾	(263)	(1,802)
Total Special Charges/(Gains)	\$ 4,730	\$ (1,802)

(1) Relates to the impairment of the product technology intangible assets associated with the NLT acquisition.

(2) Relates to the net decrease in the fair value of contingent liabilities associated with the NLT acquisition.

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

	Year Ended December 31,	
	2019	2018
	(In thousands)	
Impairment of intangible assets	\$ 4,993	\$ —
General and administrative	(263)	(1,802)
Total Special Charges/(Gains)	\$ 4,730	\$ (1,802)

Liquidity and Capital Resources

Overview

In January 2020, we sold 7,820,000 shares of our common stock in an underwritten public offering and generated approximately \$91.5 million of net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. As of December 31, 2019, we had cash, cash equivalents and investments totaling approximately \$20.2 million, and \$25.4 million of current borrowing capacity was available under our credit facility. We believe that our cash and cash equivalents on hand, including the \$91.5 million of net proceeds generated from our recent public offering described above, 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, 2019, 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 \$1.1 million from the \$25.4 million available as of December 31, 2019 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 \$42.3 million at December 31, 2019, 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, 2019, we recorded a \$1.7 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 in 2020, and a \$0.3 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.

Underwritten Offerings

In October 2018, we entered into an Underwriting Agreement with Wells Fargo Securities, LLC, Piper Jaffray and Cantor Fitzgerald relating to the issuance and sale of 3,250,000 shares of our common stock at a public offering price of \$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, resulting in net proceeds of 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 research and development, general and administrative expenses, capital expenditures and general working capital purposes.

In January 2020, we entered into an Underwriting Agreement with Piper Sandler & Co. and Canaccord Genuity LLC relating to the issuance and sale of 6,800,000 shares of our common stock at a public offering price of \$12.50 per share, before underwriting discounts and commissions. We granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,020,000 shares of common stock. The underwriters exercised this option and the offering closed on January 10, 2020 with the sale of 7,820,000 shares of our common stock, resulting in proceeds of approximately \$91.5 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the proceeds for general corporate purposes, including research and development, general and administrative expenses, capital expenditures and general working capital purposes.

Cash and Cash Equivalents

We had cash and cash equivalents totaling approximately \$20.2 million and \$24.2 million at December 31, 2019 and December 31, 2018, respectively.

Cash Flows

	Year Ended December 31,	
	2019	2018
	(In thousands)	
Net cash used in operating activities	\$ (20,277)	\$ (12,558)
Net cash provided by (used in) investing activities	17,166	(38,104)
Net cash (used in) provided by financing activities	(829)	64,197
Effect of exchange rate changes on cash and cash equivalents	(94)	(90)
Net change in cash and cash equivalents	<u>\$ (4,034)</u>	<u>\$ 13,445</u>

Net Cash Flows Used in Operating Activities

Net cash used in operating activities was \$20.3 million and \$12.6 million during 2019 and 2018, respectively.

Operating cash outflows during 2019 increased by \$7.7 million compared to 2018. The increase was due mainly to increases in accounts receivable and inventory and a decrease in accounts payable in 2019 compared to 2018. Our accounts receivable

balance increased in 2019 consistent with the increase in revenue. In 2019, we invested \$2.5 million more in inventory to support revenue growth and spinal implant product launches compared to the previous year.

Net Cash Flows Provided by (Used in) Investing Activities

Net cash provided by investing activities was \$17.2 million in 2019 compared to net cash used in investment activities of \$38.1 million in 2018. The \$55.3 million increase was due primarily due to \$30.0 million of maturities of short-term investments in 2019 compared to \$29.8 million in purchases of investments in 2018. In 2019, we increased our investments in spinal instruments and spinal implant sets by \$4.4 million compared to 2018 to support product launches.

Net Cash Flows (Used in) Provided by Financing Activities

Net cash used in financing activities was \$0.8 million in 2019 compared to net cash provided by financing activities of \$64.2 million in 2018. Cash flows provided by financings in 2018 were comprised primarily of \$54.1 million of net proceeds from the sale of shares of our common stock in an underwritten offering and \$8.5 million of net proceeds from the sale of shares of our common stock in ATM offerings.

Off-Balance Sheet Arrangements

There were no off-balance sheet arrangements as of December 31, 2019 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, 2019, 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)				
Operating Leases	14.0	3.3	4.5	2.9	3.3
Purchase Obligations	12.2	12.2	—	—	—
Other	1.1	1.1	—	—	—
Total	<u>\$ 27.3</u>	<u>\$ 16.6</u>	<u>\$ 4.5</u>	<u>\$ 2.9</u>	<u>\$ 3.3</u>

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:

- contingent milestone and royalty payments related to the NLT asset acquisition; and
- up to \$2.9 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. Preparing 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. Revenue is recognized when obligations under the terms of a contract with our customer are satisfied which occurs with the transfer of control of our products. This occurs either upon shipment or delivery of goods, depending on whether the contract is Free on Board (FOB) origin or FOB destination, or, in other situations such as consignment arrangements, when the products are used in a surgical procedure (implanted in a patient). Revenue is measured as the amount of consideration we expect to receive in exchange for transferring products to a customer (transaction price).

To the extent that the transaction price includes variable consideration, such as discounts, list price discounts, rebates, volume discounts and customer payment penalties, we estimate the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method. Variable consideration is included in the transaction price if, in our judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of our anticipated performance and all information (historical, current and forecasted) that is reasonably available.

We reduce revenue by estimates of potential future product returns and other allowances. Provisions for product returns and other allowances are recorded as a reduction to revenue in the period sales are recognized. We estimate the amount of sales returns and allowances that will eventually be incurred. Certain contracts with stocking distributors contain provisions requiring us to repurchase inventory upon termination of the contract or discontinuation of a product line. Included in the sales returns reserve within other current liabilities is an estimate of repurchases that are likely to be made under these provisions. Management analyzes sales programs that are in effect, contractual arrangements, market acceptance and historical trends when evaluating the adequacy of sales returns and allowance accounts.

Product royalties account for less than 1% of total revenue for any of the periods presented, and 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 material.

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 selling and marketing expense.

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 selling and marketing expense.

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. During the year ended December 31, 2019, we performed a recoverability test and determined that the expected net cash flows to be realized over the life of the related intangible assets were no longer recoverable and were impaired. [Note 4, "Balance Sheet"](#), to the Notes to Consolidated Financial Statements included in Part IV of this report for additional information regarding the impairment. If our estimates of expected cash flows continue to decline, we may record additional 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 is calculated using the historical weighted average term of the Company's options. 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 14% and 13% annually for all non-executive employees for the years ended December 31, 2019 and 2018, respectively. We do not apply a forfeiture rate to awards (including stock options) granted to non-employee directors or executive employees because their pre-vesting forfeitures are anticipated to be highly unlikely. As individual 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 tax law and in valuation allowances of deferred tax assets.

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.

Loss Contingencies

The Company is subject to various legal proceedings in the ordinary course of its business with respect to its products, its current or former employees, and its commercial relationships. The Company accrues 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, and do not include an estimate for legal fees expected to be incurred in connection with the loss contingency. The Company accrues legal fees expected to be incurred in connection with loss contingencies as those fees are incurred by outside counsel as a period cost. The Company's financial statements do not reflect any material amounts related to possible unfavorable outcomes of claims and lawsuits to which it is currently a party because it currently believes that such claims and lawsuits are not expected, individually or in the aggregate, to result in a material and adverse effect on its 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 12, "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, 2019, 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 fiscal quarter to which this report relates 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 “DELINQUENT SECTION 16(a) REPORTS” in our definitive proxy statement to be filed with the SEC in connection with our 2020 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, 2019, 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:

Report of Independent Registered Public Accounting Firm	F- 1
Consolidated Statements of Operations for the years ended December 31, 2019 and 2018	F- 2
Consolidated Statements of Comprehensive Loss for the years ended December 31, 2019 and 2018	F- 3
Consolidated Balance Sheets as of December 31, 2019 and 2018	F- 4
Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018	F- 5
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019 and 2018	F- 7
Notes to Consolidated Financial Statements	F- 8

2. Financial Statement Schedules.

Schedule II — Valuation and Qualifying Accounts	F- 29
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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)*#	Asset Purchase Agreement among SeaSpine Holdings Corporation, N.L.T Spine Ltd. and NLT Spine, Inc., dated August 17, 2016		Form 10-Q	001-36905-161987764	11/10/2016
2.1(b)	Amendment to the Asset Purchase Agreement among SeaSpine Holdings Corporation, N.L.T Spine Ltd. and NLT Spine, Inc., dated September 26, 2016		Form 10-Q	001-36905-161987764	11/10/2016
2.1(c)	Amendment No. 2 to Asset Purchase Agreement among SeaSpine Holdings Corporation, N.L.T Spine Ltd. and NLT Spine, Inc., dated January 31, 2017		Form 10-K	001-36905-17665133	3/3/2017
3.1	Amended and Restated Certificate of Incorporation of SeaSpine Holdings Corporation		Form 8-K	001-36905-15966132	7/1/2015
3.2	Amended and Restated Bylaws of SeaSpine Holdings Corporation		Form 10-K	001-36905-19650374	3/1/2019
4.1	Form of Common Stock Certificate of SeaSpine Holdings Corporation		Form 10	001-36905-15904590	6/1/2015
4.2	Form of Indenture for Senior Debt Securities		Form S-3	333-230047-19652069	3/4/2019
4.3	Form of Indenture for Subordinated Debt Securities		Form S-3	333-230047-19652069	3/4/2019
4.4	Description of securities of the registrant	X			
10.1	Microfibrillar Collagen Supply Agreement between Integra LifeSciences Holdings Corporation and SeaSpine Holdings Corporation, dated as of July 1, 2015		Form 8-K	001-36905-15966132	7/1/2015
10.2**	Form of Indemnification Agreement entered into between SeaSpine Holdings Corporation and each of its directors and officers		Form 8-K	001-36905-19870508	5/31/2019
10.3(a)**	SeaSpine Holdings Corporation 2015 Employee Stock Purchase Plan		Form 10	001-36905-15904590	6/1/2015
10.3(b)**	First Amendment to the SeaSpine Holdings Corporation 2015 Employee Stock Purchase Plan		DEF 14A	001-36905-19753214	4/17/2019

10.4(a)**	Employment Agreement, by and between SeaSpine Holdings Corporation, SeaSpine Orthopedics Corporation and Keith Valentine, dated April 28, 2015	Form 10	001-36905-15904590	6/1/2015
10.4(b)**	Amendment to Employment Agreement entered into effective as of April 30, 2019 by and between SeaSpine Holdings Corporation and SeaSpine Orthopedics Corporation and Keith Valentine	Form 8-K	001-36905-19781754	4/30/2019
10.5**	John Bostjancic Letter Agreement, dated March 30, 2015	Form 10	001-36905-15904590	6/1/2015
10.6**	John Winge Letter Agreement, dated January 22, 2015	Form 10	001-36905-15904590	6/1/2015
10.7	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")	Form 10	001-36905-15904590	6/1/2015
10.8(a)	Amendment No. 1 to Irvine Industrial Real Estate Lease, dated as of May 26, 2011	Form 10	001-36905-15904590	6/1/2015
10.8(b)	Amendment No. 2 to Irvine Industrial Real Estate Lease, dated as of May 14, 2013	Form 10	001-36905-15904590	6/1/2015
10.9	Sublease Agreement between SeaSpine Orthopedics Corporation, and SkinMedica, Inc., dated as of July 8, 2015	Form 8-K	001-36905-151103433	9/11/2015
10.10**	SeaSpine Holdings Corporation Senior Leadership Retention and Severance Plan, effective January 27, 2016	Form 8-K	001-36905-161378936	2/2/2016
10.11(a)	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	Form 10-K	001-36905-161510399	3/16/2016

10.11(b)	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	Form 10-K	001-36905-17665133	3/3/2017
10.11(c)	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	Form 10-Q	001-36905-181164006	11/6/2018
10.12(a)**	SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan (As Amended and Restated as of March 30, 2016)	Form S-8	333-211887-161700155	6/7/2016
10.12(b)**	First Amendment to the SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan	Form 8-K	001-36905-161841057	8/18/2016
10.12(c)**	Second Amendment to the SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan	Form S-8	333-223435-18663875	3/5/2018
10.12(d)**	SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan- Form of Stock Option Grant Notice (including Stock Option Agreement)	Form S-8	333-211887-161700155	6/7/2016
10.12(e)**	SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan - Form of Stock Option Grant Notice (including Stock Option Agreement)	Form 10	001-36905-15904590	6/1/2015
10.12(f)**	SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan- Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement	Form S-8	333-211887-161700155	6/7/2016
10.12(g)**	SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan - Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement.	Form 10-K	001-36905-17665133	3/3/2017

10.12(h)**	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)		Form 10-K	001-36905-18663242	3/2/2018
10.12(i)**	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 January 1, 2020)	X			
10.12(j)**	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)		Form 10-Q	001-36905-18979117	7/31/2018
10.12(k)**	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)		Form 10-Q	001-36905-18979117	7/31/2018
10.13(a)**	SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan		Form 10-Q	001-36905-18979117	7/31/2018
10.13(b)**	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		Form 10-Q	001-36905-18979117	7/31/2018
10.13(c)**	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)		Form 10-Q	001-36905-18979117	7/31/2018
10.13(d)**	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)		Form 10-Q	001-36905-18979117	7/31/2018
10.14**	Amended and Restated Non-Employee Director Compensation Program, effective May 30, 2018		Form 10-Q	001-36905-18979117	7/31/2018

10.15**	Patrick Keran Letter Agreement, dated October 1, 2015		Form 10-Q	001-36905-17818719	5/5/2017
10.16*	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		Form 8-K	001-36905-181116276	10/10/2018
10.17*	Tyler Lipschultz Letter Agreement, dated July 9, 2015		Form 10-Q	001-36905-19788614	5/1/2019
21.1	Subsidiaries of the Registrant		Form 10-K	001-36905-161510399	3/16/2016
23.1	Consent of RSM, Independent Registered Public Accounting Firm	X			
24.1	Power of Attorney (included on the signatures page)	X			
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1***	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
32.2***	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	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

- * 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, 2019 filed on February 28, 2020 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.

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: February 28, 2020

/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:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Keith C. Valentine</u> Keith C. Valentine	President, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	February 28, 2020
<u>/s/ John J. Bostjancic</u> John J. Bostjancic	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	February 28, 2020
<u>/s/ Kirtley C. Stephenson</u> Kirtley C. Stephenson	Chair of the Board	February 28, 2020
<u>/s/ Stuart M. Essig</u> Stuart M. Essig	Lead Independent Director	February 28, 2020
<u>/s/ Keith Bradley</u> Keith Bradley	Director	February 28, 2020
<u>/s/ Kimberly Commins-Tzoumakas</u> Kimberly Commins-Tzoumakas	Director	February 28, 2020
<u>/s/ Michael Fekete</u> Michael Fekete	Director	February 28, 2020
<u>/s/ Renee M. Gaeta</u> Renee M. Gaeta	Director	February 28, 2020
<u>/s/ John B. Henneman, III</u> John B. Henneman, III	Director	February 28, 2020

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, 2019, and 2018, 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, 2019 and 2018, 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
February 28, 2020

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

	Year Ended December 31,	
	2019	2018
Total revenue, net	\$ 159,083	\$ 143,443
Cost of goods sold	57,979	55,969
Gross profit	101,104	87,474
Operating expenses:		
Selling and marketing	83,445	75,156
General and administrative	33,594	30,231
Research and development	15,125	12,058
Intangible amortization	3,169	3,168
Impairment of intangible assets	4,993	—
Total operating expenses	140,326	120,613
Operating loss	(39,222)	(33,139)
Other (income) expense, net	(302)	256
Loss before income taxes	(38,920)	(33,395)
Provision for income taxes	356	129
Net loss	\$ (39,276)	\$ (33,524)
Net loss per share, basic and diluted	\$ (2.07)	\$ (2.18)
Weighted average shares used to compute basic and diluted net loss per share	18,977	15,358

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,	
	2019	2018
Net loss	\$ (39,276)	\$ (33,524)
Other comprehensive (loss) income		
Foreign currency translation adjustments	(171)	(345)
Unrealized gain (loss) on investments	3	(3)
Comprehensive loss	\$ (39,444)	\$ (33,872)

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

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 20,199	\$ 24,233
Short-term investments	—	29,800
Trade accounts receivable, net of allowances of \$111 and \$850	24,902	20,335
Inventories, net	47,155	42,742
Prepaid expenses and other current assets	3,906	2,948
Total current assets	96,162	120,058
Property, plant and equipment, net	25,751	22,623
Intangible assets, net	19,173	28,712
Other assets	632	949
Total assets	\$ 141,718	\$ 172,342
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable, trade	\$ 7,448	\$ 9,214
Accrued compensation	7,879	7,900
Accrued commissions	7,843	5,451
Contingent consideration liabilities	1,864	129
Other accrued expenses and current liabilities	5,444	3,852
Total current liabilities	30,478	26,546
Contingent consideration liabilities, net of current portion	230	2,367
Other liabilities	1,250	1,344
Total liabilities	31,958	30,257
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 15,000 authorized; no shares issued and outstanding at December 31, 2019 and December 31, 2018	—	—
Common stock, \$0.01 par value; 60,000 authorized; 19,124 and 18,669 shares issued and outstanding at December 31, 2019 and 2018, respectively	191	187
Additional paid-in capital	284,211	277,096
Accumulated other comprehensive income	1,434	1,602
Accumulated deficit	(176,076)	(136,800)
Total stockholders' equity	109,760	142,085
Total liabilities and stockholders' equity	\$ 141,718	\$ 172,342

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,	
	2019	2018
OPERATING ACTIVITIES:		
Net loss	\$ (39,276)	\$ (33,524)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	10,347	10,695
Instrument replacement expense	2,281	1,818
Impairment of spinal instruments	30	527
Impairment of intangible assets	4,993	—
Provision for excess and obsolete inventories	3,623	3,430
Amortization of debt issuance costs	76	113
Deferred income tax provision	285	126
Stock-based compensation	7,806	5,800
Gain from change in fair value of contingent consideration liabilities	(263)	(1,802)
Changes in assets and liabilities:		
Accounts receivable	(4,621)	1,383
Inventories	(5,924)	(3,454)
Prepaid expenses and other current assets	(420)	(963)
Other non-current assets	(50)	(249)
Accounts payable	(1,458)	1,860
Income taxes payable	25	16
Accrued commissions	2,385	(341)
Other accrued expenses and current liabilities	(26)	2,297
Other non-current liabilities	(90)	(290)
Net cash used in operating activities	(20,277)	(12,558)
INVESTING ACTIVITIES:		
Purchases of investments	—	(29,756)
Purchases of property and equipment	(12,834)	(8,348)
Maturities of short-term investments	30,000	—
Net cash provided by (used in) investing activities	17,166	(38,104)
FINANCING ACTIVITIES:		
Borrowings under credit facility	—	7,000
Repayments of credit facility	—	(7,000)
Proceeds from issuance of common stock- employee stock purchase plan and exercise of stock options	1,440	2,520
Proceeds from issuance of common stock, net of offering costs	—	62,611
Repurchases of common stock for income tax withheld upon vesting of restricted stock awards and restricted stock units	(2,129)	(627)
Payment of contingent royalty consideration liabilities in connection with acquisition of business	(140)	(137)
Debt issuance costs	—	(170)
Net cash (used in) provided by financing activities	(829)	64,197
Effect of exchange rate changes on cash and cash equivalents	(94)	(90)
Net change in cash and cash equivalents	(4,034)	13,445
Cash and cash equivalents at beginning of period	24,233	10,788
Cash and cash equivalents at end of period	\$ 20,199	\$ 24,233
Non-cash investing activities:		
Property and equipment in liabilities	\$ 713	\$ 973
Intangible assets in liabilities	\$ 850	\$ —

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

Supplemental cash flow information:

Interest paid	\$	155	\$	441
Income taxes paid	\$	101	\$	130

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Number of Shares	Amount				
	Balance December 31, 2017	13,508				
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 awards and restricted stock units	(2)	—	(629)	—	—	(629)
Stock-based compensation	—	—	5,800	—	—	5,800
Balance December 31, 2018	18,669	\$ 187	\$ 277,096	\$ 1,602	\$ (136,800)	\$ 142,085
Net loss	—	—	—	—	(39,276)	(39,276)
Foreign currency translation adjustment	—	—	—	(171)	—	(171)
Unrealized loss on short-term investments	—	—	—	3	—	3
Restricted stock issued	319	3	(1)	—	—	2
Issuance of common stock under employee stock purchase plan	120	1	1,209	—	—	1,210
Issuance of common stock- exercise of stock options	17	—	230	—	—	230
Repurchases of common stock for income tax withheld upon vesting of restricted stock awards and restricted stock units	(1)	—	(2,129)	—	—	(2,129)
Stock-based compensation	—	—	7,806	—	—	7,806
Balance December 31, 2019	19,124	191	284,211	1,434	(176,076)	109,760

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

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. BUSINESS AND BASIS OF PRESENTATION

Business

SeaSpine Holdings Corporation was incorporated in Delaware on February 12, 2015 in connection with the spin-off of the orthobiologics and spinal implant business of Integra LifeSciences Holdings Corporation, a diversified medical technology company. The spin-off occurred on July 1, 2015. Unless the context indicates otherwise, (i) references to "SeaSpine" or the "Company" refer to SeaSpine Holdings Corporation and its wholly-owned subsidiaries, and (ii) references to "Integra" refer to Integra LifeSciences Holdings Corporation and its subsidiaries other than SeaSpine.

Basis of Presentation and Principles of Consolidation

The Company prepared the consolidated financial statements included in this report in accordance with accounting principles generally accepted in the U.S. (GAAP). The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation.

Under current SEC rules, 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 most recently completed 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 until the beginning of the first quarter of the fiscal year following the date it determines it does not qualify as a smaller reporting company. The Company's public float as of the last business day of its second fiscal quarter of 2019 was less than \$250 million, and as such, the Company qualifies as a smaller reporting company, elected to reflect that determination and intends to use certain of the scaled disclosure accommodations in its SEC filings made during and for the year ended December 31, 2020.

Concentration of Risk

Integra and PcoMed, LLC (PcoMed) entered into a supply agreement on May 15, 2013 (the "Supply Agreement"), which was subsequently assigned to the Company by Integra on May 21, 2015. For the year ending December 31, 2019, the sales of products incorporating the NanoMetalene® technology licensed and supplied to the Company pursuant to the Supply Agreement represent approximately 12% of the Company's revenue.

Pursuant to the Supply Agreement, PcoMed granted the Company a worldwide exclusive license to sell certain of its products treated with certain proprietary PcoMed technology (Treatment) for use in the spinal interbody and intervertebral market (Treated Products). PcoMed serves as the sole supplier of the Treatment. As consideration for the license and the Treatment, the Company paid to PcoMed initial milestone payments prior to the initial sale and the Company will pay PcoMed a low single digit royalty on the Company's net sales of all Treated Products. In the event the Company fails to meet any of its payment obligations, the license will, at PcoMed's option and following a cure period, convert to a non-exclusive license. The Supply Agreement contains customary representations and termination provisions, including for material breach and bankruptcy. Each of the Company and PcoMed retain the rights to their respective intellectual property.

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash. Cash balances are maintained primarily at major financial institutions in the United States and exceed the regulatory limit of \$250,000 insured by the Federal Deposit Insurance Corporation (FDIC). The Company has not experienced any credit losses associated with its cash balances.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

Preparing consolidated financial statements in conformity with GAAP requires management 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 allowances for doubtful accounts receivable and sales returns and other credits, net realizable value of inventories, discount rates and estimated projected cash flows used to value and test impairments of identifiable intangible and long-lived assets, assumptions related to the timing and probability of product launch dates, discount rates matched to the estimated timing of payments, probability of success rates and discount adjustments on the related cash flows for contingent considerations in business combinations, depreciation and amortization periods for identifiable intangible and long-lived assets, computation of taxes, valuation allowances recorded against deferred tax assets, the valuation of stock-based compensation 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.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of 90 days or less at the date of purchase to be cash equivalents. Cash and cash equivalents include cash readily available in checking and money market accounts.

Investments

The Company has designated its entire portfolio of fixed income securities as available-for-sale. These securities are recorded at fair value based on quoted market prices with unrealized gains and losses, net of deferred income taxes, accounted for as a component of accumulated other comprehensive income in stockholders' equity. The Company's short-term investments have maturities of greater than three and less than 12 months when purchased and are carried at fair value.

In accordance with Financial Accounting Standard Board (FASB) Accounting Standards Codification 320, Investments - Debt and Equity Securities, the Company assesses whether it intends to sell or it is more likely than not that it will be required to sell a debt security before recovery of its amortized cost basis less any current-period credit losses. For debt securities that are considered other-than-temporarily impaired and that the Company does not intend to sell and will not be required to sell prior to recovery of its amortized cost basis, the Company separates the amount of the impairment into the amount that is credit-related (referred to as the credit loss component) and the amount due to all other factors. The credit loss component is recognized in net income and is the difference between the security's amortized cost basis and the present value of its expected future cash flows. The remaining difference between the security's fair value and the present value of future expected cash flows is due to factors that are not credit-related and is recognized in accumulated other comprehensive income ("AOCI"). For debt securities that are intended to be sold, or that management believes are more likely than not to be required to be sold prior to recovery, the full impairment is recognized immediately in earnings.

Realized gains and losses on sales of investments are determined on a specific-identification basis. Interest income is recognized on an accrual basis. See [Note 4, "Balance Sheet Details"](#), below, for further discussion regarding investments.

Fair Value of Financial Instruments

The carrying amounts of cash, cash equivalents, receivables, accounts payable and accrued expenses at December 31, 2019 and 2018, are considered to approximate fair value because of the short-term nature of those items.

The Company measures certain assets and liabilities in accordance with authoritative guidance which requires fair value measurements to be classified and disclosed in one of the following three categories:

- Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities.
- Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.
- Level 3: Unobservable inputs are used when little or no market data is available.

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The carrying amount of short-term investments at December 31, 2018 are carried at fair value based on quoted market prices in active markets. This fair value measurement is categorized within Level 1 of the fair value hierarchy. There were no short-term investments at December 31, 2019.

The carrying amounts of contingent consideration liabilities at December 31, 2019 and 2018 related to business combinations are measured at fair value on a recurring basis, and are classified within Level 3 of the fair value hierarchy because they use significant unobservable inputs. See [Note 5, "Fair Value Measurements"](#), below, for further information.

Trade Accounts Receivable and Allowances

Trade accounts receivable in the accompanying consolidated balance sheets are presented net of allowances for doubtful accounts and sales returns and other credits. The Company grants credit to customers in the normal course of business, but generally does not require collateral or any other security to support its receivables.

The Company evaluates 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 the Company, a provision to the allowances for doubtful accounts is recorded to reduce the net recognized receivable to the amount that is reasonably expected to be collected. For all other customers, a provision to the allowances for doubtful accounts is recorded based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience. Provisions to the allowances for doubtful accounts are recorded to selling and marketing expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered.

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 market.

At each balance sheet date, the Company evaluates inventories for excess quantities, obsolescence or shelf life expiration. This evaluation includes analysis of the Company's current and future strategic plans, historical sales levels by product, projections of future demand, the risk of technological or competitive obsolescence for products, general market conditions, a review of the shelf life expiration dates for products, as well as 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 there are not excess quantities in inventory. To the extent that management determines there are excess or obsolete inventory or quantities with a shelf life that is too near its expiration for the Company to reasonably expect that it can sell those products prior to their expiration, the Company adjusts the carrying value to estimated net realizable value.

The Company capitalizes inventory costs associated with certain products prior to regulatory approval, based on management's judgment of probable economic benefit. The Company 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. No material amounts were capitalized at December 31, 2019 or 2018.

Property, Plant, and Equipment

Property, plant and equipment are stated at historical cost less accumulated depreciation and any impairment charges. The Company provides for depreciation using the straight-line method over the estimated useful lives of the assets. Leasehold improvements are amortized over the lesser of the lease term or the useful life. The cost of major additions and improvements is capitalized, while maintenance and repair costs that do not improve or extend the lives of the respective assets are charged to operations as incurred. The cost of computer software obtained for internal use is accounted for in accordance with the Codification 350-40, *Internal-Use Software*.

The cost of purchased spinal instruments that the Company consigns to hospitals and independent sales agents to support surgeries is initially capitalized as construction in progress. The amount is then either reclassified to spinal instruments and sets and depreciation is initiated when instruments are put together in a newly built set with spinal implants, or directly expensed for the instruments used to replace damaged instruments in an existing set. The depreciation expense and direct expense for replacement instruments are recorded in selling and marketing expense.

Business Combinations

The purchase price of each acquisition is allocated to the net assets acquired based on estimates of their fair values at the date of the acquisition. Any purchase price in excess of these net assets is recorded as goodwill, and any fair value of these net assets, excluding goodwill, in excess of the purchase price is recorded as a bargain purchase gain. The allocation of purchase price in certain cases may be subject to revision based on the final determination of fair values during the measurement period, which may be up to one year from the acquisition date.

Contingent consideration liability is recognized at the estimated fair value on the acquisition date. Subsequent changes to the fair value of contingent consideration liability are recognized in the statement of operations. Contingent consideration liability related to acquisitions consist of commercial milestone payments and contingent royalty payments, and are valued using discounted cash flow techniques. The fair value of commercial milestone payments and contingent royalty payments reflects management's expectations of probability and amount of payment, and increases or decreases as the probability and amount of payment or expectation of timing of payment changes.

Identifiable Intangible Assets

Identifiable intangible assets are initially recorded at fair value at the time of acquisition, generally using an income or cost approach. The Company capitalizes costs incurred to renew or extend the term of recognized intangible assets and amortizes those costs over their expected useful lives.

Impairment of Long-Lived Assets

Long-lived assets held and used by the Company, including property, plant and equipment and intangible assets, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. For purposes of evaluating the recoverability of long-lived assets to be held and used, a recoverability test is performed using projected undiscounted net cash flows applicable to the long-lived assets. If an impairment exists, the amount of such impairment is calculated based on the estimated fair value of the asset. Impairments to long-lived assets to be disposed of are recorded based upon the difference between the carrying value and the fair value of the applicable assets. The Company determined an impairment exists for certain intangible assets during the year ended December 31, 2019 and there was no such determination during the year ended December 31, 2018. Excluding the impairment of spinal instruments, there was no impairment of tangible long-lived assets in any of the periods presented. See [Note 4, "Balance Sheet Details"](#), below, for additional information.

Foreign Currency

The Company generates revenues outside the United States in multiple foreign currencies including euros, Swiss francs and in U.S. dollar-denominated transactions conducted with customers who generate revenue in currencies other than the U.S. dollar. The Company also incurs operating expenses in euros and Swiss francs. All assets and liabilities of foreign subsidiaries which have a functional currency other than the U.S. dollar are translated at the rate of exchange at year-end, while elements of the income statement are translated at the average exchange rates in effect during the year. The net effect of these translation adjustments is shown as a component of accumulated other comprehensive income. These currency translation adjustments are not currently adjusted for income taxes as they relate to permanent investments in non-U.S. subsidiaries. Foreign currency transaction gains and losses are reported in other income (expense), net.

Income Taxes

The Company recognizes tax benefits in its financial statements when its uncertain tax positions are more likely than not to be sustained upon audit. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. The Company recognizes deferred tax assets for deductible temporary differences, operating loss carryforwards and tax credit carryforwards. Deferred tax assets are reduced by valuation allowance if it is more likely than not that some portion, or all, of the deferred tax assets will not be realized.

Revenue Recognition

Net sales are derived primarily from the sale of orthobiologics and spinal implant products globally. Revenue is recognized when obligations under the terms of a contract with the Company's customer are satisfied which occurs with the transfer of control of the Company's products. This occurs either upon shipment or delivery of goods, depending on whether the contract is Free on Board (FOB) origin or FOB destination, or, in other situations such as consignment arrangements, when the products are used in

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

a surgical procedure (implanted in a patient). Revenue is measured as the amount of consideration the Company expects to receive in exchange for transferring products to a customer (transaction price).

To the extent that the transaction price includes variable consideration, such as discounts, list price discounts, rebates, volume discounts and customer payment penalties, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing the most likely amount method. Variable consideration is included in the transaction price if, in the Company's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely on an assessment of the Company's anticipated performance and all information (historical, current and forecasted) that is reasonably available.

The Company reduces revenue by estimates of potential future product returns and other allowances. Provisions for product returns and other allowances are recorded as a reduction to revenue in the period sales are recognized. The Company estimates the amount of sales returns and allowances that will eventually be incurred. Certain contracts with stocking distributors contain provisions requiring the Company to repurchase inventory upon termination of the contract or discontinuation of a product line. Included in the sales returns reserve within other current liabilities is an estimate of repurchases that are likely to be made under these provisions. Management analyzes sales programs that are in effect, contractual arrangements, market acceptance and historical trends when evaluating the adequacy of sales returns and allowance accounts.

Product royalties account for less than 1% of total revenue for any of the periods presented, and are estimated and recognized in the same period that the royalty-based products are sold by licensees. The Company estimates and recognizes 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 material.

See [Note 10, "Segment and Geographic Information"](#), below for a presentation of the Company's disaggregated revenue.

Shipping and Handling Fees and Costs

The Company has elected to account for shipping and handling activities as fulfillment activities. As such, the Company does not evaluate shipping and handling as promised services to its customers. Shipping and handling costs of \$2.5 million and \$1.8 million for shipments of loaned spinal implants and instrumentation sets and costs incurred for internal movement of inventory were recorded in selling and marketing expense during the years ended December 31, 2019 and 2018, respectively.

Research and Development

Research and development costs, including salaries, stock-based compensation, depreciation, consultant, clinical study, product registration and other external fees, and facility costs directly attributable to research and development activities, are expensed in the period in which they are incurred.

Stock-Based Compensation

The Company's stock-based compensation has been recognized through the consolidated statement of operations and the Company's additional paid-in capital account on the consolidated balance sheet.

The Company recognizes the expense related to the fair value of their stock-based compensation awards. Stock-based compensation expense for stock option awards was based on the fair value on the grant date using the Black-Scholes-Merton option pricing model. The fair value of restricted stock granted prior to the spin-off was based on the Integra's stock price at the grant date, and the fair value of restricted stock granted after the spin-off was based on the Company's stock price at the grant date. The long form method was used in the determination of the windfall tax benefit.

The stock-based compensation is initially measured at the fair value of the awards on the grant date and is then recognized on a ratable basis in the financial statements over the requisite service period of the award. Stock-based compensation expense was \$7.8 million in 2019 and \$5.8 million in 2018.

Concentration of Credit Risk

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash, which is held at major financial institutions, and trade receivables.

The Company's products are sold on an uncollateralized basis and on credit terms based upon a credit risk assessment of each customer. A portion of the Company's trade receivables to customers outside the United States includes sales to foreign stocking distributors, who then sell to government owned or supported healthcare systems. The ongoing economic conditions in certain European countries, especially Greece, Ireland, Italy, Portugal and Spain remain uncertain. Accounts receivable from customers in these countries are not a material amount of the Company's overall receivables.

None of the Company's customers accounted for 10% or more of the net sales or accounts receivable for any of the periods presented.

Recent Accounting Standards Not Yet Adopted

The Company qualifies as an "emerging growth company" (EGC) under the Jumpstart Our Business Startups (JOBS) Act and elected to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, which permits EGCs to defer compliance with new or revised accounting standards (the EGC extension) until non-issuers must comply with such standards. Accordingly, so long as the Company continues to qualify as an EGC, the Company will not have to adopt or comply with new or revised accounting standards until non-issuers must adopt or comply with such standards.

In February 2016, the FASB issued Accounting Standards Update (ASU or Update) No. 2016-02, Leases (Topic 842). The new standard requires lessees to recognize lease liabilities and corresponding right-of-use assets for all leases with lease terms of greater than twelve months. It also changes the definition of a lease and expands the disclosure requirements of lease arrangements. The new standard must be adopted using the modified retrospective approach. In July 2018, the FASB issued Update No. 2018-10, Codification Improvements to Topic 842 (Leases) and Update No. 2018-11, Leases (Topic 842): Targeted Improvements. In March 2019, the FASB issued Update No. 2019-01, Leases (Topic 842): Codification Improvements. In November 2019, the FASB issued Update No. 2019-10, *Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*, which modifies the effective dates for Topic 842. The amendments in ASU 2018-10, ASU 2018-11, ASU 2019-01, and ASU 2019-10 provide additional clarification and implementation guidance on certain aspects of the previously issued ASU 2016-02 and have the same effective date and transition requirements as ASU 2019-10. The Company has early adopted the standard beginning on January 1, 2020. The Company adopted the new standard electing the optional transition method that allows for a cumulative-effect adjustment in the period of adoption and did not restate prior periods. The Company applied the transition package of practical expedients allowed by the standard. The Company has completed the assessment of the new standard and is finalizing the new required disclosures. As a result of the Company's adoption of the new standard, the Company will record right-of-use assets and lease liabilities of approximately \$9.0 million and \$10.5 million, respectively, for existing operating leases in the consolidated balance sheets at January 1, 2020. Additionally, the Company will reverse approximately \$1.5 million of deferred rent liabilities previously recorded under the previous accounting guidance. The adoption of this new standard will not have a material impact on its consolidated results of operations or cash flows.

In June 2016, the FASB issued Update No. 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires credit losses on most financial assets measured at amortized cost, including trade receivables, and certain other instruments to be measured using an expected credit loss model, referred to as the current expected credit loss (CECL) model. Under this model, entities will estimate credit losses over the entire contractual term of the instrument. The new standard will be effective for the Company beginning January 1, 2023. The FASB has subsequently issued other related ASUs, which amend ASU 2016-13 to provide clarification and additional guidance. The Company is evaluating the impact of this standard on its consolidated financial statements.

In June 2018, the FASB issued Update No. 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*. This Update will require an entity to apply the requirements of Topic 718 to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606. The new standard was effective for the Company beginning on January 1, 2020. The adoption of this new standard is not expected to have a material impact on its consolidated financial statements.

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

In July 2018, the FASB issued Update No. 2018-09, *Codification Improvements*. This Update includes several amendments to the FASB Accounting Standards Codification (Codification) intended to clarify, improve, or correct errors in the Codification. Some amendments do not require transition guidance and are effective upon issuance. The amendments requiring transition guidance was effective for the Company beginning on January 1, 2020. The adoption of this new standard is not expected to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued Update No. 2018-13, *Fair Value Measurement (Topic 820)-Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement*. The amendments in this Update modify the disclosure requirements on fair value measurements in Topic 820 based on the concepts in the Concepts Statement including the consideration of costs and benefits. The new standard was effective for the Company beginning on January 1, 2020. The adoption of this new standard is not expected to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued Update No. 2018-15, *Intangibles-Goodwill and Other-Internal Use Software (Subtopic 350-40)*. The amendments in this Update align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). The new standard will be effective for the Company beginning on January 1, 2021. Early adoption is permitted. The Company is evaluating the impact of this standard on its consolidated financial statements.

In April 2019, the FASB issued Update No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments*. This Update includes several amendments to the Codification intended to clarify, improve, or correct errors in the Codification. Some amendments do not require transition guidance and are effective upon issuance. The amendments requiring transition guidance have the same effective dates as Update No. 2016-13 and will be effective for the Company beginning on January 1, 2023. The Company is evaluating the impact of this standard on its consolidated financial statements.

Recently Adopted Accounting Standards

In May 2014, the FASB issued Update No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*. The new standard provides a five-step approach to be applied to all contracts with customers. The new standard also requires expanded disclosure about revenue recognition. The new standard as amended by ASU 2015-14, ASU 2016-10 and ASU 2016-12, was effective for the Company beginning on January 1, 2019. The Company performed an assessment of the impact of this new standard on its consolidated financial statements. In assessing the impact, the Company outlined all revenue streams, and considered the five steps outlined in the standard for product sales, from which substantially all the Company's revenue is generated. The Company analyzed the impact of this new standard on all revenue streams and on all contracts with customers, including by reviewing contracts and current accounting policies and practices to identify differences that would result from applying the requirements under the new standard. The Company adopted the new standard using the modified retrospective method under which the cumulative effect of initially applying the new guidance to open contracts as of December 31, 2018 is recognized as an adjustment to the opening balance of retained earnings as of January 1, 2019. The timing of revenue recognition under the new standard is not materially different from the Company's previous revenue recognition policy. As a result of the Company's adoption of the new standard, the Company reclassified its sales return reserve from accounts receivable to a refund liability account within other current liabilities. Based on the Company's analysis of open contracts as of December 31, 2018, the cumulative effect of applying the new standard was not material.

In August 2016, the FASB issued Update No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. This new standard addresses eight specific cash flow issues related to cash receipts and cash payments with the objective of reducing the existing diversity of presentation and classification in the statement of cash flows. The new standard was effective for the Company beginning on January 1, 2019 and was applied using a retrospective transition method to each period presented. Adoption of this new guidance had no impact on the Company's cash flows statements.

In May 2017, the FASB issued Update No. 2017-09, *Compensation- Stock Compensation (Topic 718): Scope of Modification Accounting*. The new standard provides guidance regarding which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The new standard was effective for the Company beginning on January 1, 2018. Adoption of this new guidance had no impact on the Company's consolidated financial statements.

Net Loss Per Share

Basic and diluted net loss per share was calculated using the weighted-average number of shares of common stock outstanding during the period. The weighted average number of shares used to compute diluted net loss per share excludes any assumed exercise of stock options, any assumed issuance of common stock under restricted stock awards or units, and any assumed issuances under the Company's employee stock purchase plan, because the effect, in each case, would be antidilutive. Common stock equivalents of 3.6 million and 3.4 million shares for the years ended December 31, 2019 and 2018, respectively, were excluded from the calculation because of their antidilutive effect.

3. DEBT AND INTEREST

Credit Agreement

In December 2015, the Company entered into a three-year credit facility with Wells Fargo Bank, National Association, which was amended in October 2016 and in July 2018 (as amended, the Credit Facility). The Credit Facility provides an asset-backed revolving line of credit of up to \$30.0 million with a maturity date of July 27, 2021, which is subject to a one-time, one-year extension at the Company's election. In addition, under the Credit Facility, at any time through July 27, 2020, the Company may increase the \$30.0 million borrowing limit by up to an additional \$10.0 million, subject to the Company 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. In connection with the Credit Facility, the Company was required to become a guarantor and to provide a security interest in substantially all its assets for the benefit of the counterparty.

In June 2018 and September 2018, the Company borrowed \$4.0 million and \$3.0 million under the Credit Facility, respectively. The Company elected to have the LIBOR rate apply to the amounts borrowed with an interest period of six months commencing on June 28, 2018 and three months commencing on September 25, 2018, respectively. On November 2, 2018, the Company repaid the entire \$7.3 million of outstanding borrowings plus accrued interest under the Credit Facility. There were no amounts outstanding under the Credit Facility at December 31, 2019 or 2018. At December 31, 2019, the Company had \$25.4 million of current borrowing capacity under the Credit Facility. Debt issuance costs and legal fees related to the Credit Facility totaling \$0.6 million were recorded as a deferred asset and are being amortized ratably over the term of the arrangement.

Borrowings under the Credit Facility accrue interest at the rate then applicable to base rate loans (as customarily defined), unless and until converted into LIBOR rate loans (as customarily defined) in accordance with the Credit Facility. Borrowings bear interest at a floating annual rate equal to (a) during any month for which the Company's average excess availability (as customarily defined) is greater than \$20.0 million, (i) base rate plus 1.25 percentage points for base rate loans and (ii) LIBOR rate plus 2.25 percentage points for LIBOR rate loans, (b) during any month for which the Company's average excess availability is greater than \$10.0 million but less than or equal to \$20.0 million, (i) base rate plus 1.50 percentage points for base rate loans and (ii) LIBOR rate plus 2.50 percentage points for LIBOR rate loans and (c) during any month for which the Company's average excess availability is less than or equal to \$10.0 million, (i) base rate plus 1.75 percentage points for base rate loans and (ii) LIBOR rate plus 2.75 percentage points for LIBOR rate loans. The Company will also pay an unused line fee based on the average amount borrowed under the Credit Facility for the most recently completed month. If such average amount is 25% or greater of the maximum borrowing capacity, the unused fee will be equal to 0.375% per annum of the amount unused under the Credit Facility, and if such average amount is less than 25%, the unused line fee will be equal to 0.50% per annum of the amount unused under the Credit Facility. The unused line fee is due on the first day of each month.

The Credit Facility contains various customary affirmative and negative covenants, including prohibiting the Company from incurring indebtedness without the lender's consent. The Credit Facility also includes a financial covenant, that requires the Company to maintain a minimum fixed charge coverage ratio of 1.10 to 1.00 for the applicable measurement period, if the Company's Total Liquidity (as defined in the Credit Facility) is less than \$5.0 million. The Company was in compliance with all applicable covenants at December 31, 2019.

The Credit Facility also includes customary events of default, including events of default relating to non-payment of amounts due under the Credit Facility, material inaccuracy of representations and warranties, violation of covenants, bankruptcy and insolvency, failure to comply with health care laws, violation of certain of the Company's existing agreements, and the occurrence of a change of control. Under the Credit Facility, if an event of default occurs, the lender will have the right to terminate the commitments and accelerate the maturity of any loans outstanding.

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

4. BALANCE SHEET DETAILS

Short-term investments. There were no short-term investments as of December 31, 2019. The amortized cost, estimated fair value and gross unrealized gains and losses on investments as of December 31, 2018 are shown in the table below:

	Amortized Cost	Gross Unrealized		Fair Value
		Gains	(Losses)	
(In thousands)				
As of December 31, 2018				
U.S. Treasury Bills	\$ 29,803	—	\$ (3)	\$ 29,800

As of December 31, 2018, the Company's investment portfolio included 9 U.S. Treasury Bills in an unrealized loss position. There were no other-than-temporary impairments on debt securities or realized gains or losses during the year ended December 31, 2019 and 2018.

Inventories. Inventories consisted of:

	December 31, 2019	December 31, 2018
	(In thousands)	
Finished goods	\$ 30,042	\$ 27,589
Work in process	10,847	10,367
Raw materials	6,266	4,786
	<u>\$ 47,155</u>	<u>\$ 42,742</u>

Property, Plant and Equipment. Property, plant and equipment balances and corresponding useful lives were as follows:

	December 31, 2019	December 31, 2018	Useful Lives
	(In thousands)		
Leasehold improvement	\$ 5,878	\$ 5,724	Shorter of lease term or useful life
Machinery and production equipment	8,562	7,752	3-10 years
Spinal instruments and sets	25,511	23,212	4-5 years
Information systems and hardware	7,442	7,290	3-7 years
Furniture and fixtures	1,412	1,222	3-5 years
Construction in progress	9,716	7,013	
Total	<u>58,521</u>	<u>52,213</u>	
Less accumulated depreciation and amortization	(32,770)	(29,590)	
Property, plant and equipment, net	<u>\$ 25,751</u>	<u>\$ 22,623</u>	

The balance of construction in progress as of December 31, 2019 and 2018 consists primarily of spinal instruments not yet placed into service.

Depreciation and amortization expenses totaled \$4.9 million and \$4.2 million for the years ended December 31, 2019 and 2018, respectively, and included \$0.9 million and \$0.8 million of expenses that were presented within cost of goods sold for the years ended December 31, 2019 and 2018, respectively. The cost of purchased instruments used to replace damaged instruments in existing sets and recorded directly to the instrument replacement expense totaled \$2.3 million and \$1.8 million for the years ended December 31, 2019 and 2018, respectively.

Impairment charges against spinal instruments recorded for the year ended December 31, 2019 were immaterial. For the year ended December 31, 2018, the Company recorded impairment charges totaling \$0.5 million against spinal instruments that are no longer expected to be placed into service.

SEASPIKE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Identifiable Intangible Assets.

The Company shifted its commercialization strategy with respect to the product technologies it acquired of N.L.T. Spine Ltd. (NLT) and NLT Spine, Inc., a wholly owned subsidiary of NLT, due to market trend factors, new features necessary to be competitive, and more cost-effective internal development initiatives and the Company's estimated future net sales associated with those product technologies decreased. Accordingly, the Company evaluated the ongoing value of the product technology intangible assets associated with the acquisition of these assets. Based on this evaluation, the Company determined that intangible assets with a carrying amount of \$6.8 million were no longer recoverable and were impaired, and the Company wrote those intangible assets down to their estimated fair value of \$1.8 million at June 30, 2019. Significant estimates used in determining the estimated fair value include measurements estimating cash flows and determining the appropriate discount rate, which are considered Level 3 inputs under Codification 820.

During the year ended December 31, 2019, the Company recognized \$0.9 million of product technology intangible assets related to the achievement of certain licensed technology development milestones under a license agreement.

The components of the Company's identifiable intangible assets were:

December 31, 2019				
	Weighted Average Life	Cost	Accumulated Amortization	Net
(In thousands)				
Product technology	12 years	\$ 34,158	\$ (28,912)	\$ 5,246
Customer relationships	12 years	56,830	(42,903)	13,927
Trademarks/brand names	—	300	(300)	—
		\$ 91,288	\$ (72,115)	\$ 19,173

December 31, 2018				
	Weighted Average Life	Cost	Accumulated Amortization	Net
(In thousands)				
Product technology	12 years	\$ 40,769	\$ (29,153)	\$ 11,616
Customer relationships	12 years	56,830	(39,734)	17,096
Trademarks/brand names	—	300	(300)	—
		\$ 97,899	\$ (69,187)	\$ 28,712

Annual amortization expense (including amounts reported in cost of goods sold) is expected to be approximately, \$4.3 million in 2020, \$4.3 million in 2021, \$4.2 million in 2022, \$3.6 million in 2023, and \$1.7 million in 2024. Amortization expense totaled \$5.4 million and \$6.5 million for the years ended December 31, 2019 and 2018, respectively, and included \$2.2 million and \$3.3 million, respectively, of amortization of product technology intangible assets that was presented within cost of goods sold.

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

5. FAIR VALUE MEASUREMENTS

The fair values of the Company's assets and liabilities, including contingent consideration liabilities, are measured at fair value on a recurring basis, and are determined under the fair value categories as follows (in thousands):

	Total	Quoted Price in Active Market (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2019:				
Contingent consideration liabilities- current	\$ 1,864	\$ —	\$ —	\$ 1,864
Contingent consideration liabilities- non-current	230	—	—	230
Total contingent consideration	<u>\$ 2,094</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,094</u>
	Total	Quoted Price in Active Market (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
December 31, 2018:				
Short-term investments	\$ 29,800	\$ 29,800	\$ —	\$ —
Total Assets				
Contingent consideration liabilities- current	\$ 129	\$ —	\$ —	\$ 129
Contingent consideration liabilities- non-current	2,367	—	—	2,367
Total contingent consideration	<u>\$ 2,496</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,496</u>

Short-term investments are classified with Level 1 of the fair value hierarchy because they use quoted market prices in active markets for identical assets.

The Company is obligated to pay up to a maximum of \$5.0 million in milestone payments under the 2016 asset purchase agreement with NLT, payable at the Company's election in cash or in shares of its common stock. Such milestone payments are contingent on the Company's achievement of four independent events related to the commercialization of the product technologies the Company acquired in the transaction. Additionally, the Company must pay royalty payments, in cash, to NLT equal to declining (over time) percentages of the Company's future net sales of certain of the acquired product technologies not to exceed \$43.0 million in the aggregate. The Company has the option to terminate any future obligation to make royalty payments by making a one-time cash payment to NLT of \$18.0 million.

Contingent consideration liabilities are classified within Level 3 of the fair value hierarchy because they use significant unobservable inputs. For those liabilities, fair value is determined using a probability-weighted discounted cash flow model and significant inputs which are not observable in the market. The significant inputs include assumptions related to the timing and probability of the product launch dates, estimated future sales of the products, discount rates matched to the timing of payments, and probability of success rates.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The following table sets forth the changes in the estimated fair value of the Company's liabilities measured on a recurring basis using significant unobservable inputs (Level 3). The gain from change in fair value of contingent milestone and royalty payments resulted from updated estimated timing of payments, probability of success rates, the passage of time, updated discount rates matched to the estimated timing of payments, actual net sales of certain products for the year ended December 31, 2019, and estimated net sales for future royalty payment periods.

A change in estimated timing of payments, probability of success rates, or estimated net sales for future royalty payment periods would be expected to have a material impact on the fair value of contingent milestone and royalty payments.

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Beginning Balance as of January 1	\$ 2,496	\$ 4,435
Contingent consideration liabilities settled	(139)	(137)
Gain from change in fair value of contingent consideration recorded in general and administrative expenses	(263)	(1,802)
Ending Balance as of December 31	\$ 2,094	\$ 2,496

6. EQUITY AND STOCK-BASED COMPENSATION

Common Stock

In August 2016, the Company entered into an equity distribution agreement (Distribution Agreement) with Piper Jaffray & Co. (Piper Jaffray), pursuant to which the Company may offer and sell shares of its common stock in "at the market" (ATM) offerings (as defined in Rule 415 of the Securities Act of 1933, as amended) having an aggregate offering price up to \$25.0 million in gross proceeds. The shares offered and sold under the Distribution Agreement are covered by a registration statement on Form S-3 that was declared effective on August 24, 2016. Under the Distribution Agreement, the Company sold 1,500,000 shares of common stock at an average price per share of \$10.78 and received net proceeds of approximately \$15.6 million (net of \$0.6 million of offering costs) during the year ended December 31, 2017. During the year ended December 31, 2018, the Company sold an additional 882,332 shares of common stock at an average price per share of \$10.00 and received net proceeds of approximately \$8.5 million (net of \$0.3 million of offering costs), which consumed the remaining capacity under the Distribution Agreement. The Company used the net proceeds for general corporate purposes, including sales and marketing expenditures aimed at growing its business, research and development expenditures focused on product development, and investments in inventory and spinal instruments and sets.

In May 2018, the Company entered into another equity distribution agreement with Piper Jaffray (the May 2018 Distribution Agreement), pursuant to which the Company may offer and sell shares of its common stock in ATM offerings having an aggregate offering price up to \$50.0 million in gross proceeds. On March 1, 2019, the Company terminated the May 2018 Distribution Agreement. The Company is not subject to any termination penalties related to May 2018 Distribution Agreement. Prior to termination, the Company did not sell any shares of its common stock pursuant to the May 2018 Distribution Agreement.

In October 2018, the Company entered into an Underwriting Agreement with Wells Fargo Securities, LLC, Piper Jaffray and Cantor Fitzgerald & Co. relating to the issuance and sale of 3,250,000 shares of the Company's common stock. The Company 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 the Company's common stock. The price to the public in the offering was \$15.50 per share, before underwriting discounts and commissions resulting in net proceeds to the Company of approximately \$54.1 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The Company used a portion of the net proceeds from the offering to repay all of its then-outstanding borrowings under the Credit Facility, and intends to use the remaining proceeds for general corporate purposes, including general and administrative expenses, capital expenditures and general working capital purposes.

In March 2019, the Company entered into a controlled equity offering sales agreement (Sales Agreement) with Cantor Fitzgerald to sell shares of its common stock in ATM offerings having an aggregate offering price of up to \$50.0 million in gross proceeds. The Company and Cantor Fitzgerald mutually agreed to terminate the Sales Agreement effective as of October

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23, 2019. The Company is not subject to any termination penalties related to the Sales Agreement. Prior to termination, the Company did not sell shares of its common stock pursuant to the Sales Agreement.

Equity Award Plans

Stock-based compensation expense, all related to employees and non-employee directors, was recognized as follows:

	December 31,	
	2019	2018
	(In Thousands)	
Selling and marketing	\$ 1,628	1,399
General and administrative	4,607	\$ 3,873
Research and development	1,278	365
Cost of goods sold	293	163
Total stock-based compensation expense	7,806	5,800
Total estimated tax benefit related to stock-based compensation expense	—	—
Net effect on net income	\$ 7,806	\$ 5,800

As of June 30, 2015, Integra had stock options, restricted stock awards, performance stock awards, contract stock awards and restricted stock units outstanding under three plans, the 2000 Equity Incentive Plan, the 2001 Equity Incentive Plan, and the 2003 Equity Incentive Plan. In connection with the spin-off, Integra equity awards granted to individuals who became employees of SeaSpine were converted to equity awards denominated in SeaSpine common stock. In general, each post-conversion award is subject to the same terms and conditions as were applicable to the pre-conversion award.

In May 2015, the Company adopted the 2015 Incentive Award Plan, which was subsequently amended and restated with approval of the Company's stockholders. In February and March 2018, the Company's board of directors approved amendments to the plan that increased the share reserve by an aggregate of 2,726,000 shares over the then-existing share reserve thereunder, subject to stockholder approval. The Company's stockholders approved both amendments in May 2018 (the 2015 Incentive Award Plan, as amended and restated to date, the Restated Plan). Under the Restated Plan, the Company can grant its employees, non-employee directors and consultants incentive stock options and non-qualified stock options, restricted stock, performance stock, dividend equivalent rights, stock appreciation rights, stock payment awards and other incentive awards. The aggregate number of shares that may be issued or transferred pursuant to awards under the Restated Plan is the sum of (1) the number of shares issuable upon exercise or vesting of the number of Integra equity awards converted to the Company's equity awards under the Restated Plan as of the date of the spin-off and (2) 6,235,500 shares of its common stock in respect of awards granted under the Restated Plan. As of December 31, 2019, 1,832,700 shares were available for issuance under the Restated Plan.

In 2016, the Company established the 2016 Employment Inducement Incentive Award Plan (the 2016 Plan), a broad-based incentive plan which allows for the issuance of stock-based awards, including non-qualified stock options, restricted stock awards, performance awards, restricted stock unit awards and stock appreciation rights, to those individuals and in those circumstances described below. An aggregate of 1,000,000 shares are reserved for issuance under the 2016 Plan. The Company has not awarded any shares under the 2016 Plan as of December 31, 2019. As a result of the stockholders' approval of the Restated Plan, the Company's board of directors will not grant any awards under the 2016 Plan.

In June 2018, the Company established the 2018 Employment Inducement Incentive Award Plan (the 2018 Inducement Plan). The terms of the 2018 Plan are substantially similar to the terms of the Restated Plan with these principal exceptions: (1) incentive stock options may not be granted under the 2018 Inducement Plan; (2) there are no annual limits on awards that may be issued to an individual under the 2018 Inducement Plan; (3) awards granted under the 2018 Inducement Plan are not required to be subject to any minimum vesting period; and (4) awards may be granted under the 2018 Inducement Plan only to those individuals and in those circumstances described below. An aggregate of 2,000,000 shares are reserved under the 2018 Inducement Plan. As of December 31, 2019, 1,939,750 shares were available for issuance under the 2018 Inducement Plan.

Both the 2016 Inducement Plan and the 2018 Inducement Plan were adopted by the Company's board of directors without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Listing Rules. In accordance with Rule 5635(c)(4) of the Nasdaq Listing Rules, awards under those plans may only be made to an employee who has not previously been an employee or member of the Company's board of directors or of any board of directors of any parent or subsidiary of the Company, or

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary.

Restricted Stock Awards and Restricted Stock Units

Restricted stock awards (RSAs) granted to non-employee directors generally have a requisite service period of one year; restricted stock units (RSUs) granted to employees generally have a requisite service period of three years. Both are subject to graded vesting. The Company expenses the fair value of RSAs and RSUs on an accelerated basis over the vesting period or requisite service period, whichever is shorter. Stock-based compensation expense related to all equity awards includes an estimate for forfeitures. The expected forfeiture rate of all equity-based compensation is based on historical experience of pre-vesting forfeitures on awards by each homogeneous group of shareowners. For awards granted to non-executive employees, the forfeiture rate is estimated to be 14% and 13% annually for the years ended December 31, 2019 and 2018, respectively. There is no forfeiture rate applied to awards granted to non-employee directors or executive employees because their pre-vesting forfeitures are anticipated to be highly unlikely. As individual awards become fully vested, stock-based compensation expense is adjusted to recognize actual forfeitures.

The following table summarizes RSAs and RSUs granted to SeaSpine employees and non-employee directors during 2019:

	Restricted Stock Awards and Units	
	Shares (In thousands)	Weighted Average Grant Date Fair Value Per Share
Unvested, January 1, 2019	976	\$9.56
Granted	346	16.31
Cancellations	(27)	12.50
Released/Vested	(443)	9.57
Unvested, December 31, 2019	852	12.21

The weighted average grant date fair value of RSAs and RSUs granted during 2019 and 2018 was \$16.31 and \$10.72, respectively. The total fair value of shares subject to RSAs and RSUs that vested in 2019 and 2018 was \$4.3 million and \$2.6 million, respectively.

The Company recognized \$5.9 million and \$4.9 million in expense related to RSAs and RSUs for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there was approximately \$3.0 million of unrecognized compensation expense related to the unvested portions of RSAs and RSUs. This expense to be recognized over a weighted-average period of approximately 1.1 years.

Stock Options

Stock option grants to employees generally have a requisite service period of four years, and stock option grants to non-employee directors generally have a requisite service period of one year. Both are subject to graded vesting. The Company records stock-based compensation expense associated with stock options on an accelerated basis over the applicable vesting period within each grant and based on their fair value at the date of grant using the Black-Scholes-Merton option pricing model. The following weighted-average assumptions were used in the calculation of fair value for options granted during the period indicated.

	December 31,	
	2019	2018
Expected dividend yield	0%	0%
Risk-free interest rate	2.5%	2.8%
Expected volatility	30.3%	25.6%
Expected term (in years)	2.9	4.9

The Company considered that it has never paid, and does not currently intend to pay, cash dividends. 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. Due to the Company's limited historical data, 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

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

period of time. The expected term is calculated using the historical weighted average term of the Company's options. In addition, the Company applies an expected forfeiture rate when amortizing stock-based compensation expense. The expected forfeiture rate of options is based on historical experience of pre-vesting forfeitures on awards by each homogeneous group of shareowners. For options granted to non-executive employees, the forfeiture rate is estimated to be 14% and 13% annually for the years ended December 31, 2019 and 2018, respectively. There is no forfeiture rate applied to options granted to non-employee directors and executive employees because their pre-vesting forfeitures are anticipated to be highly unlikely. As individual options become fully vested, stock-based compensation expense is adjusted to recognize actual forfeitures.

A summary of the options granted during 2019 and the total number of options outstanding as of December 31, 2019 and changes since January 1, 2019 are set forth below:

	Number of Shares Outstanding (In thousands)	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (In years)	Aggregate Intrinsic Value (In thousands)
Outstanding, January 1, 2019	2,321	\$ 14.64	5.06	\$ 8,365
Granted	435	\$ 18.09	—	—
Exercised	(17)	\$ 13.42	—	—
Forfeited	(102)	\$ 15.58	—	—
Outstanding, December 31, 2019	2,637	\$ 15.18	4.65	\$ 506
Vested or expected to vest, December 31, 2019	2,618	\$ 15.16	4.63	\$ 504
Exercisable, December 31, 2019	2,163	\$ 14.68	4.16	\$ 442

The weighted average grant date fair value of options granted during 2019 and 2018 was \$4.14 and \$3.49, respectively. The total fair value of shares vested in 2019 and 2018 was \$1.3 million and \$1.4 million, respectively.

The Company recognized \$1.2 million and \$0.6 million in expense related to stock options for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, there was approximately \$0.8 million of unrecognized compensation expense related to unvested stock options. This expense is expected to be recognized over a weighted-average period of approximately 1.5 years.

Employee Stock Purchase Plan

In May 2015, the Company adopted the SeaSpine Holdings Corporation 2015 Employee Stock Purchase Plan, which was amended in November 2018, as described below (as amended, the ESPP). Under the ESPP, eligible employees may purchase shares of the Company's common stock through payroll deductions of up to 15% of eligible compensation during an offering period. Generally, each offering period will be for 24 months as determined by the Company's board of directors. There are four six-month purchase periods in each offering period for contributions to be made and to be converted into shares at the end of the purchase period. In no event may an employee purchase more than 2,500 shares per purchase period based on the closing price on the first trading date of an offering period or more than \$25,000 worth of stock during any calendar year. The purchase price for shares to be purchased under the ESPP is 85% of the lesser of the market price of the Company's common stock on the first trading date of an offering period or on any purchase date during an offering period (June 30 or December 31).

Subject to stockholder approval, on and effective as of November 2, 2018, the Company's board of directors approved an amendment to the ESPP pursuant to which the share reserve under the ESPP would increase from 400,000 shares to 800,000 shares. The Company's stockholders approved that amendment in May 2019. The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended (the IRC). The ESPP contains a restart feature, such that if the market price of the stock at the end of any six-month purchase period is lower than the market price at the original grant date of an offering period, that offering period will terminate after that purchase date, and a new two-year offering period will commence on the January 1 or July 1 immediately following the date the original offering period terminated. This restart feature was triggered on the purchase date that occurred on December 31, 2016, such that the offering period that commenced on July 1, 2016 was terminated, and a new two-year offering period commenced on January 1, 2017 and ended on December 31, 2018. The restart feature was triggered again on the purchase date that occurred on June 30, 2019, such that the offering period that commenced on January 1, 2019 was terminated, and a new two-year offering period commenced on July 1, 2019 and will end on June 30, 2021. The Company applied share-based payment modification accounting to the awards that were initially valued at

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

the grant date to determine the amount of any incremental fair value associated with the modified awards. The impact to stock-based compensation expense for modifications during the year ended December 31, 2019 was immaterial.

During the years ended December 31, 2019 and 2018, there were 119,602 and 160,059 shares of common stock, respectively, purchased under the ESPP. The Company recognized \$0.7 million and \$0.3 million in expense related to the ESPP for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, 280,462 shares were available under the ESPP for future issuance.

The Company estimates the fair value of shares issued to employees under the ESPP using the Black-Scholes-Merton option-pricing model. The following weighted average assumptions were used in the calculation of fair value of shares under the ESPP at the grant date for the periods indicated:

	December 31,	
	2019	2018
Expected dividend yield	0%	0%
Risk-free interest rate	1.4%	2.0%
Expected volatility	21.9%	29.4%
Expected term (in years)	0.7	1.3

7. LEASES

The Company leases administrative, manufacturing, research, and distribution facilities and various manufacturing, office and transportation equipment through operating lease agreements.

Future minimum lease payments under the Company's operating leases at December 31, 2019 are as follows:

	Payments Due by Calendar Year (In thousands)
2020	\$ 3,299
2021	2,218
2022	2,238
2023	1,563
2024	1,369
Thereafter	3,278
Total minimum lease payments	<u>\$ 13,965</u>

Total lease expense for each of the years ended December 31, 2019 and 2018 was \$2.1 million.

8. INCOME TAXES

The Company is subject to income taxes in the U.S., Switzerland and France. Income taxes are accounted for under the asset and liability method. Deferred income tax assets and liabilities are calculated based on the difference between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using the enacted income tax rates expected to be in effect during the years in which the temporary differences are expected to reverse. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. Significant judgment is required in determining whether a valuation allowance should be recorded against deferred tax assets. In assessing the need for a valuation allowance, management considers all available evidence for each jurisdiction including past operating results, estimates of future taxable income and the feasibility of ongoing tax planning strategies. In the event that the Company changes its determination as to the amount of deferred tax assets that can be realized, the Company will adjust its valuation allowance with a corresponding impact to income tax expense in the period in which such determination is made.

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

Income Tax Provision (Benefit)

Income (loss) before income taxes consisted of:

	Year Ended December 31,	
	2019	2018
	(In thousands)	
United States operations	\$ (39,342)	\$ (33,843)
Foreign operations	422	448
	<u>\$ (38,920)</u>	<u>\$ (33,395)</u>

A reconciliation of the U.S. federal statutory rate to the Company's effective tax rate is:

	Year Ended December 31,	
	2019	2018
Federal statutory rate	21.0%	21.0%
Increase (decrease) in income taxes resulting from:		
State income taxes, net of federal tax benefit	2.7%	3.2%
Foreign operations	(0.8)%	(0.5)%
Changes in valuation allowances	(24.7)%	(25.5)%
Uncertain tax positions	0.1%	0.3%
Research and development credit	0.2%	0.2%
Other	0.6%	0.9%
Effective tax rate	<u>(0.9)%</u>	<u>(0.4)%</u>

The provision/(benefit) for income taxes consisted of:

	Year Ended December 31,	
	2019	2018
	(In thousands)	
Current:		
Federal	\$ (27)	\$ (93)
State	59	52
Foreign	39	44
Total current	<u>\$ 71</u>	<u>\$ 3</u>
Deferred:		
Federal	—	—
State	—	—
Foreign	285	126
Total deferred	<u>\$ 285</u>	<u>\$ 126</u>
Provision (benefit) for income taxes	<u>\$ 356</u>	<u>\$ 129</u>

SEASPIKE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The income tax effects of significant temporary differences that give rise to deferred tax assets and liabilities, shown before jurisdictional netting, are presented below:

	Year Ended December 31,	
	2019	2018
(In thousands)		
Deferred tax assets:		
Doubtful accounts	\$ 27	\$ 212
Inventory related items	10,508	9,677
Tax credits	319	229
Accrued vacation	369	340
Accrued bonus	1,099	1,192
Stock compensation	4,431	3,790
Net operating loss carryforwards	38,149	30,210
Intangible and fixed assets	10,806	10,611
Other	1,000	942
Total deferred tax assets	66,708	57,203
Less valuation allowance	(65,576)	(55,954)
Deferred tax assets after valuation allowance	\$ 1,132	\$ 1,249
Deferred tax liabilities:		
Other	988	817
Total deferred tax liabilities	\$ 988	\$ 817
Net deferred tax assets	\$ 144	\$ 432

At December 31, 2019, the Company had net operating loss carryforwards of \$156.3 million for federal and state income tax purposes. The Company also had net operating loss carryforwards of \$0.6 million for foreign income tax purposes. These loss carryforwards begin to expire in 2021 for foreign income tax purposes and in 2027 for federal and state income tax purposes, and continue to expire through 2039. The Company's net operating loss carryforwards generated after 2017 for federal income tax purposes do not expire. The tax expense recorded for net operating losses, net of valuation allowance, was \$0.3 million which relates only to foreign net operating losses.

At December 31, 2018, the Company had net operating loss carryforwards of \$122.4 million for federal and state income tax purposes. The Company also had foreign net operating loss carryforwards of \$1.9 million. These tax loss carryforwards begin to expire in 2021 and 2027 for foreign and federal and state income tax, respectively, and will expire through 2037. The tax benefit recorded for net operating losses, net of valuation allowance, was \$0.1 million which relates only to foreign net operating losses.

The valuation allowance relates to deferred tax assets for certain items that will be deductible for income tax purposes under very limited circumstances and for which the Company believes it is not more likely than not that it will realize the associated tax benefit. However, in the event that the Company determines that it would be able to realize more or less than the recorded amount of net deferred tax assets, an adjustment to the deferred tax asset valuation allowance would be recorded in the period such a determination is made. In assessing the realizability of deferred tax assets, management considers whether it is more-likely-than-not that some portion of all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities (including the impact of available carryback and carryforward periods), projected future taxable income, and tax planning strategies in making this assessment. Based upon the levels of historical taxable income, projections of future taxable income and the reversal of deferred tax liabilities over the periods in which the deferred tax assets are deductible, management believes it is more-likely-than-not that the Company will realize the benefits of these deductible differences, net of the existing valuation allowance. The amount of deferred tax asset considered realizable, however, could change in the near term if estimates which require significant judgment of future taxable income during the carryforward period are increased or decreased.

SEASPIKE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

The Company is not subject to the one-time transition tax on accumulated foreign earnings or the GILTI provisions enacted by the Tax Act because the Company's foreign operations have been included in its U.S. tax filings pursuant to an election to disregard its foreign entity for federal income tax purposes.

A reconciliation of the Company's uncertain tax benefits is as follows:

	Year Ended December 31,	
	2019	2018
	(In thousands)	
Balance, beginning of year	\$ 255	\$ 277
Gross increases:		
Prior years' tax positions	15	1
Additions to tax positions in prior years due to spin-off	—	—
Current year tax positions	75	71
Gross decreases:		
Settlements	—	—
Statute of limitations lapses	(26)	(94)
Balance, end of year	<u>\$ 319</u>	<u>\$ 255</u>

The Company recognizes interest and penalties relating to uncertain tax positions in income tax expense. The amounts recorded in 2019 and 2018 were not significant.

The Company files income tax returns as prescribed by tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal, state, local and foreign jurisdictions where applicable based on the statute of limitations that apply in each jurisdiction. The Company has no open tax audits with any taxing authority as of December 31, 2019. The Company is still subject to income tax examinations by U.S. federal and state tax authorities for the years 2015 through 2019. Open years for foreign jurisdictions are from 2014 through 2019. However, to the extent allowed by law, the tax authorities may have the right to examine prior periods where net operating losses were generated and carried forward, and make adjustments up to the amount of the net operating loss carryforward amount.

9. COMMITMENTS AND CONTINGENCIES

In consideration for certain technology, manufacturing, distribution, and selling rights and licenses granted to the Company, the Company agreed to pay royalties on sales of certain products sold by the Company. Except for the royalties paid to NLT, the royalties the Company paid are included as a component of cost of goods sold in the consolidated statements of operations.

The Company is subject to various legal proceedings in the ordinary course of its business with respect to its products, its current or former employees, and its commercial relationships, some of which have been settled by the Company. In the opinion of management, such proceedings are either adequately covered by insurance or otherwise indemnified, or are not expected, individually or in the aggregate, to result in a material adverse effect on the Company's financial condition. However, it is possible that the Company's results of operations, financial position and cash flows in a particular period could be materially affected by these contingencies.

The Company accrues 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, and do not include an estimate for legal fees expected to be incurred in connection with the loss contingency. While uncertainty exists, the Company does not believe there are any pending legal proceedings that would have a material impact on the Company's financial position, cash flows or results of operations.

10. SEGMENT AND GEOGRAPHIC INFORMATION

Management assessed its segment reporting based on how it internally manages and reports the results of its business to its chief operating decision maker. Management reviews financial results, manages the business and allocates resources on an aggregate

SEASPINE HOLDINGS CORPORATION
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (continued)

basis. Therefore, financial results are reported in a single operating segment: the development, manufacture and marketing of orthobiologics and of spinal implants. The Company reports revenue in two product categories: orthobiologics and spinal implants. Orthobiologics products consist of a broad range of advanced and traditional bone graft substitutes that are designed to improve bone fusion rates following surgery. The spinal implants portfolio consists of an extensive line of products for minimally invasive surgery, complex spine, deformity and degenerative procedures. The Company attributes revenues to geographic areas based on the location of the customer.

The following table disaggregates revenue by major sales channel for each of the periods presented (in thousands):

	Year Ended December 31, 2019				
	United States		International		Total
	(In thousands)				
Orthobiologics	\$	73,543	\$	7,756	\$ 81,299
Spinal implants	\$	68,308	\$	9,476	\$ 77,784
Total revenue, net	\$	141,851	\$	17,232	\$ 159,083

	Year Ended December 31, 2018				
	United States		International		Total
	(In thousands)				
Orthobiologics	\$	67,363	\$	7,976	\$ 75,339
Spinal implants	\$	60,520	\$	7,584	\$ 68,104
Total revenue, net	\$	127,883	\$	15,560	\$ 143,443

11. EMPLOYEE BENEFIT PLAN

The Company has a defined contribution savings plan under section 401(k) of the IRC. The plan covers substantially all employees. The Company matches employee contributions made to the plan according to a specified formula. The Company's matching contributions totaled approximately \$0.6 million and \$0.7 million for the years ended 2019 and 2018, respectively.

12. SELECTED QUARTERLY INFORMATION - UNAUDITED

	First Quarter		Second Quarter		Third Quarter		Fourth Quarter	
	(In thousands, except per share data)							
Total revenue, net:								
2019	\$	36,150	\$	39,306	\$	39,888	\$	43,739
2018		33,175		36,409		35,834		38,025
Gross profit:								
2019	\$	22,571	\$	24,989	\$	25,481	\$	28,063
2018		20,996		21,849		21,587		23,042
Net loss:								
2019	\$	(8,989)	\$	(12,036)	\$	(9,663)	\$	(8,588)
2018		(7,105)		(7,361)		(9,532)		(9,526)
Basic/diluted net loss per common share⁽¹⁾:								
2019	\$	(0.48)	\$	(0.64)	\$	(0.51)	\$	(0.45)
2018		(0.50)		(0.50)		(0.65)		(0.53)

(1) Per common share amounts for the quarters and full years have been calculated separately. Accordingly, quarterly amounts do not necessarily add to the annual amount because of differences in the weighted average common shares outstanding during each period principally due to the effect of the Company's issuing or canceled shares of its common stock during the year.

13. SUBSEQUENT EVENT

In January 2020, the Company entered into an Underwriting Agreement with Piper Sandler & Co. and Canaccord Genuity LLC relating to the issuance and sale of 6,800,000 shares of the Company's common stock at a price to the public of \$12.50 per share, before underwriting discounts and commissions. Under the terms of that agreement, the Company granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 1,020,000 shares of common stock. The underwriters exercised this option and the offering closed on January 10, 2020 with the sale of 7,820,000 shares of common stock, resulting in net proceeds to the Company of approximately \$91.5 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 that was declared effective on May 22, 2019.

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

Description	Balance at Beginning of Period	Charged to Costs and Expenses	Charged to Other Accounts	Additions/Deductions	Balance at End of Period
(In thousands)					
Year ended December 31, 2019:					
Allowance for doubtful accounts and other credits	\$ 850	\$ 20	\$ (417)	\$ (342)	\$ 111
Inventory Reserves	29,309	4,747	—	(1,819)	32,237
Deferred tax asset valuation allowance	55,954	9,622	—	—	65,576
Year ended December 31, 2018:					
Allowance for doubtful accounts and sales returns and other credits	\$ 466	\$ 21	\$ —	\$ 363	\$ 850
Inventory Reserves	\$ 27,071	\$ 4,686	\$ —	\$ (2,448)	\$ 29,309
Deferred tax asset valuation allowance	47,433	8,521	—	—	55,954

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934**

As of February 21, 2020, SeaSpine Holdings Corporation (the "Company," "we," "our" and "us") had one classes of securities registered under Section 12 of the Securities Exchange Act of 1934 (the "Exchange Act"): common stock, \$0.01 par value per share ("common stock").

General

The following is a brief description of the rights of our common stock. The description is qualified in its entirety by reference to, and should be read in conjunction with, our Amended and Restated Certificate of Incorporation ("Certificate"), our Amended and Restated Bylaws ("Bylaws"), and the applicable provisions of the Delaware General Corporation Law (the "DGCL"). Our Certificate and Bylaws are filed as exhibits to the Annual Report on Form 10-K of which this exhibit is a part. The Annual Report is filed with the U.S. Securities and Exchange Commission and is publicly available. We encourage you to read our Certificate, our Bylaws and the applicable provisions of the DGCL for additional information.

Authorized Capital

We are authorized to issue up to 60,000,000 shares of common stock and up to 15,000,000 shares of preferred stock, \$0.01 par value per share (the "preferred stock"). As of February 21, 2020, no shares of Preferred Stock are outstanding.

The issued and outstanding shares of common stock are duly authorized, validly issued, fully paid and nonassessable.

Rights of Holders of our Common Stock

Dividend Rights. Subject to preferences that may apply to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Voting Rights. Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors.

Liquidation Rights. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

No Preemptive Rights. Holders of our common stock have no preemptive, conversion, subscription or other rights, and there are no redemption or sinking fund provisions applicable to our common stock.

Rights of Preferred Stock May be Senior to Rights of Common Stock. Our board of directors has the authority, without further action by our stockholders, to issue up to 15,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, and liquidation preferences, any or all of which may be greater than the rights of the holders of our common stock.

Anti-Takeover Effect Provisions

Certain provisions in our Certificate and in our Bylaws may have an anti-takeover effect, including:

Classified Board. We have 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. Our stockholders cannot cumulate their votes in the election of directors, which limits the ability of minority stockholders to elect director candidates.

Filling of Vacancies. Our board of directors have the exclusive right 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.

Removing Directors. A director may be removed only for cause and only by the affirmative vote of at least 66 2/3% of the voting power of all the then-outstanding shares of voting stock entitled to vote at an election of directors in accordance with the DGCL, our Certificate and our Bylaws.

Prohibition on Written Consent. Our stockholders are prohibited from acting by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders.

Calling Special Meetings. Special meetings of our stockholders may 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. Stockholders must comply with the advance notice procedures in our Bylaws to nominate candidates to our board of directors and to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from soliciting proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us;

Supermajority Provisions. 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, is required to amend or repeal the provisions of our Certificate and of our Bylaws that relate to the matters described above, which may inhibit the ability of an acquirer from amending our Certificate or our Bylaws to facilitate a hostile acquisition.

Bylaw Amendments. Our board of directors, by majority vote, may amend our 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.

Preferred Stock. Our board of directors can 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 significantly dilute the ownership of a hostile acquirer.

Additional Authorized Shares of Capital Stock. The shares of authorized common stock and preferred stock available for issuance under our Certificate could be issued at such times, under such circumstances, and with such terms as to impede a change in control.

In addition, we are subject to Section 203 of the DGCL, which, subject to certain exceptions, prohibits a Delaware corporation from engaging in any "business combination" with any "interested stockholder" for three years following the date that such stockholder became an interested stockholder, unless: (i) before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder; (ii) on consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned (a) by persons who are directors and also officers and (b) by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock not owned by the interested stockholder.

The term "business combination" generally includes mergers or consolidations resulting in a financial benefit to the interested stockholder. The term "interested stockholder" generally means any person, other than the corporation and any direct or indirect majority-owned subsidiary of the corporation, who, together

with affiliates and associates, owns (or owned within three years prior to the determination of interested stockholder status) 15% or more of the outstanding voting stock of the corporation.

Exclusive Forum

Our Certificate 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 Certificate also 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.

Dissenters' Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, our stockholders have appraisal rights in connection with a merger or consolidation of the Company. Under the DGCL, stockholders who properly request and perfect appraisal rights in connection with such merger or consolidation will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery.

Listing

The Common Stock is listed on the NASDAQ Global Market under the symbol "SPNE."

Transfer Agent and Registrar

The transfer agent and registrar for the Common Stock is American Stock Transfer & Trust Company, LLC.

SEASPINE HOLDINGS CORPORATION

2015 INCENTIVE AWARD PLAN

RESTRICTED STOCK AWARD GRANT NOTICE AND RESTRICTED STOCK AWARD AGREEMENT

SeaSpine Holdings Corporation, a Delaware corporation (the “*Company*”), pursuant to its 2015 Incentive Award Plan (as may be amended and/or restated from time to time, the “*Plan*”), hereby grants to the individual listed below (the “*Participant*”), an award of restricted stock units (“*Restricted Stock Units*” or “*RSUs*”) with respect to the number of shares of Common Stock, par value \$0.01 per share, of the Company (the “*Shares*”), set forth below. This Restricted Stock Unit award (the “*Award*”) is subject to all of the terms and conditions set forth herein and in the Restricted Stock Unit Award Agreement attached hereto as Exhibit A (the “*Agreement*”) and the Plan, each of which is incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Restricted Stock Unit Award Grant Notice (this “*Grant Notice*”) and the Agreement.

Participant:

Grant Date:

Number of Restricted Stock Units:

Distribution Schedule: Subject to the terms of the Agreement, the RSUs shall be distributable in accordance with Section 2.1 of the Agreement.

Vesting Schedule: Subject to the terms of the Agreement, the RSUs shall vest [_____], provided that Participant does not experience a Termination of Service prior to each such vesting date. For clarity, in addition to the foregoing, if a Change in Control occurs, the RSUs shall be subject to accelerated vesting as provided in Section 12.2(d)(ii) and (iii) of the Plan.

By his or her signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Agreement and this Grant Notice. Participant has reviewed the Agreement, the Plan and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of this Grant Notice, the Agreement and the Plan. Participant hereby agrees to accept as binding, conclusive and final all decisions and/or interpretations of the Administrator upon any questions arising under the Plan or relating to the Award.

SEASPINE HOLDINGS CORPORATION

PARTICIPANT

By: _____
 Print Name: _____
 Title: _____
 Address: 5770 Armada Dr.
 Carlsbad, CA 92008

By: _____
 Print Name: _____
 Address: _____
 Email: _____

EXHIBIT A

TO RESTRICTED STOCK UNIT AWARD GRANT NOTICE

RESTRICTED STOCK UNIT AWARD AGREEMENT

Pursuant to the Restricted Stock Unit Award Grant Notice (the “**Grant Notice**”) to which this Restricted Stock Unit Agreement (this “**Agreement**”) is attached, SeaSpine Holdings Corporation, a Delaware corporation (the “**Company**”), has granted to Participant the number of Restricted Stock Units under the Company’s 2015 Incentive Award Plan (as amended from time to time, the “**Plan**”) indicated in the Grant Notice.

ARTICLE I.

GENERAL

1.1 Incorporation of Terms of Plan. The Award is subject to the terms and conditions of the Plan, which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

1.2 Defined Terms. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and the Grant Notice.

ARTICLE II.

AWARD OF RESTRICTED STOCK UNITS

2.1 Award of Restricted Stock Units.

(a) Award. In consideration of Participant’s continued employment or service with the Company or any Affiliate thereof and for other good and valuable consideration, which the Company has determined exceeds the par value of the Shares to be issued upon settlement of the RSUs, the Company hereby grants to Participant the number of RSUs set forth in the Grant Notice, subject to all of the terms and conditions set forth in this Agreement, the Grant Notice and the Plan. Prior to actual issuance of any Shares, the RSUs and the Award represent an unsecured obligation of the Company, payable only from the general assets of the Company.

(b) Vesting. The RSUs subject to the Award shall vest in accordance with the Vesting Schedule set forth in the Grant Notice. Unless and until the RSUs have vested in accordance with the Vesting Schedule set forth in the Grant Notice, Participant will have no right to any distribution with respect to such RSUs. Unless otherwise provided in the Grant Notice, in the event of Participant’s Termination of Service prior to the vesting of all of the RSUs, any unvested RSUs will terminate automatically without any further action by the Company and be forfeited without further notice and at no cost to the Company.

(c) Distribution of RSUs.

(i) Shares shall be distributed to Participant (or in the event of Participant’s death, to his or her estate) with respect to Participant’s vested RSUs within sixty (60) days following the

date on which such RSUs vest as specified in the Vesting Schedule set forth in the Grant Notice, subject to the terms and provisions of the Plan and this Agreement.

(ii) All distributions of the RSUs shall be made by the Company in the form of whole shares of Common Stock.

(iii) Neither the time nor form of distribution of Shares with respect to the RSUs may be changed, except as may be permitted by the Administrator in accordance with the Plan and Section 409A of the Code and the Treasury Regulations thereunder.

(d) Generally. Shares issued under the Award shall be issued to Participant or Participant's beneficiaries, as the case may be, at the sole discretion of the Administrator, in either (i) uncertificated form, with the Shares recorded in the name of Participant in the books and records of the Company's transfer agent with appropriate notations regarding the restrictions on transfer imposed pursuant to this Agreement; or (ii) certificate form. In no event will fractional shares be issued upon settlement of the Award. In lieu of any fractional Share, the Company shall make a cash payment to Participant equal to the Fair Market Value of such fractional Share on the date the RSUs are settled pursuant to this Section 2.1.

2.2 Tax Withholding. Notwithstanding any other provision of this Agreement (including, without limitation, Section 2.1(b) hereof):

(a) The Company shall not be obligated to deliver any certificate representing Shares issuable with respect to the RSUs to Participant or his or her legal representative unless and until Participant or his or her legal representative shall have paid or otherwise satisfied in full the amount of all federal, state, local and foreign taxes (including Participant's social security, Medicare and any other employment tax obligation) required by Applicable Law to be withheld with respect to the taxable income of Participant resulting from the grant or vesting of the RSUs, the distribution of the Shares issuable with respect thereto, or any other taxable event related to the RSUs (the "**Tax Withholding Obligation**").

(b) To the maximum extent permitted by applicable law, the Company and its Affiliates have the authority and the right to deduct or withhold, or require Participant to remit to the Company or an Affiliate, an amount sufficient to satisfy the Tax Withholding Obligation with respect to any taxable event arising from the vesting of the RSUs or the receipt of the Shares upon settlement of the RSUs. Participant may satisfy the Tax Withholding Obligation by delivering to the Company an amount sufficient to satisfy the Tax Withholding Obligation in one or more of the forms specified below:

(i) Cash or check;

(ii) Delivery of a written or electronic notice that Participant has placed a market sell order with a broker with respect to Shares then issuable upon settlement of the RSUs, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the aggregate Tax Withholding Obligation; *provided*, that payment of such proceeds is then made to the Company upon settlement of such sale;

(iii) With the consent of the Administrator, surrender of other Shares which have been held by Participant for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences and having a Fair Market Value on the date of surrender equal to the Tax Withholding Obligation (based on the minimum statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes as of the date of delivery (or such higher rate as may be determined

by the Administrator, which higher rate may not exceed the maximum individual statutory tax rate in the applicable jurisdiction at the time of such withholding (or such other rate as may be required to avoid the liability classification of the applicable award under generally accepted accounting principles in the United States of America), provided, that, such Shares shall be rounded up to the nearest whole Share to the extent rounding up to the nearest whole share does not result in the liability classification of the applicable Award under generally accepted accounting principles in the United States of America));

(iv) With the consent of the Administrator, surrender of Shares issuable upon settlement of the RSUs having a Fair Market Value on the date of settlement equal to the Tax Withholding Obligation (based on the minimum statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes as of the date of delivery (or such higher rate as may be determined by the Administrator, which higher rate may not exceed the maximum individual statutory tax rate in the applicable jurisdiction at the time of such withholding (or such other rate as may be required to avoid the liability classification of the applicable award under generally accepted accounting principles in the United States of America), provided, that, such Shares shall be rounded up to the nearest whole Share to the extent rounding up to the nearest whole share does not result in the liability classification of the applicable Award under generally accepted accounting principles in the United States of America)); or

(v) With the consent of the Administrator, such other form of legal consideration as may be acceptable to the Administrator.

(c) In the event Participant fails to elect to provide timely payment of all sums required pursuant to Section 2.2(a) prior to the time the Tax Withholding Obligation arises pursuant to one of the permitted payment forms specified in Section 2.2(b), the Company shall have the right and option, but not the obligation, to treat such failure as an election by Participant to satisfy all or any portion of Participant's Tax Withholding Obligation pursuant to Section 2.2(b)(iv) above. If the Participant is subject to Section 16 of the Exchange Act at the time the Tax Withholding Obligation arises, the prior approval of the Administrator shall be required for any election by the Company pursuant to Section 2.2(b)(iv) above pursuant to this Section 2.2(c).

(d) In the event of any broker-assisted sale of Shares in connection with the payment of withholding taxes as provided in Section 2(b)(ii) or Section 2(c): (i) any Shares to be sold through a broker-assisted sale will be sold on the day the Tax Withholding Obligation arises, or as soon thereafter as practicable; (ii) such Shares may be sold as part of a block trade with other participants in the Plan in which all participants receive an average price; (iii) Participant will be responsible for all broker's fees and other costs of sale, and Participant agrees to indemnify and hold the Company and its Affiliates harmless from any losses, costs, damages, or expenses relating to any such sale; (iv) to the extent the proceeds of such sale exceed the Tax Withholding Obligation, the Company agrees to pay such excess in cash to Participant as soon as reasonably practicable; (v) Participant acknowledges that the Company or its designee and any broker is under no obligation to arrange for such sale at any particular price, and that the proceeds of any such sale may not be sufficient to satisfy the Tax Withholding Obligation; and (vi) in the event the proceeds of such sale are insufficient to satisfy the Tax Withholding Obligation, Participant agrees to pay immediately upon demand to the Company or its Affiliates with respect to which the Tax Withholding Obligation arises, an amount sufficient to satisfy any remaining portion of the Company's or the applicable Affiliate's Tax Withholding Obligation.

(e) In the event any Tax Withholding Obligation arising in connection with the RSUs will be satisfied under Section 2.2(b)(iv) or Section 2(c) above, then, unless the Participant is subject to Section 16 of the Exchange Act at the time the Tax Withholding Obligation arises (in which case the approval

of the Administrator shall be required for any election by the Company pursuant to this Section 2.2(e)), the Company may elect to instruct any brokerage firm determined acceptable to the Company for such purpose to sell on the Participant's behalf a whole number of shares from those Shares that are issuable upon settlement of the RSUs as the Company determines to be appropriate to generate cash proceeds sufficient to satisfy the Tax Withholding Obligation (based on the minimum statutory withholding rates for federal, state, local and foreign income tax and payroll tax purposes as of the date of delivery (or such higher rate as may be determined by the Administrator, which higher rate may not exceed the maximum individual statutory tax rate in the applicable jurisdiction at the time of such withholding (or such other rate as may be required to avoid the liability classification of the applicable award under generally accepted accounting principles in the United States of America), provided, that, such Shares shall be rounded up to the nearest whole Share to the extent rounding up to the nearest whole share does not result in the liability classification of the applicable Award under generally accepted accounting principles in the United States of America)) and to remit the proceeds of such sale to the Company or the Affiliate with respect to which the Tax Withholding Obligation arises. The Participant's acceptance of the RSUs constitutes the Participant's instruction and authorization to the Company and such brokerage firm to complete the transactions described in this Section 2.2(e), including the transactions described in the previous sentence, as applicable. Participant hereby appoints the Company as Participant's agent and attorney-in-fact to instruct such brokerage firm with respect to the number of Shares to be sold under this Section 2.2(e).

ARTICLE III.

RESTRICTIONS

3.1 Award Not Transferable. Without limiting the generality of any other provision hereof, the Award shall be subject to the restrictions on transferability set forth in Section 10.3 of the Plan.

3.2 Rights as Stockholder. Neither Participant nor any person claiming under or through Participant shall have any of the rights or privileges of a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of any Shares issuable hereunder unless and until such Shares shall have been issued by the Company to such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment shall be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Section 12.2 of the Plan.

3.3 Forfeiture and Claw-Back Provisions. Participant hereby acknowledges and agrees that the Award is subject to the provisions of Section 10.5 of the Plan.

ARTICLE IV.

OTHER PROVISIONS

4.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement as provided in the Plan. All interpretations and determinations made by the Administrator in good faith shall be final and binding upon Participant, the Company and all other interested persons.

4.2 Adjustments. Participant acknowledges that the Award is subject to modification and termination in certain events as provided in this Agreement and Article 12 of the Plan.

4.3 Tax Consultation. **Participant understands that the Participant may suffer adverse tax consequences as a result of the grant, vesting and/or settlement of the Award, and/or with the disposition of the Shares issuable pursuant to the Award. Participant represents that Participant has consulted with any tax consultants Participant deems advisable in connection with the purchase or disposition of such shares and that Participant is not relying on the Company for any tax advice.**

4.4 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however*, that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Award in any material way without the prior written consent of Participant.

4.5 Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall confer upon Participant any right to continue to serve as an Employee, Director, Consultant or other service provider of the Company or any of its Affiliates or shall interfere with or restrict in any way the rights of the Company and its Affiliates, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or an Affiliate and Participant.

4.6 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, then the Plan, the Award and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

4.7 Conformity to Securities Laws. Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act, and any and all regulations and rules promulgated by the Securities and Exchange Commission thereunder, as well as all applicable state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Award is granted only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by applicable law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.

4.8 Limitation on Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. The Plan, in and of itself, has no assets. Participant shall have only the rights of a general unsecured creditor of the Company and its Affiliates with respect to amounts credited and benefits payable, if any, with respect to Award, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to the Award, as and when payable hereunder.

4.9 Successors and Assigns. The Company or any Affiliate may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company and its Affiliates. Subject to the restrictions on transfer set forth in this Agreement,

this Agreement shall be binding upon Participant and his or her heirs, executors, administrators, successors and assigns.

4.10 Entire Agreement. The Plan, the Grant Notice and this Agreement (including all Exhibits thereto, if any) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and its Affiliates and Participant with respect to the subject matter hereof.

4.11 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to Participant shall be addressed to Participant at Participant's last address reflected on the Company's records. Any notice shall be deemed duly given when sent via email or when sent by reputable overnight courier or by certified mail (return receipt requested) through the United States Postal Service.

4.12 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

4.13 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

4.14 Counterparts. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which shall be deemed an original and all of which together shall constitute one instrument.

4.15 Paperless Administration. By accepting this Award, Participant hereby agrees to receive documentation related to the Award by electronic delivery, such as a system using an internet website or interactive voice response, maintained by the Company or a third party designated by the Company.

4.16 Section 409A.

(a) Notwithstanding any other provision of the Plan, this Agreement or the Grant Notice, the Plan, this Agreement and the Grant Notice shall be interpreted in accordance with, and incorporate the terms and conditions required by, Section 409A of the Code (together with any Treasury Regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the Grant Date, "**Section 409A**"). The Administrator may, in its discretion, adopt such amendments to the Plan, this Agreement or the Grant Notice or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate to comply with the requirements of Section 409A.

(b) This Agreement is not intended to provide for any deferral of compensation subject to Section 409A of the Code, and, accordingly, the Shares issuable pursuant to the RSUs shall be distributed to Participant no later than the later of: (i) the fifteenth (15th) day of the third month following Participant's first taxable year in which such RSUs are no longer subject to a substantial risk of forfeiture, and (ii) the fifteenth (15th) day of the third month following first taxable year of the Company in which such RSUs are no longer subject to substantial risk of forfeiture, as determined in accordance with Section 409A and any Treasury Regulations and other guidance issued thereunder.

(c) For purposes of Section 409A of the Code (including, without limitation, for purposes of Treasury Regulation Section 1.409A-2(b)(2)(iii)), each payment that Participant may be eligible to receive under this Agreement shall be treated as a separate and distinct payment.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement (Nos. 333-230047, 333-216450, and 333-213089) on Form S-3 and the Registration Statement (Nos. 333-205334, 333-211887, 333-216448, 333-223435, 333-225291, 333-226046, and 333-228217) on Form S-8 of SeaSpine Holdings Corporation of our report dated February 28, 2019, relating to the consolidated financial statements and the financial statement schedule of SeaSpine Holdings Corporation, appearing in this Annual Report on Form 10-K of SeaSpine Holdings Corporation for the year ended December 31, 2019.

/s/ RSM US LLP

Los Angeles, California

February 28, 2020

Certification of Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Keith C. Valentine, certify that:

1. I have reviewed this annual report on Form 10-K of SeaSpine Holdings Corporation;

Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

2.

Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

3.

The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

4.

Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(a)

Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(b)

Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(c)

Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

(d)

The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

5.

All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(a)

Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

(b)

Date: February 28, 2020

/s/ Keith C. Valentine

Keith C. Valentine

Chief Executive Officer

Certification of Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, John J. Bostjancic, certify that:

1. I have reviewed this annual report on Form 10-K of SeaSpine Holdings Corporation;

Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

2. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

3. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

- (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

- (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

- (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

- (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

- (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2020

/s/ John J. Bostjancic

 John J. Bostjancic

Chief Financial Officer

Certification of Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Keith C. Valentine, President and Chief Executive Officer of SeaSpine Holdings Corporation (the "Company"), hereby certify that, to my knowledge:

1. The Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the "Report") fully complies with the requirement of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2020

/s/ Keith C. Valentine

Keith C. Valentine

Chief Executive Officer

Certification of Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, John J. Bostjancic, Senior Vice President and Chief Financial Officer of SeaSpine Holdings Corporation (the “Company”), hereby certify that, to my knowledge:

1. The Annual Report on Form 10-K of the Company for the year ended December 31, 2019 (the “Report”) fully complies with the requirement of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2020

/s/ John J. Bostjancic

John J. Bostjancic

Chief Financial Officer