

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

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

or

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

For the transition period from _____ to _____

Commission file number: 000-52024

ALPHATEC HOLDINGS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

5818 El Camino Real, Carlsbad,
California
(Address of Principal Executive Offices)

20-2463898
(I.R.S. Employer
Identification No.)

92008
(Zip Code)

(760) 431-9286

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Exchange Act:

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

Securities registered pursuant to Section 12(g) of the Exchange 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 Exchange Act. Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See 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="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input 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 a check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of the last business day of the registrant's most recently completed second fiscal quarter (June 29, 2018), was approximately \$70.2 million.

The number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, as of March 25, 2019 was 46,847,652.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required in Part III of this Annual Report on Form 10-K is incorporated from the Registrant's Proxy Statement for the 2019 Annual Meeting of Stockholder.

ALPHATEC HOLDINGS, INC.
FORM 10-K—ANNUAL REPORT
For the Fiscal Year Ended December 31, 2018

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In this Annual Report on Form 10-K, the terms “we,” “us,” “our,” “Alphatec Holdings” and “Alphatec” mean Alphatec Holdings, Inc. and our subsidiaries and their subsidiaries. “Alphatec Spine” refers to our wholly-owned operating subsidiary Alphatec Spine, Inc. “Scient’x” refers to our operating affiliate, Scient’x S.A.S., which is wholly-owned by several of our subsidiaries, and Scient’x’s subsidiaries. “SafeOp” refers to our wholly-owned operating subsidiary SafeOp Surgical, Inc.

PART I

Item 1. Business

We are a medical technology company focused on the design, development, and advancement of technology for better surgical treatment of spinal disorders. We are dedicated to revolutionizing the approach to spine surgery. We have a broad product portfolio designed to address the majority of U.S. market for fusion-based spinal disorder solutions. We intend to drive growth by exploiting our collective spine experience and investing in the research and development to continually differentiate our solutions and improve spine surgery. We believe our future success will be fueled by introducing market-shifting innovation to the spine market, and we believe that we are well-positioned to capitalize on current spine market dynamics.

We market and sell our products in the U.S. through a network of independent distributors and direct sales representatives. An objective of our leadership team is to deliver increasingly consistent, predictable growth. To accomplish this, we have partnered more closely with new and existing distributors to create a more dedicated and loyal sales channel for the future. We have added, and intend to continue to add, new high-quality dedicated distributors to expand future growth. We believe this will allow us to reach an untapped market of surgeons, hospitals, and national accounts across the U.S., as well as better penetrate existing accounts and territories.

We have made significant progress in the transition of our sales channel since early 2017. Going forward, we intend to continue to relentlessly drive toward a fully exclusive network of independent and direct sales agents. Recent consolidation in the industry is facilitating the process, as large, seasoned agents are seeking opportunities to re-enter the spine market by partnering with spine-focused companies that have broad, growing product portfolios.

Recent Developments

In March 2019, we entered into an amendment to our credit facility with Squadron Medical Finance Solutions, LLC (“Squadron”), pursuant to which Squadron extended an additional \$30 million in draws available to us through November 2023. Additional borrowings will be subject to the same terms as the original credit agreement. At such time as we make our first draw under the Expanded Credit Facility, we will issue to Squadron warrants to purchase 4.8 million shares of our common stock at an exercise price of \$2.17 per share. The warrants will have a seven-year term and will be immediately exercisable upon issuance.

Strategy

By leveraging our team’s extensive spine experience to create clinically distinct solutions that improve surgical outcomes, we believe that we will be positioned to take a greater share of the U.S. spine market, becoming the partner of choice for spine surgeons, hospitals, healthcare systems, and payers. We are committed to attracting, engaging, and retaining the best talents in the industry. We are also driving an organizational transformation by prioritizing the following vital initiatives:

Create Clinical Distinction

We are committed to the development, launch, and promotion of technologies intended to simplify surgical procedures, provide enhanced information for surgeons, and improve patient outcomes. We offer a broad portfolio of products that address the core spine pathologies. Currently, over 90% of our revenue is generated by products developed and launched before 2017, but we are making investments to significantly advance the clinical distinction of our portfolio and accelerate revenue growth.

We believe that surgeons yearn for intra-operative information that can drive objective decision-making and improve patient outcomes. Our answer to that need is the Alpha Informatix™ platform, which delivers relevant, real-time information via a small footprint. In February 2019, we received 510(k) clearance for our automated SafeOp neuromonitoring system for use in real-time intraoperative nerve location and health assessment. The SafeOp neuromonitoring system is the first solution delivered as part of our Alpha Informatix platform, which we plan to expand to provide surgeons with intraoperative information beyond neuromonitoring.

We are developing next-generation access systems, implants, and biologics that are expected to seamlessly integrate into the Alpha Informatix platform to enable elegant, minimally disruptive spine access that achieves clinical success regardless of the surgical approach. We expect our revenue mix to shift increasingly toward newly developed solutions as we bring next generation products to market. That shift began late in 2018 as we executed on several new product alpha evaluations that will uniquely address a broad range of surgical procedures. During the third quarter of 2018, we introduced our IdentiTi collection of porous titanium interbody implants. Our IdentiTi product family offers implant options that take advantage of bone’s affinity for titanium. Because of their porosity, IdentiTi implants have a surface roughness that enhances stability. The implants are also designed for the biological, biomechanical, and imaging characteristics that surgeons seek in a fusion construct. In September 2018, we received 510(k) clearance

for our OsseoScrew System, a next-generation expandable posterior fixation implant designed to restore the integrity of the spinal column in patients with advanced stage thoracolumbar tumors. In the third quarter of 2018, we introduced the alpha release of our next generation, comprehensive thoracolumbar fixation system. With a substantially expanded offering that will distinguish itself in minimally disruptive and open techniques, the feature set of this new fixation system seamlessly integrates into any ATEC Spine procedure, and will serve as an anchor as we increasingly shift toward proceduralization.

We plan to commercially launch 12 new products in 2019. Looking beyond 2019, we intend to be a leader in the industry in innovation by releasing eight to ten new products each year. We expect our growth potential to compound as our new solutions drive surgeon adoption of ATEC procedures, and increase the number of ATEC products sold into each of those procedures.

Compel Surgeon Adoption

We are re-introducing the surgical community to Alphatec, and laying the groundwork to drive surgeon adoption of not only our existing portfolio, but also the innovation that we have introduced in 2018 and intend to introduce over the next several years. A key component of our drive to renew surgeon interest is our “ATEC Experience” events, our educational program for visiting surgeons. For the year ended December 31, 2018, we have hosted nearly three times the number of surgeons at ATEC Experience events compared to the year ended December 31, 2017.

Importantly, the surgeon relationships that we are creating are both strong, and accelerating. Throughout 2018, revenue attributable to new surgeon customers has substantially outpaced overall revenue growth. Also, the initiation of new surgeon relationships has accelerated in each quarter during 2018.

We are especially encouraged by the progress being made with surgeon adoption considering that the vast majority of our revenue is currently being driven by legacy Alphatec products. We believe that the surgeons that are partnering with us today recognize our team’s ability to architect meaningful innovation. With the investments that we have made into research and development and spine talent, we intend to continue to deliver innovative technologies into the operating room over the coming years.

Revitalize the Sales Channel

Currently, we market and sell our products in the U.S. through a network of independent distributors and direct sales representatives. We seek to deliver consistent, predictable growth through a durable brand commitment. To accomplish this, we believe there is significant opportunity for us to partner closely with our distributors to create a more dedicated and focused network. We believe that recent consolidation in the industry is increasingly affording us an opportunity to attract large, experienced distributors and agents seeking partnerships with companies like ours; partners that can offer a robust product portfolio and a pipeline of technologies focused solely on spine solutions.

During 2018, we continued adding higher-volume, more sophisticated distributors to our sales channel, while simultaneously terminating non-strategic distribution relationships that do not serve our long-term vision. This has enabled us, and we believe will continue to enable us, to reach new surgeons, hospitals, and national accounts across the U.S., and more effectively penetrate existing accounts and territories. Since 2016, we have decreased our total number of distributors from more than 200 to less than 80, driving the percent of sales contributed by our strategic distribution channel to approximately 80% for the year ended December 31, 2018.

We also employ a national accounts team that is responsible for securing access at hospitals and group purchasing organizations, or GPOs, across the U.S. We have been very successful securing access to hospitals and GPOs, and today the majority of our business is achieved through these accounts. We will continue to focus on developing and maintaining relationships with key GPOs and hospital networks to secure favorable contracts and develop strategies to convert or grow business within existing accounts.

We are also enhancing our sales training and education programs for independent distributors and direct sales representatives to optimize overall sales productivity.

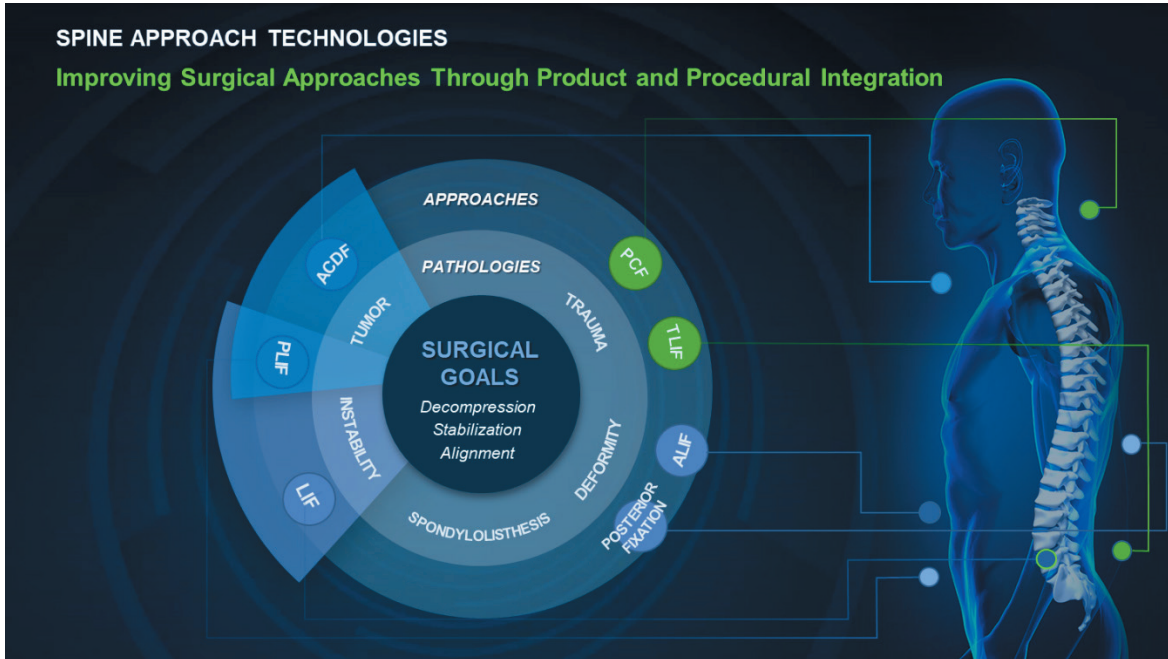
Spine Anatomy

The spine is the core of the human skeleton and provides important structural support and alignment while remaining flexible to allow movement. The spine is a column of 33 bones that protects the spinal cord and provides the main support for your body. Each bony segment of the spine is referred to as a vertebra (two or more are called vertebrae). The spine has five regions containing groups of similar bones, listed from top to bottom: seven cervical vertebrae in the neck, twelve thoracic vertebrae in the mid-back (each attached to a rib), five lumbar vertebrae in the lower back, five sacral vertebrae fused together to form one bone in the hip region, and four coccygeal bones fused together that form the tailbone. At the front of each vertebra is a block of bone called the vertebral body, Vertebrae are stacked on top of each other and enable people to sit and stand upright. Vertebrae in the cervical, thoracic and lumbar

regions are separated from each other and cushioned by a rubbery soft tissue called the intervertebral disc. Strong muscles and bones, flexible tendons and ligaments and sensitive nerves contribute to a healthy spine. Pain can be caused when any of these structures are affected by strain, injury or disease.

The Alphatec Solution

Our principal procedural offerings include a wide variety of Spine Approach Technologies™, designed to achieve clinical success in conditions from degenerative to complex deformity and trauma. Our Spine Approach Technologies are comprised of intra-operative information and neuromonitoring technologies, access systems, interbody implants, fixation systems, and various biologics offerings all designed to improve patient outcomes by achieving the three tenets of spine surgery: (1) decompression, (2) stabilization, and (3) alignment.



A summary of our core products is provided below.

Currently Marketed Products

Minimally Invasive Surgery, or MIS, Products

Battalion Lateral Spacer System and Squadron Lateral Retractor. The Battalion Lateral Spacer System with the Alphatec Squadron Lateral Retractor provides surgeons with a next-generation lateral system with innovative, unique design characteristics including, total blade control technology that allows the surgeon to maintain approach aperture throughout the procedure, in-situ blade height adjustment and blade replacement, combined with the Battalion Lateral Spacer is available in 0° and 15° lordosis with a variety of width and height options for lumbar and thoracic approaches. Our Battalion Lateral Spacer System and Squadron Lateral Retractor received clearance of an FDA 510(k) premarket notification from the U.S. Food and Drug Administration, or FDA, in 2016, and was commercially released in 2017.

Illico Minimally Invasive Surgery System. The Illico Minimally Invasive Surgery System is a cannulated pedicle screw system that is designed to be inserted via a minimally invasive surgical procedure. Access to the spine is gained through a small incision. The surgeon is then able to see the surgical site by using a small canal through which implants are inserted into the patient with a minimum amount of disruption to the surrounding tissue. The Illico Minimally Invasive Surgery System is designed to limit trauma to the tissue surrounding the location of the surgery and to enable patients to recover faster.

Thoracolumbar Fixation Products

Arsenal Degenerative System. Arsenal Degenerative Spinal Fixation System is a comprehensive system for both simple and complex degenerative spinal fusion procedures. The Arsenal Degenerative Spinal Fixation System is designed to provide operational

efficiency, biomechanical strength, and surgical simplicity while providing a complete solution to combat most complex degenerative pathologies. The system combines low-profile implants with intuitive instrumentation and proven strength.

Arsenal Deformity System. The Arsenal Deformity System expands the Arsenal platform to address complex deformity including adult and adolescent idiopathic scoliosis, or AIS, spinal deformity pathologies. The Arsenal Deformity System was thoughtfully designed to provide surgeons with a complete solution to address complex deformity procedures. The Arsenal Deformity System provides surgeons with unique uniplanar screws, which enable easier screw positioning and rod placement through a tulip that has 360 degrees of rotation while restricting motion in the medial/lateral plane for de-rotation correction. Additionally, the Arsenal Deformity System includes a wide variety of low-profile implants providing a better anatomical fit and increased ability to address patient pathologies, ergonomically designed instrumentation to improve surgical efficiency and comfort during complex surgeries and proven biomechanical strength.

Arsenal CBx Cortical Bone Fixation System. The Arsenal CBx Cortical Bone Fixation System is the first extension to the Arsenal platform. An alternative to traditional pedicle screw placement, the Arsenal CBx Cortical Bone Fixation System utilizes a midline approach and cortical bone trajectory to achieve maximum fixation through a less-invasive procedure. This Arsenal CBx Cortical Bone Fixation System leverages the strengths of the Arsenal product platform with the benefits of a minimally disruptive procedure to enhance patient outcomes. Due to the midline approach and inward-outward screw trajectory, soft tissue and muscle exposure requirements are greatly reduced compared to the approach for traditional screw trajectory. The Arsenal CBx Cortical Bone Fixation System is a compatible fixation option for both posterior lumbar interbody fusion, or PLIF, or transforaminal lumbar interbody fusion, or TLIF. Additionally, this system can be a unique muscle sparing approach to revision surgery.

Zodiac Degenerative Spinal Fixation System. The Zodiac Degenerative Spinal Fixation System is a comprehensive spinal system that can be used to address both degenerative spinal conditions, as well as deformity correction. The Zodiac Degenerative Spinal Fixation System offers polyaxial pedicle screws, accompanying implants and advanced instruments for the stabilization of the thoracolumbar spine, as well as deformity specific instrumentation and implants that are designed to enable the surgeon to address patient-specific spinal deformity correction procedures.

Cervical and Cervico-Thoracic Products

Trestle Luxe Anterior Cervical Plate System. The Trestle Luxe Anterior Cervical Plate System has a large window that enables the surgeon to have improved graft site and end plate visualization, which is designed to allow for better placement of the plate. The Trestle Luxe Anterior Cervical Plate System also has a low-profile design. Low-profile cervical plates are intended to reduce the irritation of the tissue adjacent to the plate following surgery. Other key features of the Trestle Luxe Anterior Cervical Plate System include a self-retaining screw-locking mechanism that is designed to ensure quick and easy locking of the plate and a flush profile after the screws are inserted.

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

Interbody Systems

Battalion Universal Spacer System. The Battalion Universal Spacer System offers comfort, control and innovative design for surgeons performing PLIF and TLIF procedures. The Battalion implants introduce a new alternative to interbody fusion by combining the elasticity and radiolucency of polyetheretherketone, or PEEK, with a titanium coating for potential osseointegration. The implants, which come in both a straight and curved footprint, feature a bulletted nose for easy insertion and distraction of the disc space. The Battalion Universal Spacer System also features an intuitive and innovative 180-degree locking inserter that assists with protection of neural elements during insertion of the implant. The Battalion Universal Spacer System also features state-of-the-art instrumentation for access, disc preparation, and implant insertion.

Novel PEEK and Titanium Spinal Spacers. Our family of Novel spinal spacers addresses the surgical need to accommodate varying patient anatomies, surgical approaches and composite material options. The system offers multiple unique implant designs, in numerous shapes and heights, and in both titanium and PEEK.

Alphatec Solus Locking ALIF Spinal Spacer. The Alphatec Solus locking ALIF spinal spacer, or Alphatec Solus, is a zero-profile PEEK and titanium device offering four points of fixation for improved stability. Alphatec Solus features a one-step insertion and deployment feature and is used in ALIF procedures.

Biologics

AlphaGraft Structural Allograft Spacers. Alphatec offers a broad portfolio of allograft spacers available in a wide range of shapes and sizes, each with corresponding instrumentation, which are intended for use in the cervical, thoracic, and lumbar regions of the spine. In addition, many of our allograft spacers are packaged in our vacuum-infusion packaging system, or VIP System. The VIP System is a packaging and fluid delivery system that allows for fast and efficient infusion of the surgeon's choice of hydration fluid. The VIP System provides rapid and uniform hydration, which may reduce the brittleness of the graft and shorten the length of the surgical procedure.

AlphaGraft ProFuse Demineralized Bone Scaffold. Our AlphaGraft ProFuse Demineralized Bone Scaffold consists of a sponge-like demineralized bone matrix that has been pre-cut into sizes to fit within a spinal spacer. The AlphaGraft ProFuse Demineralized Bone Scaffold provides a natural scaffold derived entirely from bone that can be placed into a void within a spinal spacer or on top of a spinal spacer. The sponge-like qualities of the scaffold allow a surgeon to compress the scaffold and place it into a small space. Following placement, the scaffold expands for maximum contact between the spinal spacer and the endplate of the vertebral body and is designed to promote fusion. The AlphaGraft ProFuse Demineralized Bone Scaffold is pre-packaged in our proprietary VIP System.

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

Alphagraft Demineralized Bone Matrix. Our Alphagraft Demineralized Bone Matrix consists of demineralized human tissue that is mixed with a bioabsorbable carrier and intended for use in surgery for bone grafting.

Neocore Osteoconductive Matrix. Our Neocore Osteoconductive Matrix is designed to provide an effective core environment for bone growth through a synthetic scaffold. When hydrated with patient bone marrow aspirate, or BMA, Neocore becomes a complete bone graft, which possesses all the necessary components of bone growth. Engineered to perform like natural bone, Neocore's composition and porosity provide the benefits of rapid revascularization throughout graft and supports replacement of three-dimensional matrix with healthy new bone growth. Offering excellent handling characteristics, these pre-formed strips are flexible to conform to adjacent structures, compressible, and moldable.

Products and Technologies in Limited Release or Under Development

Alpha Informatix Platform. Alpha Informatix is our platform for providing surgeons with intra-operative information that is objective, real-time, and actionable. Our first release from the Alpha Informatix Platform is our advanced neuromonitoring solution, which is designed to prevent the intraoperative risk of nerve injury with automated assessment of nerve health. We acquired this technology through our acquisition of SafeOp Surgical, Inc., or SafeOp. SafeOp has developed patented technology that automates Somatosensory Evoked Potentials, or SSEPs, designed to provide surgeons with unprecedented, objective feedback during surgery. We received FDA clearance for our SafeOp neuromonitoring system and released it for alpha evaluation in February 2019. We expect full commercial launch of the system in Spring 2019.

We are developing next-generation access systems, implants, and biologics that will seamlessly integrate into the Alpha Informatix Platform to enable elegant, minimally disruptive spine access that achieves clinical success regardless of the surgical approach.

IdentiTi Porous Titanium Interbody Implants. During 2018 we developed our procedure-specific IdentiTi Porous Ti Interbody System, a collection of porous titanium interbody implants for Anterior Cervical Discectomy and Fusion, or ACDF, TLIF, PLIF and Anterior Lumbar Interbody Fusion, or ALIF procedures, and lateral interbody fusion, or LIF.

Our IdentiTi Porous Ti Interbody Systems offer implant options that take advantage of bone's affinity for titanium. Because of their porosity, IdentiTi implants have a surface roughness that enhances stability. The implants are also designed to provide the biological, biomechanical, and imaging characteristics that surgeons seek in a fusion construct.

Key features include:

- Consistent, fully interconnected porosity throughout the implant, designed to mimic the structure and porosity of cancellous bone;
- Pore structure (resulting in surface roughness) and an architecture that enables both immediate and long-term stability;
- Reduced density (60% porous), allowing enhanced intraoperative and postoperative imaging;
- Stiffness similar to bone;
- Predictable performance associated with the subtractive manufacturing process, creating a porous titanium material with consistent and reproducible interconnected pore sizes; and
- Instrumentation that is intuitive, low profile, and exacting, to optimize the surgeon experience and facilitate outstanding patient outcomes.

We commercially launched IdentiTi-C for ACDF in March 2019, the first of six planned commercial launches. The remaining five IdentiTi implant systems are currently available in alpha evaluation with expected commercial launches beginning in the second quarter of 2019.

OsseoScrew System. In September 2018, we received 510(k) clearance from the FDA for OsseoScrew, a unique, next-generation expandable posterior fixation implant. OsseoScrew (for use with the Zodiac Spinal Fixation System and Illico MIS Posterior Fixation System) is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. OsseoScrew has been clinically proven to increase pullout and holding strength, improving fixation in the bone-implant interface by 29%, as compared to conventional pedicle screws. It performs comparably to cemented fenestrated screws without the risk associated with cement leakage. OsseoScrew has performed successfully in international markets. OsseoScrew is undergoing an alpha evaluation in the US market with a targeted commercial launch in 2019.

Thoracolumbar Spinal Fixation System. In September of 2018 we received 510(k) clearance for our next-generation Thoracolumbar Spinal Fixation System, our comprehensive spinal fixation solution, designed to treat a range of spinal pathologies, with intraoperative adaptability and surgical efficiency, through an OPEN, MIS or Hybrid approach. The Thoracolumbar Spinal Fixation System provides surgeons with a unique lock screw design that potentially reduces head splay and cross threading. Additionally, the Thoracolumbar Spinal Fixation System includes a wide variety of low-profile implants providing a better anatomical fit and increased ability to address patient pathologies, ergonomically designed instrumentation to improve surgical efficiency and comfort during complex surgeries, and proven biomechanical strength necessary to achieve a solid fusion. We initiated a limited alpha release in November 2018 and expect a targeted commercial launch in the second half of 2019.

Research and Development

Our research and development department seeks to continually improve our core product offering and introduce new products to increase our penetration in the U.S. spine market. We are focused on developing technology platforms and products that span the largest market segments addressing degenerative and deformity spine pathologies. We have transformed our development process by focusing our development programs and leveraging integrated teams to reduce the time frame from product concept to market commercialization. We also collaborate with our surgeon partners to design products to enhance the surgeon experience, simplify surgical techniques, and reduce overall costs, while improving patient outcomes. Most of our product development efforts are fully integrated in one facility, allowing us to bring products from concept to market rapidly responding to surgeon and patient needs. Our resources include a technology advancement cell for rapid prototyping, a cadaveric lab, and mechanical testing laboratory.

Sales and Marketing

We market and sell our products through a sales force consisting of dedicated and non-dedicated independent distributors and dedicated employee direct sales representatives. We employ a team of area vice-presidents, or AVP's, and regional business managers, or RBMs, who are responsible for overseeing the overall sales channel process in their territories. Although surgeons in the U.S. typically make the ultimate decision to use our products, we generally bill the hospital for the products that are used and pay commissions to the sales representative or the sales agent based on payment received from the hospital. We compensate our direct sales employees, AVP's and RBMs through salaries and incentive bonuses based on performance measures.

We are currently in the process of making significant changes to drive a more dedicated and loyal sales channel, including; (i) moving many of our existing distributor relationships to more dedicated partnerships; and (ii) attracting new, high-quality dedicated distributors. We believe these changes will provide us with opportunities for future growth as we secure more dedicated distribution partners that can further penetrate existing and new geographic markets.

We evaluate and select our distribution partners and sales employees based upon their expertise in selling spinal devices, reputation within the surgeon community, geographical coverage and established sales network.

We also employ a national accounts team that is responsible for securing access at hospitals and GPOs, across the U.S. We have had strong success with securing access to hospitals and GPOs. We believe this access is a key differentiator for us and much of our current business is achieved through these accounts. We will continue to focus our efforts and investment on developing and maintaining relationships with key GPOs and hospital networks to secure favorable contracts and develop strategies to convert or grow business within existing accounts.

We market our products at various industry conferences, organized surgical training courses, and in industry trade journals and periodicals.

Surgeon Training and Education

We focus our surgeon training efforts on delivering critical technical skills needed on the entire spinal fusion procedure through a peer-to-peer approach to qualified surgeon customers. Well-timed surgeon education programs drive customer conversion and loyalty through leadership and excellence by focusing on delivering value through improved surgeon outcomes. We devote significant resources to training and education and are committed to a culture of scientific excellence and ethics.

We believe that one of the most effective ways to introduce and build market demand for our products is by training and educating spine surgeons, independent distributors, and direct sales representatives in the benefits and use of our products. Sales training programs will be a platform for learning and organizational development, ensuring the sales force is clinically competitive and considered an essential resource to all stakeholders. We focus on cross functional collaboration and alignment to deliver timely and relevant programs to meet surgeon and representative needs and positively impact the business.

Our training and education programs are designed to support new product introductions to the market as well as ongoing portfolio advancement. Our resources are nimble and responsive and include field based engagements to supplement our core curriculum. We believe this is an effective way to increase overall surgeon adoption of our new products.

We believe that surgeons, independent distributors, and direct sales representatives will become exposed to the merits and distinguishing features of our products through our training and education programs, and that such exposure will increase the use and promotion of our products. With a focus on the entire procedure, we expect to build awareness of the breadth of our product offering. We are conscientious in the pursuit of delivering value to all stakeholders. Our goal is to provide surgeon education programs coupled with a growing and comprehensive sales training platform that create a sustainable competitive advantage for our organization.

Manufacture and Supply

We rely on third-party suppliers for the manufacture of all our implants and instruments. Outsourcing implant manufacturing reduces our need for capital investment and reduces operational expense. Additionally, outsourcing provides expertise and capacity necessary to scale up or down based on demand for our products. We select our suppliers to ensure that all of our products are safe, effective, adhere to all applicable regulations, are of the highest quality, and meet our supply needs. We employ a rigorous supplier assessment, qualification, and selection process targeted to suppliers that meet the requirements of the U.S. Food and Drug Administration, or FDA, and International Organization for Standardization, or ISO, and quality standards supported by internal policies and procedures. Our quality assurance process monitors and maintains supplier performance through qualification and periodic supplier reviews and audits.

The raw materials used in the manufacture of our non-biologic products are principally titanium, titanium alloys, stainless steel, cobalt chrome, ceramic, allograft, and PEEK. None of our raw material requirements is limited to any significant extent by critical supply. We believe our supplier relationships and quality processes will support our potential capacity needs for the foreseeable future.

With respect to biologics products, we are FDA-registered and licensed in the states of California, New York, and Florida, the only states that currently require licenses. Our facility and the facilities of the third-party suppliers we use are subject to periodic unannounced inspections by regulatory authorities and may undergo compliance inspections conducted by the FDA and corresponding state and foreign agencies. Because our biologics products are processed from human tissue, maintaining a steady supply can sometimes be challenging. We have not experienced significant difficulty in locating and obtaining the materials necessary to fulfill our production requirements, and we have not experienced a meaningful disruption to sales orders.

In connection with the sale of our international business to Globus in September 2016, we and Globus entered into a product manufacture and supply agreement, or the Supply Agreement, pursuant to which, at agreed-upon prices, we agreed to supply to Globus certain of our implants and instruments that at the time were being offered for sale by us outside of the United States. Pursuant

to the Supply Agreement, we are responsible for ensuring that all of the products delivered to Globus meet all agreed-upon specifications for such products. The initial term of the Supply Agreement expires in September 2019, and Globus has the right to renew the Supply Agreement for two additional 12-month periods, subject to Globus meeting certain purchase requirements. We have agreed to not market and sell spinal implant products outside of the United States for a period ending two years following the termination of the Supply Agreement.

Competition

Although we believe that our current broad product portfolio and development pipeline is differentiated and has numerous competitive advantages, the spinal implant industry is highly competitive, subject to rapid technological change, and significantly affected by new product introductions. We believe that the principal competitive factors in our market include:

- improved outcomes for spine pathology procedures;
- ease of use, quality and reliability of product portfolio;
- effective and efficient sales, marketing and distribution;
- quality service and an educated and knowledgeable sales network;
- technical leadership and superiority;
- surgeon services, such as training and education;
- responsiveness to the needs of surgeons;
- acceptance by spine surgeons;
- product price and qualification for reimbursement; and
- speed to market.

Both our currently marketed products and any future products we commercialize are subject to intense competition. We believe that our most significant competitors are Medtronic, Johnson & Johnson (DePuy/Synthes), Stryker, NuVasive, Zimmer Biomet, Globus and others, many of which have substantially greater financial resources than we do. In addition, these companies may have more established distribution networks, entrenched relationships with physicians and greater experience in developing, launching, marketing, distributing and selling spinal implant products.

Some of our competitors also provide non-operative therapies for spine disorder conditions. While these non-operative treatments are considered to be an alternative to surgery, surgery is typically performed in the event that non-operative treatments are unsuccessful. We believe that, to date, these non-operative treatments have not caused a material reduction in the demand for surgical treatment of spinal disorders.

Intellectual Property

We rely on a combination of patent, trademark, copyright, trade secret and other intellectual property laws, nondisclosure agreements, proprietary information ownership agreements and other measures to protect our intellectual property rights. We believe that in order to have a competitive advantage, we must develop, maintain and enforce the proprietary aspects of our technologies. We require our employees, consultants, co-developers, distributors and advisors to execute agreements governing the ownership of proprietary information and use and disclosure of confidential information in connection with their relationship with us. In general, these agreements require these individuals and entities to agree to disclose and assign to us all inventions that were conceived on our behalf or which relate to our property or business and to keep our confidential information confidential and only use such confidential information in connection with our business.

Patents. As of March 25, 2019, we and our affiliates owned, or we exclusively owned, 139 issued U.S. patents, 37 pending U.S. patent applications and 163 issued or pending foreign patents. We own multiple patents relating to unique aspects and improvements for several of our products. We do not believe that the expiration of any single patent is likely to significantly affect our intellectual property position.

Trademarks. As of March 25, 2019, we and our affiliates owned 25 registered U.S. trademarks and 9 registered trademarks outside of the U.S.

Government Regulation

Our products are subject to extensive regulation by the FDA and other U.S. federal and state regulatory bodies and comparable authorities in other countries. Our products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FDCA, and in the case of our tissue products, also under the Public Health Service Act, or PHSA. To ensure that our products are safe and effective for their intended use, the FDA regulates, among other things, the following activities that we or our partners perform and will continue to perform:

- product design and development;
- product testing;
- non-clinical and clinical research;
- product manufacturing;
- product labeling;
- product storage;
- premarket clearance or approval;
- advertising and promotion;
- product marketing, sales and distribution;
- import and export; and
- post-market surveillance, including reporting deaths or serious injuries related to products and certain product malfunctions.

Government Regulation—Medical Devices

FDA's Premarket Clearance and Approval Requirements. Unless an exemption applies, each medical device we seek to commercially distribute in the United States requires either FDA clearance of a premarket notification requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, also referred to as a 510(k) clearance, or approval of a premarket approval application, or PMA. The information that must be submitted to the FDA in order to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Under the FDCA medical devices are classified as Class I, Class II or Class III depending on the degree of risk associated with the use of the device and the extent of manufacturer and regulatory controls deemed to be necessary by the FDA to reasonably ensure their safety and effectiveness.

Class I devices are those with the lowest risk to the patient for which safety and effectiveness can be reasonably assured by adherence to a set of regulations, referred to as General Controls, which require compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require 510(k) clearance by the FDA, though most Class I devices are exempt from the premarket notification requirements. Class II devices are those that are subject to the General Controls, as well as Special Controls, which can include performance standards, product-specific guidance documents and post-market surveillance. Manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA. Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by compliance with the General Controls and Special Controls described above. Therefore, these devices must be the subject of an approved PMA. Both 510(k)s and PMAs are subject to the payment of user fees at the time of submission for FDA review.

If the FDA determines that the device is not "substantially equivalent" to a predicate device following submission and review of a 510(k) premarket notification, or if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk, the device sponsor may either pursue a PMA approval or seek reclassification of the device through the de novo process. The products we currently market in the U.S. are Class II devices marketed under FDA 510(k) clearance.

510(k) Clearance Pathway. To obtain 510(k) clearance, we must submit a 510(k) premarket notification demonstrating that the proposed device is substantially equivalent to a device legally marketed in the United States. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was

found substantially equivalent through the 510(k) clearance process. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

The FDA’s goal is to review and act on each 510(k) premarket notification within 90 days of submission, but the process usually takes from nine to 12 months, and it may take longer if the FDA requests additional information. Most 510(k)s premarket clearances do not require supporting data from clinical trials, but the FDA may request such data. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, require premarket approval. The FDA requires each manufacturer to determine whether the proposed change requires the submission of a 510(k) or premarket notification PMA, but the FDA can review any such decision and can disagree with a manufacturer’s determination. If the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained. If the FDA requires us to seek a new 510(k) clearance or PMA for any modifications to a previously cleared product, we may be required to cease marketing or recall the modified device until we obtain this clearance or approval. Also, in these circumstances, we may be subject to significant fines or penalties. We have made and plan to continue to make enhancements to our products for which we have not submitted 510(k)s, premarket notifications or PMAs, and we will consider on a case-by-case basis whether a new 510(k) premarket notification or PMA is necessary.

The FDA began to consider proposals to reform its 510(k) clearance process in 2011, and such proposals could include increased requirements for clinical data and a longer review period. Specifically, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) regulatory pathway, the FDA initiated an evaluation of the 510(k) program, and as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several “Medical Device Regulatory Improvements” and miscellaneous reforms, which are further intended to clarify and improve medical device regulation both pre- and post-clearance and approval. Further, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of devices and spur innovation, but its ultimate implementation is unclear.

Premarket Approval Pathway. Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) clearance process. The PMA process is generally more complex, costly and time consuming than the 510(k) clearance process. A PMA must be supported by extensive data including, but not limited to, extensive technical information regarding device design and development, preclinical and clinical trials, manufacturing and labeling information to demonstrate to the FDA’s satisfaction the safety and effectiveness of the device for its intended use. The PMA application must provide valid scientific evidence that demonstrates to the FDA’s satisfaction reasonable assurance of the safety and effectiveness of the device for its intended use. Following receipt of a PMA approval, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of the PMA, although in practice, the FDA’s review often takes significantly longer, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant’s response to deficiencies communicated by the FDA. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel’s recommendation. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with quality system regulation, or QSR. The PMA approval process can be expensive, uncertain and lengthy, and a number of devices for which FDA approval has been sought by other companies have never been approved by the FDA for marketing.

Clinical Trials. Clinical trials are almost always required to support a PMA and are sometimes required for a 510(k) premarket notification. All clinical investigations of investigational devices to determine safety and effectiveness must be conducted in accordance with the FDA’s investigational device exemption, or IDE, regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device is determined to present a “significant risk” to human health, the manufacturer may not begin a clinical trial until it submits an IDE application to the FDA and obtains approval of the IDE from the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE application, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE

requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. A clinical trial may be suspended by FDA, the sponsor or an IRB at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the trial. Even if a clinical trial is completed, the results may not demonstrate the safety and efficacy of a device to the satisfaction of the FDA, or may be equivocal or otherwise not be sufficient to obtain approval of a device.

Pervasive and Continuing FDA Regulation. After a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include:

- registration and listing requirements, which require manufacturers to register all manufacturing facilities and list all medical devices placed into commercial distribution;
- the QSR, which requires manufacturers, including third-party contract manufacturers, to follow stringent design, testing, control, supplier/contractor selection, documentation, record maintenance and other quality assurance controls, during all aspects of the manufacturing process and to maintain and investigate complaints;
- labeling regulations and unique device identification requirements;
- advertising and promotion requirements;
- restrictions on sale, distribution or use of a device;
- FDA prohibitions against the promotion of products for uncleared or unapproved “off-label” uses;
- medical device reporting obligations, which require that manufacturers submit reports to the FDA of device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to reoccur;
- medical device correction and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- device tracking requirements; and
- other post-market surveillance requirements, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following:

- warning letters and untitled letters;
- fines, injunctions, consent decrees, and civil penalties;
- recalls, withdrawals, administrative detention, or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- withdrawals of 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant 510(k) clearance or PMA approvals of new products; and/or
- criminal prosecution.

Our facilities, records and manufacturing processes are subject to periodic announced and unannounced inspections by the FDA to evaluate compliance with applicable regulatory requirements.

Regulation of Human Cells, Tissues, and Cellular and Tissue-based Products. Certain of our products are regulated as human cells, tissues, and cellular and tissue-based products, or HCT/Ps. Section 361 of the PHSA 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, or Good Tissue Practice, when processing, storing, labeling, and distributing HCT/Ps, including required labeling information, stringent record keeping, and adverse event reporting, among other applicable requirements and laws. If the HCT/P is minimally manipulated, is intended for homologous use only and meets other requirements, the HCT/P will not require 510(k) clearance, PMA approval, a Biologics License Applications, or other premarket authorization from the FDA before marketing.

Environmental Matters

Our facilities and operations are subject to extensive federal, state, and local environmental and occupational health and safety laws and regulations. These laws and regulations govern, among other things, air emissions; wastewater discharges; the generation, storage, handling, use and transportation of hazardous materials; the handling and disposal of hazardous wastes; the cleanup of contamination; and the health and safety of our employees. Under such laws and regulations, we are required to obtain permits from governmental authorities for some of our operations. If we violate or fail to comply with these laws, regulations or permits, we could be fined or otherwise sanctioned by regulators. We could also be held responsible for costs and damages arising from any contamination at our past or present facilities or at third-party waste disposal sites. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials, and we may incur material liability as a result of any contamination or injury.

Compliance with Certain Applicable Statutes

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws, false claims laws, criminal health care fraud laws, physician payment transparency laws, data privacy and security laws and foreign corrupt practice laws. Violations of these laws are punishable by criminal and/or civil sanctions, including, in some instances, fines, imprisonment and, within the United States, exclusion from participation in government healthcare programs, including Medicare, Medicaid and Veterans Administration health programs. These laws are administered by, among others, the U.S. Department of Justice, the Office of Inspector General of the Department of Health and Human Services and state attorneys general. Many of these agencies have increased their enforcement activities with respect to medical device manufacturers in recent years.

The federal Anti-Kickback Statute, prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending a good or service, for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. The Anti-Kickback Statute is broad and prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. For example, the definition of “remuneration” has been broadly interpreted to include anything of value, including, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payments, ownership interests and providing anything at less than its fair market value. In addition, the Patient Protection and Affordable Health Care Act, which, as amended by the Health Care and Education Reconciliation Act, and collectively referred to as ACA. ACA, among other things, amends the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. In addition, ACA provides that the government may assert that a claim including items or services resulting from a violation of the Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

In implementing the Anti-Kickback Statute, the Department of Health and Human Services Office of Inspector General, or OIG, has issued a series of regulations, known as the safe harbors, which began in July 1991. These safe harbors set forth provisions that, in circumstances where all the applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy all requirements of an applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Penalties for violations of the Anti-Kickback Statute include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Many states have anti-kickback laws that are similar to the federal law, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, and may also result in penalties, fines, sanctions for violations, and exclusions from state or commercial programs.

We have entered into various agreements with certain surgeons that perform services for us, including some who make clinical decisions to use our products. Some of our referring surgeons own our stock, which they received from us as consideration for services performed. From time to time, we review these arrangements to determine whether they are in compliance with applicable laws and regulations. In addition, physician-owned distribution companies, or PODs, have increasingly become involved in the sale and distribution of medical devices, including products for the surgical treatment of spine disorders. In many cases, these distribution companies enter into arrangements with hospitals that bill Medicare or Medicaid for the furnishing of medical services, and the physician-owners are among the physicians who refer patients to the hospitals for surgery. On March 26, 2013 the OIG issued a Special Fraud Alert entitled “Physician-Owned Entities”, in which the OIG concluded, among other things, that PODs are “inherently suspect under the anti-kickback statute” and that PODs present “substantial fraud and abuse risk and pose dangers of patient safety.” Since 2013, the OIG has further increased its scrutiny of PODs and the Department of Justice has brought several high-profile cases against physician owners.

The federal False Claims Act prohibits persons from knowingly filing or causing to be filed a false or fraudulent claim to, or the knowing use of false statements to obtain payment from, the federal government. Private suits filed under the False Claims Act, known as qui tam actions, can be brought by individuals on behalf of the government. These individuals, sometimes known as “relators” or, more commonly, as “whistleblowers,” may share in any amounts paid by the entity to the government in fines or settlement. The number of filings of qui tam actions has increased significantly in recent years, causing more healthcare companies to have to defend a False Claim Act action. If an entity is determined to have violated the federal False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties of between \$10,000 to \$22,000 for each separate false claim and may be subject to exclusion from Medicare, Medicaid and other federal healthcare programs. Various states have also enacted similar laws modeled after the federal False Claims Act which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

The Health Insurance Portability and Accountability Act, or HIPAA, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payers. The ACA changed the intent requirement of the healthcare fraud statute to such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. A violation of this statute is a felony and may result in fines, imprisonment or possible exclusion from Medicare, Medicaid and other federal healthcare programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in similar sanctions.

ACA also includes various provisions designed to strengthen significantly fraud and abuse enforcement in addition to those changes discussed above. Among these additional provisions include increased funding for enforcement efforts and new “sunshine” provisions to require us to report and disclose to the Centers for Medicare and Medicaid Services, or CMS, any payment or “transfer of value” made or distributed to physicians or teaching hospitals. These sunshine provisions also require certain GPOs, including physician-owned distributors, to disclose physician ownership information to CMS. We and other device manufacturers are required to collect and annually report specific data on payments and other transfers of value to physicians and teaching hospitals. There are various state laws and initiatives that require device manufacturers to disclose to the appropriate regulatory agency certain payments or other transfers of value made to physicians, and in certain cases prohibit some forms of these payments, with the risk of fines for any violation of such requirements.

HIPAA also includes privacy and security provisions designed to regulate the use and disclosure of “protected health information”, or PHI, which is health information that identifies a patient and that is held by a health care provider, a health plan or health care clearinghouse. We are not directly regulated by HIPAA, but our ability to access PHI for purposes such as marketing, product development, clinical research or other uses is controlled by HIPAA and restrictions placed on health care providers and other covered entities. HIPAA was amended in 2009 by the Health Information Technology for Economic and Clinical Health Act, or HITECH, which strengthened the rule, increased penalties for violations and added a requirement for the disclosure of breaches to affected individuals, the government and in some cases the media. We must carefully structure any transaction involving PHI to avoid violation of HIPAA and HITECH requirements.

Almost all states have adopted data security laws protecting personal information including social security numbers, state issued identification numbers, credit card or financial account information coupled with individuals’ names or initials. We must comply with all applicable state data security laws, even though they vary extensively, and must ensure that any breaches or accidental disclosures of personal information are promptly reported to affected individuals and responsible government entities. We must also ensure that we maintain compliant, written information security programs or run the risk of civil or even criminal sanctions for non-compliance as well as reputational harm for publicly reported breaches or violations.

If any of our operations are found to have violated or be in violation of any of the laws described above and other applicable state and federal fraud and abuse laws, we may be subject to penalties, among them being civil and criminal penalties, damages, fines, exclusion from government healthcare programs, and the curtailment or restructuring of our operations.

Third-Party Reimbursement

In the U.S., healthcare providers generally rely on third-party payers, principally private insurers and governmental payers such as Medicare and Medicaid, to cover and pay for all or part of the cost of a spine surgery in which our medical devices are used. We expect that sales volumes and prices of our products will depend in large part on the continued availability of reimbursement from such third-party payers. These third-party payers may deny reimbursement if they determine that a device used in a procedure was not medically necessary in accordance with cost-effective treatment methods, as determined by the third-party payer, or was used for an unapproved indication. Particularly in the U.S., third-party payers continue to carefully review, and increasingly challenge, the prices charged for procedures and medical products. Medicare coverage and reimbursement policies are developed by CMS, the federal agency responsible for administering the Medicare program, and its contractors. CMS establishes these Medicare policies for medical

products and procedures and such policies are periodically reviewed and updated. While private payers vary in their coverage and payment policies, the Medicare program is viewed as a benchmark. Medicare payment rates for the same or similar procedures vary due to geographic location, nature of the facility in which the procedure is performed (i.e., teaching or community hospital) and other factors. We cannot assure you that government or private third-party payers will cover and provide adequate payment for the procedures in which our products are used. ACA and other reform proposals contain significant changes regarding Medicare, Medicaid and other third party payers.

Among these changes was the imposition of a 2.3% excise tax on domestic sales of medical devices that went into effect on January 1, 2013. This tax has resulted in a significant increase in the tax burden on our industry. In December 2015, the U.S. Congress adopted and President Obama signed into law the Consolidated Appropriations Act of 2016. Among other things, this legislation put in place a two-year moratorium on the device tax through the end of 2017. The moratorium was extended to an additional two years beginning January 1, 2018 and ending December 31, 2019. Other elements of the ACA include numerous provisions to limit Medicare spending through reductions in various fee schedule payments and by instituting more sweeping payment reforms, such as bundled payments for episodes of care, the establishment of “accountable care organizations” under which hospitals and physicians will be able to share savings that result from cost control efforts, comparative effectiveness research, value-based purchasing, and the establishment of an independent payment advisory board.

We expect that political forces, including presidential administration and party control of the House of Representatives, the Senate and even State-level elections, could shift health policy, including potential to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA or other healthcare regulations. Since its enactment, there have also been other judicial and Congressional challenges to certain aspects of the ACA. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. In March 2017, the House of Representatives introduced legislation known as the American Health Care Act, or the AHCA, which, if enacted, would amend or repeal significant portions of the ACA. Among other changes, the AHCA, would repeal the medical device tax, eliminate penalties on individuals and employers that fail to maintain or provide minimum essential coverage and create refundable tax credits to assist individuals in buying health insurance. The AHCA would also make significant changes to Medicaid by, among other things, making Medicaid expansion optional for states, repealing the requirement that state Medicaid plans provide the same essential health benefits that are required by plans available on the exchanges, modifying federal funding, including implementing a per capita cap on federal payments to states, and changing certain eligibility requirements. Given recent changes of political party control of the House of Representatives, it is uncertain when or if the provisions in the AHCA will become law, or the extent to which any such changes may impact our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include the Budget Control Act of 2011, which resulted in reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2025 unless additional Congressional action is taken, as well as, the American Taxpayer Relief Act of 2012, which, among other things, further reduced Medicare payments to several types of providers, including hospitals and imaging centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. An expansion in government’s role in the U.S. healthcare industry may lower reimbursements for procedures using our products, reduce medical procedure volumes, and adversely affect our business and results of operations, possibly materially.

We believe that the overall escalating cost of medical products and services has led to, and will continue to lead to, increased pressures on the healthcare industry to reduce the costs of products and services. We cannot assure you that government or private third-party payers will cover and provide adequate payment for the procedures using our products. In addition, it is possible that future legislation, regulation, or reimbursement policies of third-party payers will adversely affect the demand for procedures using our products or our ability to sell our products on a profitable basis. The unavailability or inadequacy of third-party payer coverage or reimbursement could have a significant adverse effect on our business, operating results and financial condition.

Employees

As of March 25, 2019, we had 195 employees in the U.S. and Canada, approximately 159 of which were based in our Carlsbad, California headquarters, covering all of the following functional areas: sales, customer service, marketing, clinical education, advanced manufacturing, quality assurance, regulatory affairs, research and development, human resources, finance, legal, information technology and administration. We have never experienced a work stoppage due to labor difficulties and believe that our relations with our employees are good. We currently have no employees working under collective bargaining agreements.

Corporate and Available Information

We are a Delaware corporation. We were incorporated in March 2005. Our principal executive office is located at 5818 El Camino Real, Carlsbad, California 92008 and our telephone number is (760) 431-9286. Our Internet address is www.atecspine.com. We are not including the information contained on our website as a part of, or incorporating it by reference into, this Annual Report on

Form 10-K. Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and all amendments to those reports, are available to you free of charge through the Investor Relations section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the Securities and Exchange Commission, or SEC.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors and all other information contained or incorporated by reference in this Annual Report on Form 10-K. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties that we are unaware of, or that we currently deem immaterial, also may become important factors that affect us. If any of such risks or the risks described below, either alone or taken together, occur, our business, financial condition or results of operations could be materially and adversely affected. In that case, the trading price of our common stock could decline, and you may lose some or all of your investment.

Risks Related to Our Business and Industry

Our business plan relies on certain assumptions pertaining to the market for our products that, if incorrect, may adversely affect our growth and profitability.

We allocate our design, development, marketing, management and financial resources based on our business plan, which includes assumptions about various demographic trends in the treatment of spine disorders and the resulting demand for our products. However, these trends are uncertain. There can be no assurance that our assumptions with respect to an aging population with broad medical coverage and longer life expectancy, which we expect to lead to increased spinal injuries and degeneration, are accurate. In addition, an increasing awareness and use of non-invasive means for the prevention and treatment of back pain and rehabilitation purposes may reduce demand for, or slow the growth of sales of, spine fusion products. A significant shift in technologies or methods used in the treatment of back pain or damaged or diseased bone and tissue could adversely affect demand for some or all of our products. For example, pharmaceutical advances could result in non-surgical treatments gaining more widespread acceptance as a viable alternative to spine fusion. The emergence of new biological or synthetic materials to facilitate regeneration of damaged or diseased bone and to repair damaged tissue could increasingly minimize or delay the need for spine fusion surgery and provide other biological alternatives to spine fusion. New surgical procedures could diminish demand for some of our products. The increased acceptance of emerging technologies that do not require spine fusion, such as artificial discs and nucleus replacement, for the surgical treatment of spine disorders would reduce demand for, or slow the growth of sales of, spine fusion products. If our assumptions regarding these factors prove to be incorrect or if alternative treatments to those offered by our products gain further acceptance, then demand for our products could be significantly less than we anticipate and we may not be able to achieve or sustain growth or profitability.

We are in a highly competitive market segment, face competition from large, well-established medical device companies with significant resources, and may not be able to compete effectively.

The market for spine fusion products and procedures is intensely competitive, subject to rapid technological change and significantly affected by new product introductions and other market activities of industry participants. In 2018, a significant percentage of global spine implant product revenues was generated by Medtronic Sofamor Danek, a subsidiary of Medtronic, Inc.; Depuy Spine, a subsidiary of Johnson & Johnson; and Stryker Spine. Our competitors also include numerous other publicly-traded companies such as NuVasive, Zimmer Biomet, Globus and SeaSpine.

Several of our competitors enjoy competitive advantages over us, including:

- more established relationships with spine surgeons;
- more established distribution networks;
- broader spine surgery product offerings;
- stronger intellectual property portfolios;
- greater financial and other resources for product research and development, sales and marketing, and patent litigation;
- greater experience in, and resources for, launching, marketing, distributing and selling products;
- greater name recognition as well as more recognizable trademarks for products similar to the products that we sell;
- more established relationships with healthcare providers and payers;

- products supported by more extensive clinical data; and
- greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancements.

In addition, at any time our current 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 spine surgery products. For these reasons, we may not be able to compete successfully against our existing or potential competitors. Any such failure could lead us to modify our strategy, lower our prices, increase the commissions we pay on sales of our products and have a significant adverse effect on our business, financial condition and results of operations.

A significant percentage of our revenues are derived from the sale of our systems that include polyaxial pedicle screws.

Net sales of our systems that include polyaxial pedicle screws represented approximately 50% our net sales for both 2018 and 2017. A decline in sales of these systems, due to lower market demand, the introduction by a third party of a competitive product, an intellectual property dispute involving these systems, or otherwise, would have a significant adverse impact on our business, financial condition and results of operations. Some of the technology related to our polyaxial pedicle screw systems is licensed to us. Any action that would prevent us from manufacturing, marketing and selling our polyaxial pedicle screw systems would have a significant adverse effect on our business, financial condition and results of operations.

Our sales and marketing efforts are largely dependent upon third parties, many of which are free to market products that compete with our products.

Many of our independent distributors also market and sell the products of our competitors, and those competitors may have the ability to influence the products that our independent distributors choose to market and sell. Our competitors may be able, by offering higher commission payments or otherwise, to convince our independent distributors to terminate their relationships with us, carry fewer of our products or reduce their sales and marketing efforts for our products.

If pricing pressures cause us to decrease prices for our goods and services and we are unable to compensate for such reductions through changes in our product mix or reductions to our expenses, our results of operations will suffer.

We have experienced and may continue to experience decreasing prices for our goods and services we offer due to pricing pressure exerted by our customers in response to increased cost containment efforts from managed care organizations and other third-party payers and increased market power of our customers as the medical device industry consolidates. If we are unable to offset such price reductions through changes in our product mix or reductions in our expenses, our business, financial condition, results of operations and cash flows will be adversely affected.

To be commercially successful, we must convince the spine surgeon community that our products are an attractive alternative to our competitors' products. If the spine surgeon community does not use our products, our sales will decline and we will be unable to increase our sales and generate profits.

In order for us to sell our products, surgeons must be convinced that our products are superior to competing products. Acceptance of our products depends on educating the spine surgeon community as to the distinctive characteristics, perceived benefits, safety and cost-effectiveness of our products compared to our competitors' products and on training surgeons in the proper application of our products. If we are not successful in convincing the spine surgeon community of the merit of our products, our sales will decline and we will be unable to increase or achieve and sustain growth or profitability.

There is a learning process involved for spine surgeons to become proficient in the use of our products. Although most 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 spine surgeons in the use of our products. If surgeons are not properly trained, they may misuse or ineffectively use our products. This may also 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.

We must retain the current distributors of our products and attract new distributors of our products.

We plan to continue to focus on increasing our network of independent distributors. The establishment and development of a broader distribution network may be expensive and time consuming. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified independent distributors. Often, our competitors enter into distribution agreements with independent distributors that require such distributors to exclusively sell the products of our competitors. Further, we may not be able to enter into agreements with independent distributors on commercially reasonable terms, if at all. Even if we do enter into agreements with additional independent distributors, it often takes 90 to 120 days for new distributors to reach full operational effectiveness and such distributors may not generate revenue as quickly as we expect them to, commit the necessary resources to effectively market and sell our products or ultimately be successful in selling our products. Our business, financial condition and results of operations will be materially adversely affected if we do not retain our existing independent distributors and attract new, additional independent distributors or if the marketing and sales efforts of our independent distributors and our own direct sales representatives are unsuccessful.

We rely on a limited number of third parties to manufacture and supply our products. Any problems experienced by any of these manufacturers could result in a delay or interruption in the supply of our products to us until such manufacturer cures the problem or until we locate and qualify an alternative source of supply.

We rely on third party suppliers for the manufacture of our implants and instruments. We currently rely on a limited number of third party suppliers and any prolonged disruption in the operations of our third party suppliers could have a significant negative impact on our ability to supply our products to customers and to perform our obligations under the Supply Agreement with Globus, and would cause us to seek additional third-party manufacturing contracts, which may not be available on acceptable terms, if at all. We may suffer losses as a result of business interruptions that exceed coverage under our manufacturer's insurance policies. Events beyond our control, such as natural disasters, fire, sabotage or business accidents could have a significant negative impact on our operations by disrupting our product development and commercialization efforts until such third-party supplier can repair its facility or put in place third-party contract manufacturers to assume this manufacturing role, which we may not be able to do on reasonable terms, if at all. In addition, if we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer or the re-verification of an existing manufacturer could negatively affect our ability to develop products or supply products to customers in a timely manner. Any disruption in the manufacture of our products by our third party suppliers could have a material adverse impact on our business, financial condition and results of operations.

We depend on various third-party suppliers, and in one case a single third-party supplier, for key raw materials used in the manufacturing processes for our products and the loss of any of these third-party suppliers, or their inability to supply us with adequate raw materials, could harm our business.

We use a number of raw materials, including titanium, titanium alloys, stainless steel, PEEK, and human tissue. We rely from time to time on a number of suppliers and in one case on a single source vendor, Invibio. We have a supply agreement with Invibio, pursuant to which it supplies us with PEEK, a biocompatible plastic that we use in some of our spacers. Invibio is one of a limited number of companies approved to distribute PEEK in the U.S. for use in implantable devices. During both 2018 and 2017, approximately 20% of our revenues were derived from products manufactured using PEEK.

We depend on a limited number of sources of human tissue for use in our biologics products, and any failure to obtain tissue from these sources or to have the tissue processed by these entities for us in a timely manner will interfere with our ability to meet demand for our biologics products effectively. The processing of human tissue into biologics products is labor intensive and it is therefore difficult to maintain a steady supply stream. In addition, due to seasonal changes in mortality rates, some scarce tissues used for our biologics products are at times in particularly short supply. We cannot be certain that our supply of human tissue from our current suppliers and our current inventory of biologics products will be available at current levels or will be sufficient to meet our needs.

Our dependence on a single third-party PEEK supplier and the challenges we may face in obtaining adequate supplies of biologics products involve several risks, including limited control over pricing, availability, quality and delivery schedules. In addition, any supply interruption in a limited or sole sourced component or raw material, such as PEEK or human tissue, could materially harm the ability of our third party manufacturers to manufacture our products until a new source of supply, if any, could be found. We may be unable to find a sufficient alternative supply channel in a reasonable time period or on commercially reasonable terms, if at all, which would have a significant adverse effect on our business, financial condition and results of operations.

Our tissue-based products and related technologies could become subject to significantly greater regulation by the FDA, which could disrupt our business.

The FDA regulates human cells, tissues, and cellular and tissue-based products, or HCT/Ps, but the extent to which they are regulated depends on how they are manufactured and used and whether they meet other criteria for minimal regulation. These criteria include but are not limited to the use of the HCT/Ps for homologous use only and minimal manipulation of the HCT/Ps. These HCT/Ps are regulated by the FDA solely under Section 361 of the Public Health Service Act, or PHSA, and are referred to as “Section 361 HCT/Ps,” while other HCT/Ps are subject to FDA’s regulatory requirements applicable to medical devices or biologics. Section 361 HCT/Ps do not require 510(k) clearance, PMA approval, licensure of a biologics license application, or BLA, or other premarket authorization from FDA before marketing. We believe our HCT/Ps are regulated solely under Section 361 of the PHSA, and therefore, we have not sought or obtained 510(k) clearance, PMA approval, or licensure through a BLA. The FDA could disagree with our determination that our tissue-based products are Section 361 HCT/Ps and could determine that these products are biologics requiring a BLA or medical devices requiring 510(k) clearance or PMA approval, and could require that we cease marketing such products and/or recall them pending appropriate clearance, approval or license from the FDA. If the FDA determines that any of our current or future products contain HCT/Ps that do not meet the criteria for regulation as a Section 361 HCT/P, it could subject some of our products to additional review and regulatory oversight. If this were to happen, further distribution of the affected products could be interrupted for a substantial period of time, which would reduce our revenues and hurt our profitability.

If we or our suppliers fail to comply with the FDA’s quality system and good tissue practice regulations, the manufacture of our products could be delayed.

We and our suppliers are required to comply with the FDA’s QSR, which covers, among other things, the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, record keeping, storage and shipping of our products. In addition, suppliers and processors of products derived from HCT must comply with the FDA’s current good tissue practice requirements, or cGTPs, which govern the methods used in and the facilities and controls used for the manufacture of HCT/Ps, record keeping and the establishment of a quality program. The FDA audits compliance with the QSR and cGTPs through inspections of manufacturing and other facilities. If we or our suppliers have significant non-compliance issues or if any corrective action plan is not sufficient, we or our suppliers could be forced to halt the manufacture of our products until such problems are corrected to the FDA’s satisfaction, which could have a material adverse effect on our business, financial condition and results of operations. Further, our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective. Any recall or FDA requirement demanding that we seek additional approvals or clearances could result in delays, costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA, all of which could have a material adverse effect on our business, financial condition and results of operations.

Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse effect on us.

In response to perceived increases in health care costs in recent years, there have been and continue to be proposals by the federal government, state governments, regulators and third-party payers to control these costs and, more generally, to reform the U.S. healthcare system. Certain of these proposals could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products, limit the acceptance and availability of our products, and have a material adverse effect on our financial position and results of operations. An expansion in government’s role in the U.S. healthcare industry may lower reimbursements for procedures using our products, reduce medical procedure volumes and adversely affect our business and results of operations, possibly materially.

The demand for products and the prices at which customers and patients are willing to pay for our products depend upon the ability of our customers to obtain adequate third-party coverage and reimbursement for their purchases of our products.

Sales of our products depend in part on the availability of adequate coverage and reimbursement from governmental and private payers. In the U.S., healthcare providers that purchase our products generally rely on third-party payers, principally Medicare, Medicaid and private health insurance plans, to pay for all or a portion of the costs and fees associated with the use of our products. While procedures using our currently marketed products are eligible for reimbursement in the U.S., if surgical procedures utilizing our products are performed on an outpatient basis, it is possible that private payers may no longer provide reimbursement for the procedures using our products without further supporting data on the procedure. Any delays in obtaining, or an inability to obtain, adequate coverage or reimbursement for procedures using our products could significantly affect the acceptance of our products and have a significant adverse effect on our business. Additionally, third-party payers continue to review their coverage policies carefully for existing and new therapies and can, without notice, deny coverage for treatments that include the use of our products. Our business would be negatively impacted if there are any changes that reduce reimbursement for our products.

Furthermore, healthcare costs have risen significantly over the past decade. There have been and may continue to be proposals by legislators, regulators and third-party payers to contain these costs. Several such proposals were enacted as part of ACA, and include numerous provisions to limit Medicare spending through reductions in various fee schedule payments and sweeping payment reforms. Other federal and state cost-control measures include prospective payment systems, capitated rates, group purchasing, redesign of benefits, requiring pre-authorizations or second opinions prior to major surgery, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare. Some healthcare providers in the U.S. have adopted or are considering a managed care system in which the providers contract to provide comprehensive healthcare for a fixed cost per person. Healthcare providers may also attempt to control costs by authorizing fewer elective surgical procedures or by requiring the use of the least expensive devices possible. These cost-control methods also potentially limit the amount which healthcare providers may be willing to pay for medical devices. In addition, in the U.S., no uniform policy of coverage and reimbursement for medical technology exists among all these payers. Therefore, coverage of and reimbursement for medical technology can differ significantly from payer to payer. The continuing efforts of third-party payers, whether governmental or commercial, whether inside or outside the U.S., to contain or reduce these costs, combined with closer scrutiny of such costs, could restrict our customers' ability to obtain adequate coverage and reimbursement from these third-party payers. The cost containment measures contained in ACA and other measures being considered at the federal and state level, as well as internationally, could harm our business by adversely affecting the demand for our products or the price at which we can sell our products.

Consolidation in the healthcare industry could lead to demands for price concessions or to the exclusion of some suppliers from certain of our markets, which could have an adverse effect on our business, financial condition or results of operations.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms initiated by legislators, regulators and third-party payers to curb these costs have resulted in a consolidation trend in the healthcare industry to create new companies with greater market power, including hospitals. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and will continue to become more intense. This in turn has resulted and will likely continue to result in greater pricing pressures and the exclusion of certain suppliers from important market segments as group purchasing organizations, independent delivery networks and large single accounts continue to use their market power to consolidate purchasing decisions for some of our customers. We expect that market demand, government regulation, third-party reimbursement policies and societal pressures will continue to change the worldwide healthcare industry, resulting in further business consolidations and alliances among our customers, which may reduce competition, exert further downward pressure on the prices of our products and may adversely impact our business, financial condition or results of operations.

We may be subject to or otherwise affected by federal and state healthcare laws, including fraud and abuse, health information privacy and security, and disclosure laws, and could face substantial penalties if we are unable to fully comply with such laws.

Although we do not provide healthcare services, submit claims for third-party reimbursement, or receive payments directly from Medicare, Medicaid, or other third-party payers for our products or the procedures in which our products are used, healthcare regulation by federal and state governments significantly impacts our business. Healthcare fraud and abuse, health information privacy and security, and disclosure laws potentially applicable to our operations include:

- the federal Anti-Kickback Statute, as well as state analogs, which constrains our marketing practices and those of our independent sales agents and distributors, educational programs, pricing policies, and relationships with healthcare providers by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or providing remuneration, intended to induce the purchase or recommendation of an item or service reimbursable under a federal (or state or commercial) healthcare program (such as the Medicare or Medicaid programs);
- the federal ban, as well as state analogs, on physician self-referrals, which prohibits, subject to certain exceptions, physician referrals of Medicare and Medicaid patients to an entity providing certain “designated health services” if the physician or an immediate family member of the physician has any financial relationship with the entity;
- federal false claims laws which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- HIPAA, and its implementing regulations, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the state and federal laws “sunshine” provisions that require detailed reporting and disclosures to CMS and applicable states of any payments or “transfer of value” made or distributed to prescribers and other health care providers, and for certain states prohibit some forms of these payments, require the adoption of marketing codes of conduct, require the reporting of marketing expenditures and pricing information and constrain relationships with physicians and other referral sources;

- state laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the Administrative Simplification provisions of HIPAA, specifically, privacy and security provisions including recent amendments under HITECH which impose stringent restrictions on uses and disclosures of protected health information such as for marketing or clinical research purposes and impose significant civil and criminal penalties for non-compliance and require the reporting of breaches to affected individuals, the government and in some cases the media in the event of a violation; and
- a variety of state-imposed privacy and data security laws which require the protection of information beyond health information, such as employee information or any class of information combining name with state issued identification numbers, social security numbers, credit card, bank or other financial information and which require reporting to state officials in the event of breach or violation and which impose both civil and criminal penalties.

ACA includes various provisions designed to strengthen significantly fraud and abuse enforcement, such as increased funding for enforcement efforts and the lowering of the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statute such that a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them.

If our past or present operations, or those of our independent sales agents and distributors are found to be in violation of any of such laws or any other governmental regulations that may apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from federal healthcare programs and/or the curtailment or restructuring of our operations. Similarly, if the healthcare providers, sales agents, distributors or other entities with which we do business are found to be non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the Courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

The sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies, and we believe that this trend will continue. Prosecutorial scrutiny and governmental oversight over some major device companies regarding the retention of healthcare professionals as consultants has affected and may continue to affect the manner in which medical device companies may retain healthcare professionals as consultants. Any precautions we take to detect and prevent noncompliance with applicable laws may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

If we fail to obtain, or experience significant delays in obtaining, FDA clearances or approvals for our future products or modifications to our products, our ability to commercially distribute and market our products could suffer.

Our medical devices are subject to extensive regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory clearances or approvals to market a medical device, particularly from the FDA, can be costly and time consuming, and there can be no assurance that such clearances or approvals will be granted on a timely basis, if at all. In particular, the FDA permits commercial distribution of most new medical devices only after the devices have received clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or 510(k), or are the subject of an approved premarket approval application, or a PMA. The 510(k) process generally takes three to nine months, but can take significantly longer, especially if the FDA requires a clinical trial to support the 510(k) application. Currently, we do not know whether the FDA will require clinical data in support of any 510(k)s that we intend to submit for other products in our pipeline. In addition, the FDA continues to re-examine its 510(k) clearance process for medical devices and published several draft guidance documents that could change that process. Any changes that make the process more restrictive could increase the time it takes for us to obtain clearances or could make the 510(k) process unavailable for certain of our products. A PMA must be submitted to the FDA if the device cannot be cleared through the 510(k) process or is not exempt from premarket review by the FDA. A PMA must be supported by extensive data, including results of preclinical studies and clinical trials, manufacturing and control data and proposed labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. The PMA process is more costly and uncertain than the 510(k) clearance process, and generally takes between one and three years, if not longer. In addition, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, a PMA.

Modifications to products that are approved through a PMA application generally need FDA approval. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Our commercial distribution and marketing of any products or product modifications that we develop will be delayed until regulatory clearance or approval is obtained. In addition, because we cannot assure you that any new products or any product modifications we develop will be subject to the shorter 510(k) clearance process, the regulatory approval process for our new products or product modifications may take significantly longer than anticipated. There is no assurance that the FDA will not require a new product or product modification to go through the lengthy and expensive PMA approval process. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our products are safe or effective for their intended uses;
- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; or
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

Delays in obtaining regulatory clearances and approvals may:

- delay or prevent commercialization of products we develop;
- require us to perform costly tests or studies;
- diminish any competitive advantages that we might otherwise have obtained; and
- reduce our ability to collect revenues.

To date, all of our non-biologic medical device products that have required FDA review that are being sold in the U.S. have been cleared through the 510(k) process without any required clinical trials. However, the FDA may require clinical data in support of any future 510(k)s or PMAs that we intend to submit for products in our pipeline. We have limited experience in performing clinical trials that might be required for a 510(k) clearance or PMA approval. If any of our products require clinical trials, the commercialization of such products could be delayed which could have a material adverse effect on our business, financial condition and results of operations.

The safety of our products is not yet supported by long-term clinical data and may therefore prove to be less safe and effective than initially thought.

We obtained clearance to offer all of our current non-biologic medical device products through the 510(k) process. The ability to obtain a 510(k) clearance is generally based on the FDA's agreement that a new product is substantially equivalent to certain already marketed products. Because most 510(k)-cleared products were not the subject of pre-market clinical trials, surgeons may be slow to adopt our 510(k)-cleared products, we may not have the comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. 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 expect. Such results would reduce demand for our products and this could cause us to withdraw our products from the market. Moreover, if future research or experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability, significant negative publicity, damage to our reputation and 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.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

Once a medical device is cleared or approved, a manufacturer must notify the FDA of any modifications to the device. Any modification to a device that has received FDA clearance that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires 510(k) clearance or possibly PMA approval. The FDA requires every manufacturer to make the determination in the first instance regarding whether a modification to a cleared or approved device necessitates the filing of a new 510(k) premarket notification or PMA supplement. The FDA may review any manufacturer's decision and can disagree. If the FDA disagrees with any future determination by us that a new 510(k) clearance or PMA approval is not required, we may need to cease marketing or to recall the modified product until and unless we obtain the clearance or approval. In addition, we could also be subject to significant regulatory fines or penalties. Any of these outcomes would harm our business.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory clearance or approval to market a product, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, the Cures Act was signed into law in December 2016. The Cures Act, among other things, is intended to modernize the regulation of devices and spur innovation, but its ultimate implementation is unclear. The FDA, state and foreign regulatory authorities have broad enforcement powers. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future 510(k) clearances, PMA approvals or foreign regulatory approvals of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and/ or
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, results of operations and financial condition.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the U.S. or abroad. For example, political policies and agendas change with changes in political power, and such changes may impact our business and industry.

If we choose to acquire new and complementary businesses, products or technologies, we may be unable to complete these acquisitions or successfully integrate them in a cost-effective and non-disruptive manner.

Our success depends in part on our ability to continually enhance and broaden our product offering in response to changing customer demands, competitive pressures and technologies and our ability to increase our market share. Accordingly, we have pursued and intend to pursue the acquisition of complementary businesses, products or technologies instead of developing them ourselves. We do not know if we will be able to successfully complete any acquisitions, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel, suppliers or distributors. Our ability to successfully grow through acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financing. These efforts could be expensive and time consuming, disrupt our ongoing business and distract management. If we are unable to integrate any future or recently acquired businesses, products or technologies effectively, our business, financial condition and results of operations will be materially adversely affected. For example, an acquisition could materially impair our operating results by causing us to incur debt or requiring us to amortize significant amounts of expenses, including non-cash acquisition costs, and acquired assets.

We may not be able to timely develop new products or product enhancements that will be accepted by the market.

We sell our products in a market that is characterized by technological change, product innovation, evolving industry standards, competing patent claims, patent litigation and intense competition. Our success will depend in part on our ability to develop and introduce new products and enhancements or modifications to our existing products, which we will need to do before our competitors do so and in a manner that does not infringe issued patents of third parties from which we do not have a license. We cannot assure you that we will be able to successfully develop or market new, improved or modified products, or that any of our future products will be accepted by even the surgeons who use our current products. Our competitors' product development capabilities could be more effective than our capabilities, and their new products may get to market before our products. In addition, the products of our competitors may be more effective or less expensive than our products. The introduction of new products by our competitors may lead us to have price reductions, 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 in a timely manner;
- obtain the necessary regulatory approvals for new products or product enhancements;
- provide adequate training to potential users of new products;
- receive adequate reimbursement approval of third-party payers such as Medicaid, Medicare and private insurers; and
- develop an effective marketing and distribution network.

Developing products in a timely manner can be difficult, in particular because product designs change rapidly to adjust to third-party patent constraints and to market preferences. As a result, we may experience delays in our product launches which may significantly impede our ability to enter or compete in a given market and may reduce the sales that we are able to generate from these products. We may experience delays in any phase of a product launch, including during research and development, clinical trials, manufacturing, marketing and the surgeon training process. In addition, our suppliers of products or components can suffer similar delays, which could cause delays in our product introductions. If we do not develop new products or product enhancements in time to meet market demand or if there is insufficient demand for these new products or enhancements, it could have a significant adverse effect on our business financial condition and results of operations.

We are dependent on our senior management team, sales and marketing team, engineering team and key surgeon advisors, and the loss of any of them could harm our business.

Our continued success depends in part upon the continued availability and contributions of our senior management, sales and marketing team and engineering team and the continued participation of our key surgeon advisors. While we have entered into employment agreements with all members of our senior management team, none of these agreements guarantees the services of the individual for a specified period of time. We would be adversely affected if we fail to adequately prepare for future turnover of our senior management team. Our ability to grow or at least maintain our sales levels depends in large part on our ability to attract and retain sales and marketing personnel and for these sales people to maintain their relationships with surgeons directly and through our distributors. We rely on our engineering team to research, design and develop potential products for our product pipeline. We also rely on our surgeon advisors to advise us on our products, our product pipeline, long-term scientific planning, research and development and industry trends. We compete for personnel and advisors with other companies and other organizations, many of which are larger and have greater name recognition and financial and other resources than we do. Over the past 3 years, we have implemented numerous changes in our management team, including in the roles of Chief Executive Officer, Chief Financial Officer, Executive Vice President, People & Culture, and General Counsel, which could have an adverse effect on our retention of our employees, advisors and distributors. Changes to our senior management team, sales and marketing team, engineering team and key surgeon advisors, or our inability to attract or retain other qualified personnel or advisors, could have a significant adverse effect on our business, financial conditions and results of operations.

Compliance with laws and regulations and standards for accounting, corporate governance and public disclosure is time consuming and results in significant expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, other SEC regulations, NASDAQ Stock Market listing rules, and new accounting pronouncements create uncertainty and additional complexities for companies such as ours. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time consuming and costly.

As of June 30, 2018, September 30, 2018 and December 31, 2018, we identified a material weakness in internal control over financial reporting. This material weakness was remediated during the first quarter of 2019 prior to filing this Form 10-K; however, if we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results. As a result, investors may be misled and lose confidence in our financial reporting and disclosures, and the price of our common stock may be negatively affected.

The Sarbanes-Oxley Act of 2002 requires that we report annually on the effectiveness of our internal control over financial reporting. A “significant deficiency” means a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness yet important enough to merit attention by those responsible for oversight of the Company’s financial reporting. A “material weakness” is a deficiency, or a combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the assessment of our internal control over financial reporting for the Annual Report on Form 10-K, as further described in Item 9A, we determined that as of June 30, 2018, September 30, 2018 and December 31, 2018 our internal controls over financial reporting were ineffective due to a material weakness related to our review and accounting associated with complex equity transactions. We remediated this material weakness during the first quarter of 2019, prior to filing this Form 10-K.

If we fail to maintain effective internal controls and procedures for financial reporting, we could be unable to provide timely and accurate financial information and therefore be subject to delisting from The NASDAQ Global Select Market, an investigation by the SEC, and civil or criminal sanctions. Additionally, ineffective internal control over financial reporting would place us at increased risk of fraud or misuse of corporate assets and could cause our stockholders, lenders, suppliers and others to lose confidence in the accuracy or completeness of our financial reports. This, in turn could adversely affect our ability to access the capital markets. We cannot assure you that material weaknesses or significant deficiencies will not occur in the future and that we will be able to remediate such weaknesses or deficiencies in a timely manner, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows.

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.

The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers, viruses, breaches or interruptions due to employee error or malfeasance, terrorist attacks, earthquakes, fire, flood, other natural disasters, power loss, computer systems failure, data network failure, Internet failure, or lapses in compliance with privacy and security mandates. Any such attack, virus, breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. We have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as HIPAA, government enforcement actions and regulatory penalties. 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 damage our reputation, any of which could adversely affect our business.

Nearly all of our operations are currently conducted in locations that may be at risk of damage from fire, earthquakes or other natural disasters.

We currently conduct nearly all of our development and management activities in Carlsbad, California near known wildfire areas and earthquake fault zones. We have taken precautions to safeguard our facilities, including obtaining property and casualty insurance, and implementing health and safety protocols. We have developed an information technology disaster recovery plan. However, any future natural disaster, such as a fire or an earthquake, could cause substantial delays in our operations, damage or destroy our equipment or inventory and cause us to incur additional expenses. A disaster could seriously harm our business, financial condition and results of operations. Our facilities would be difficult to replace and would require substantial lead time to repair or replace. The insurance we maintain against earthquakes, fires, and other natural disasters would not be adequate to cover a total loss of our facilities, may not be adequate to cover our losses in any particular case and may not continue to be available to us on acceptable terms, or at all.

Alphatec Holdings is a holding company with no operations, and unless it receives dividends or other payments from its subsidiaries, it will be unable to fulfill its cash obligations.

As a holding company with no business operations, Alphatec Holdings' material assets consist only of the common stock of its subsidiaries, dividends and other payments received from time to time from its subsidiaries, and the proceeds raised from the sale of debt and equity securities. Alphatec Holdings' subsidiaries are legally distinct from Alphatec Holdings and have no obligation, contingent or otherwise, to make funds available to Alphatec Holdings. Alphatec Holdings will have to rely upon dividends and other payments from its subsidiaries to generate the funds necessary to fulfill its cash obligations. Alphatec Holdings may not be able to access cash generated by its subsidiaries in order to fulfill cash commitments. The ability of Alphatec Spine or SafeOp Surgical to make dividend and other payments to Alphatec Holdings is subject to the availability of funds after taking into account its subsidiaries' funding requirements, the terms of its subsidiaries' indebtedness and applicable state laws.

If we fail to properly manage our anticipated growth, our business could suffer.

We will continue to pursue growth in the number of surgeons using our products, the types of products we offer and the geographic regions where our products are sold. Such anticipated growth has placed and will continue to place significant demands on our managerial, operational and financial resources and systems. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional personnel. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these anticipated growth activities. We are currently focused on increasing the size and effectiveness of our sales force and distribution network, marketing activities, research and development efforts, inventory management systems, management team and corporate infrastructure. If we do not manage our anticipated growth effectively, the quality of our products, our relationships with physicians, distributors and hospitals, and our reputation could suffer, which would have a significant adverse effect on our business, financial condition and results of operations. We must attract and retain qualified personnel and third-party distributors and manage and train them effectively. Personnel qualified in the design, development, production and marketing of our products are difficult to find and hire, and enhancements of information technology systems to support our growth are difficult to implement. We will also need to carefully monitor and manage our surgeon services, our third-party manufacturing resources, quality assurance and efficiency, and the quality assurance and efficiency of our suppliers and distributors. This managing, training and monitoring will require allocation of valuable management resources and significant expense. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced and we may not be able to implement our business strategy.

Risks Related to Our Financial Results, Credit and Certain Financial Obligations and Need for Financing

We may need to raise additional funds in the future and such funds may not be available on acceptable terms, if at all.

At December 31, 2018, our principal sources of liquidity consisted of cash of \$29.1 million, accounts receivable, net of \$15.1 million and available borrowings under our revolving credit facility. We believe that our current sources of liquidity will be sufficient to fund our planned expenditures and meet our obligations for at least 12 months.

We will seek additional funds from public and private equity or debt financings, borrowings under new debt facilities or other sources to fund our projected operating requirements. Our capital requirements will depend on many factors, including:

- the payments due in connection with the settlement of the Orthotec matter;
- the revenues generated by sales of our products;
- the costs associated with expanding our sales and marketing efforts;

- the expenses that we incur from the manufacture of our products by third parties and that we incur from selling our products;
- the costs of developing new products or technologies;
- the cost of obtaining and maintaining FDA or other regulatory approval or clearance for our products and products in development;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the number and timing of acquisitions and other strategic transactions;
- the costs and any payments we may make related to our pending litigation matters;
- the costs associated with increased capital expenditures; and
- the costs associated with our employee retention programs and related benefits.

As a result of these factors, we may need to raise additional funds and such funds may not be available on favorable terms, if at all. Under the securities purchase agreement we entered into in connection with our March 2018 private placement, we are required to issue additional shares of our common stock to purchasers under such agreement if we issue or enter into an agreement to issue any shares of our common stock or securities exercisable or convertible into shares of our common stock, subject to certain permitted exceptions, prior to May 11, 2019 at prices below \$3.15. In addition, rules and regulations of the SEC may restrict our ability to conduct certain types of financing activities, or may affect the timing of and the amounts we can raise by undertaking such activities. For example, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or our public float, is less than \$75 million, the amount that we can raise through primary public offerings of securities in any twelve-month period using one or more registration statements on Form S-3 will be limited to an aggregate of one-third of our public float. As of March 25, 2019, our public float was \$81.7 million.

Furthermore, if we issue additional equity or debt securities to raise additional funds, our existing stockholders may experience dilution and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our potential products or proprietary technologies, or to grant licenses on terms that are not favorable to us. If we cannot raise funds on acceptable terms, we may not be able to repay debt or other liabilities, develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. Any of these events could adversely affect our ability to achieve our development and commercialization goals and have a significant adverse effect on our business, financial condition and results of operations.

If we default on our obligations to make settlement payments to Orthotec LLC, the amounts due under the settlement agreements accelerate and become due and payable.

Any default of our payment obligation under the settlement agreements we entered into with Orthotec LLC, or Orthotec, would give Orthotec the right to declare all of the future payments to be immediately payable. As of December 31, 2018, the outstanding amount to be paid to Orthotec through January 2024 including future interest was \$21.6 million. If acceleration of payments occurs, our business, financial condition and results of operations could be materially and adversely affected.

We have a history of net losses, we expect to continue to incur net losses in the near future, and we may not achieve or maintain profitability.

We have typically incurred net losses from our continuing operations since our inception. As of December 31, 2018, we had an accumulated deficit of \$501.9 million. We have incurred significant net losses since inception and have relied on our ability to fund our operations through revenues from the sale of our products, equity financings and debt financings. As we have incurred losses, successful transition to profitability is dependent upon achieving a level of revenues adequate to support our cost structure. This may not occur and, unless and until it does, we will continue to need to raise additional capital. We may seek additional funds from public and private equity or debt financings, borrowings under new debt facilities or other sources to fund our projected operating requirements. However, there is no guarantee that we will be able to obtain further financing, or do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected.

We may be unable to comply with the covenants of our credit facilities.

We must comply with certain affirmative and negative covenants, including financial covenants and affirmative and negative covenants under the Term Loan with Squadron and our Amended Credit Facility with MidCap Funding IV, LLC (“MidCap”). There can be no assurance that at all times in the future we will satisfy all such financial or other covenants of the Term Loan or the Amended Credit Facility, or obtain any required waiver or amendment, in which event of default the lender could refuse to make further extensions of credit to us and Squadron/MidCap could require all amounts borrowed under the Term Loan and/or the Amended Credit Facility together with accrued interest and other fees, to be immediately due and payable. In addition to allowing the lender to accelerate the loan, several events of default under the Term Loan and the Amended Credit Facility, such as our failure to make required payments of principal and interest and the occurrence of certain bankruptcy or insolvency events, could require us to pay interest at a rate which is up to five percentage points higher than the interest rate effective immediately before the event of default.

An event of default under the Term Loan or the Amended Credit Facility could have a material adverse effect on us. Upon an event of default, if the lender under the Term Loan or the Amended Credit Facility accelerate the repayment of all amounts borrowed, together with accrued interest and other fees, or if the lender select to charge us additional interest, we cannot assure you that we will have sufficient cash available to repay the amounts due, and we may be forced to seek to amend the terms of the Term Loan or the Amended Credit Facility or obtain alternative financing, which may not be available to us on acceptable terms, if at all.

In addition, if we fail to pay amounts when due under the Term Loan or the Amended Credit Facility or upon the occurrence of another event of default, the lender under the Term Loan or the Amended Credit Facility could proceed against the collateral granted to it pursuant to the agreements governing the Term Loan or the Amended Credit Facility. We have granted to the lender under the Term Loan a first priority security interest in substantially all of our assets, other than all accounts receivable, and all securities evidencing our interests in our subsidiaries, as collateral under the agreement governing the Term Loan. We have granted to the lender under the Amended Credit Facility a first priority security interest in our accounts receivable and a second priority lien on substantially all of our other assets, as collateral under the agreement governing Amended Credit Facility. If either lender proceeds against the collateral, such assets would no longer be available for use in our business, which would have a significant adverse effect our business, financial condition and results of operations.

Our quarterly financial results could fluctuate significantly.

Our quarterly financial results are difficult to predict and may fluctuate significantly from period to period, particularly because our sales prospects are uncertain. The level of our revenues and results of operations at any given time will be based primarily on the following factors:

- acceptance of our products by surgeons, patients, hospitals and third-party payers;
- demand and pricing of our products;
- the mix of our products sold, because profit margins differ among our products;
- timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors;
- our ability to grow and maintain a productive sales and marketing organization and independent distributor network;
- regulatory approvals and legislative changes affecting the products we may offer or those of our competitors;
- the effect of competing technological and market developments;
- levels of third-party reimbursement for our products;
- interruption in the manufacturing or distribution of our products;
- our ability to produce or obtain products of satisfactory quality or in sufficient quantities to meet demand; and
- changes in our ability to obtain FDA, state and international approval or clearance for our products.

In addition, until we have a larger base of surgeons using our products, occasional fluctuations in the use of our products by individual surgeons or small groups of surgeons will have a proportionately larger impact on our revenues than for companies with a larger customer base.

Many of the products we may seek to develop and introduce in the future will require FDA approval or clearance. We cannot begin to commercialize any such products in the U.S. without FDA approval or clearance. As a result, it will be difficult for us to forecast demand for these products with any degree of certainty. We cannot assure you that our revenue will increase or be sustained in future periods or that we will be profitable in any future period. Any shortfalls in revenue or earnings from levels expected by our stockholders or by securities or industry analysts could have an immediate and significant adverse effect on the trading price of our common stock in any given period.

Risks Related to Our Intellectual Property; Regulatory Penalties and Litigation

If our patents and other intellectual property rights do not adequately protect our products, we may lose market share to our competitors and be unable to operate our business profitably.

Our success depends significantly on our ability to protect our proprietary rights of the technologies used in our products. We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions to protect our proprietary technology. 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. For example, we cannot assure you that any of our pending patent applications will result in the issuance of patents to us. The U.S. Patent and Trademark Office, or PTO, may deny or require significant narrowing of claims in our pending patent applications, and patents issued as a result of the pending patent applications, if any, may not provide us with significant commercial protection or be issued in a form that is advantageous to us. We could also incur substantial costs in proceedings before the PTO. These proceedings could result in adverse decisions as to the priority of our inventions and the narrowing or invalidation of claims in issued patents. Our issued patents and those that may be issued in the future could subsequently be successfully challenged by others and invalidated or rendered unenforceable, which could limit our ability to stop competitors from marketing and selling related products. In addition, our pending patent applications include claims to aspects of our products and procedures that are not currently protected by issued patents.

Both the patent application process and the process of managing patent disputes can be time consuming and expensive. Competitors may be able to design around our patents or develop products that provide outcomes that are comparable to our products but fall outside of the scope of our patent protection. Although we have entered into confidentiality agreements and intellectual property assignment agreements with certain of our employees, consultants and advisors as one of the ways we seek to protect our intellectual property and other proprietary technology, such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements. In the event a competitor infringes upon one of our patents or other intellectual property rights, enforcing those patents and rights may be difficult and time consuming. Even if successful, litigation to defend our patents against challenges or to enforce our intellectual property rights could be expensive and time consuming and could divert management's attention from managing our business. Moreover, we may not have sufficient resources to defend our patents against challenges or to enforce our intellectual property rights.

The medical device industry is characterized by patent and other intellectual property litigation and we could become subject to litigation that could be costly, result in the diversion of management's time and efforts, require us to pay damages, and/or prevent us from marketing our existing or future products.

The medical device industry is characterized by extensive litigation and administrative proceedings over patent and other intellectual property rights. Determining whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Our competitors may assert that our products, the components of those products, the methods of using those products, or the methods we employ in manufacturing or processing those products are covered by patents held by them. In addition, they may claim that their patents have priority over ours because their patents were filed first. Because patent applications can take many years to issue, there may be applications now pending of which we are unaware, which may later result in issued patents that our products may infringe. There could also be existing patents that one or more components of our products may be inadvertently infringing, of which we are unaware. As the number of participants in the market for spine disorder devices and treatments increases, the possibility of patent infringement claims against us also increases.

Any such claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation. If the relevant patents are upheld as valid and enforceable and we are found to infringe, we could be required to pay substantial damages, including treble, or triple, damages if an infringement is found to be willful, and/or royalties and we could be prevented from selling our products unless we could obtain a license or were 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 those patents, and any such redesign, if possible, may be costly. 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, either of which could have a significant adverse effect on our business, financial condition and results of operations. We may lose market share to our competitors if we fail to protect our intellectual property rights.

In addition, in order to further our product development efforts, from time to time we enter into agreements with surgeons to develop new products. As consideration for product development activities rendered pursuant to these agreements, in certain instances we have agreed to pay such surgeons royalties on products developed by cooperative involvement between us and such surgeons. There can be no assurance that surgeons with whom we have entered into such an arrangement will not claim to be entitled to a royalty even if we do not believe that such products were developed by cooperative involvement between us and such surgeons. Any such claim against us, even those without merit, may cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business and harm our reputation.

We are currently involved in a patent litigation action involving NuVasive, Inc. and, if we do not prevail in this action, we could be liable for past damages and might be prevented from making, using, selling, offering to sell, importing or exporting certain of our products.

On February 15, 2018, NuVasive, Inc. (“NuVasive”) filed suit against us in the U.S. District Court for the Southern District of California, alleging that certain of our products infringe, or contribute to the infringement of, U.S. patents owned by NuVasive. NuVasive is a large, publicly-traded corporation with significantly greater financial resources than us.

Intellectual property litigation is expensive, complex and lengthy and its outcome is difficult to predict. We may also be subject to negative publicity due to the litigation. Pending or future patent litigation against us or any strategic partners or licensees may force us or any strategic partners or licensees to stop or delay developing, manufacturing or selling potential products that are claimed to infringe a third party’s intellectual property, unless that party grants us or any strategic partners or licensees rights to use its intellectual property, and may significantly divert the attention of our technical and management personnel. In the event that our right to market any of our products is successfully challenged, and if we fail to obtain a required license or are unable to design around a patent, our business, financial condition or results of operations could be materially adversely affected. In such cases, we may be required to obtain licenses to patents or proprietary rights of others in order to continue to commercialize our products. However, we may not be able to obtain any licenses required under any patents or proprietary rights of third parties on acceptable terms, or at all and any licenses may require substantial royalties or other payments by us. Even if any strategic partners, licensees or we were able to obtain rights to the third party’s intellectual property, these rights may be non-exclusive, thereby giving our competitors access to the same intellectual property. Furthermore, if we are found to infringe patent claims of a third party, we may, among other things, be required to pay damages, including up to treble damages and attorney’s fees and costs, which may be substantial.

An unfavorable outcome for us in this patent litigation could significantly harm our business if such outcome makes us unable to commercialize some of our current or potential products or cease some of our business operations. In addition, costs of defense and any damages resulting from the litigation may materially adversely affect our business and financial results. The litigation may also harm our relationships with existing customers and subject us to negative publicity, each of which could harm our business and financial results.

If we become subject to product liability claims, we may be required to pay damages that exceed our insurance coverage.

Our business exposes us to potential product liability claims that are inherent in the testing, design, manufacture and sale of medical devices for spine surgery procedures. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. To date, our products have not been the subject of any material product liability claims. We carry product liability insurance. However, our existing product liability insurance coverage may be inadequate to satisfy liabilities we might incur. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or our inability to secure coverage in the future on commercially reasonable terms, if at all. In addition, if our product liability insurance proves to be inadequate to pay a damage award, we may have to pay the excess out of our cash reserves, which could harm our financial condition. If longer-term patient results and experience indicate that our products or any component of our products cause tissue damage, motor impairment or other adverse effects, we could be subject to significant liability. Even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and result in the diversion of management’s attention from managing our business. If a product liability claim or series of claims is brought against us in excess of our insurance coverage limits, our business could suffer and our financial condition, results of operations and cash flow could be materially adversely impacted.

Because biologics products entail a potential risk of communicable disease to human recipients, we may be the subject of product liability claims regarding our biologics products.

Our biologics products may expose us to additional potential product liability claims. The development of biologics products entails a risk of additional product liability claims because of the risk of transmitting disease to human recipients, and substantial product liability claims may be asserted against us. In addition, successful product liability claims made against one of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. Even a meritless or unsuccessful product liability claim could harm our reputation in the industry, lead to significant legal fees and result in the diversion of management’s attention from managing our business.

Any claims relating to our improper handling, storage or disposal of biological, hazardous and radioactive materials could be time consuming and costly.

The manufacture of certain of our products, including our biologics products, involves the controlled use of biological, hazardous and/or radioactive materials and waste. Our business and facilities and those of our suppliers are subject to foreign, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials and waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for damages or penalized with fines. This liability could exceed our resources and any applicable insurance. 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. We may incur significant expenses in the future relating to any failure to comply with environmental laws. Any such future expenses or liability could have a significant negative impact on our business, financial condition and results of operations.

We may be subject to damages resulting from claims that we, our employees or our independent 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 previously employed at other medical device companies, including our competitors or potential competitors. Many of our independent 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 distributors have inadvertently or otherwise used or disclosed the trade secrets or other proprietary information of our competitors. In addition, we have been and may in the future be subject to claims that we caused an employee or independent distributor to break the terms of his or her non-competition agreement or non-solicitation agreement. Litigation may be necessary to defend against such claims. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and/or personnel. A loss of key personnel and/or their work product could hamper or prevent our ability to commercialize products, which could have an adverse effect on our business, financial condition and results of operations.

Risks Related to Our Common Stock

If we fail to continue to meet all applicable NASDAQ Global Select Market requirements and our common stock is delisted, the delisting could adversely affect the market liquidity of our common stock, impair the value of your investment and harm our business.

Our common stock is currently listed on the NASDAQ Global Select Market. In order to maintain that listing, we must satisfy minimum financial and other requirements. Although we are currently in compliance with applicable NASDAQ Global Select Market requirements, if we fail to continue to meet all such requirements in the future and NASDAQ determines to delist our common stock, the delisting could substantially decrease trading in our common stock and adversely affect the market liquidity of our common stock; adversely affect our ability to obtain financing on acceptable terms, if at all, to continue our operations; and may result in the potential loss of confidence by investors, suppliers, customers and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline further and stockholders may lose some or all of their investment.

We expect that the price of our common stock will fluctuate substantially and the market price of our common stock may decline in value in the future.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including those described elsewhere in this “Risk Factors” section and the following:

- volume and timing of orders for our products;
- quarterly variations in our or our competitors’ results of operations;
- our announcement or our competitors’ announcements regarding new products, product enhancements, significant contracts, number of distributors, number of hospitals and surgeons using products, acquisitions, and collaborative or strategic investments;
- announcements of technological or medical innovations for the treatment of spine pathology;
- changes in earnings estimates or recommendations by securities analysts;
- our ability to develop, obtain regulatory clearance or approval for, and market new and enhanced products on a timely basis;
- changes in healthcare policy in the U.S.;

- product liability claims or other litigation involving us;
- sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders;
- changes in governmental regulations or in the status of our regulatory approvals, clearances or applications;
- disputes or other developments with respect to intellectual property rights;
- changes in the availability of third-party reimbursement in the U.S.;
- changes in accounting principles; and
- general market conditions and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

We may become involved in securities class action litigation that could divert management’s attention and harm our business.

The stock market in general, The NASDAQ Global Select Market and the market for medical device companies in particular, has experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. Further, the market prices of securities of medical device companies have been particularly volatile. In the past, following periods of volatility in the market price of a particular company’s securities, securities class action litigation has often been brought against that company. We may become involved in this type of litigation in the future. Litigation is often expensive and diverts management’s attention and resources, which could materially harm our financial condition, results of operations and business.

Securities analysts may not provide coverage of our common stock or may issue negative reports, which may have a negative impact on the market price of our common stock.

Securities analysts may not provide research coverage of our common stock. If securities analysts do not cover our common stock, the lack of research coverage may cause the market price of our common stock to decline. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about our business. If one or more of the analysts who elects to cover us downgrades our stock, our stock price would likely decline rapidly. If one or more of these analysts ceases coverage of us, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, it may be difficult for companies such as ours, with smaller market capitalizations, to attract independent financial analysts that will cover our common stock. This could have a negative effect on the market price of our stock.

Because of their significant stock ownership, our executive officers, directors and principal stockholders will be able to exert control over us and our significant corporate decisions.

Based on shares outstanding at March 25, 2019, our executive officers, directors and stockholders holding more than 5% of our outstanding common stock and their affiliates, in the aggregate, beneficially own approximately 34.7% of our outstanding common stock. As a result, these persons will have the ability to impact significantly the outcome of all matters requiring stockholder approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets.

This concentration of ownership may harm the market price of our common stock by, among other things:

- delaying, deferring or preventing our change in control;
- impeding a merger, consolidation, takeover or other business combination involving us;
- causing us to enter into transactions or agreements that are not in the best interests of all of our stockholders; or
- reducing our public float held by non-affiliates.

Anti-takeover provisions in our organizational documents and change of control provisions in some of our employment agreements and agreements with distributors, and in some of our outstanding debt agreements, as well as the terms of our redeemable preferred stock, may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely.

Certain provisions of our amended and restated certificate of incorporation and restated by-laws could discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management. These provisions:

- allow the authorized number of directors to be changed only by resolution of our Board of Directors;
- allow vacancies on our Board of Directors to be filled only by resolution of our Board of Directors;
- authorize our Board of Directors to issue, without stockholder approval, blank check preferred stock that, if issued, could operate as a “poison pill” to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our Board of Directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;
- establish advance notice requirements for stockholder nominations to our Board of Directors and for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call stockholder meetings.

Some of our employment agreements and all of our restricted stock agreements, incentive stock option agreements, performance-based stock units and restricted common stock provide for accelerated vesting of benefits, including full vesting of restricted stock and options, upon a change of control. A limited number of our agreements with our distributors include a provision that extends the term of the distribution agreement upon a change in control and makes it more difficult for us or our successor to terminate the agreement. These provisions may discourage or prevent a change of control.

In addition, in the event of a change of control, we would be required to redeem all outstanding shares of our redeemable preferred stock for an aggregate of \$29.9 million, at the price of \$9.00 per share. Further, our amended and restated certificate of incorporation permits us to issue additional shares of preferred stock. The terms of our redeemable preferred stock or any new preferred stock we may issue could have the effect of delaying, deterring or preventing a change in control.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (“Section 382”), if a corporation undergoes an “ownership change,” generally defined as a cumulative change in its equity ownership by “5-percent shareholders” of greater than 50 percentage points (by value) over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and certain other pre-change tax attributes (such as research tax credits) to offset its post-change taxable income and taxes, as applicable, may be limited. We have completed multiple rounds of financing and entered into transactions which may have resulted in an ownership change or could result in an ownership change in the future. We have not completed an analysis of our equity shifts which occurred during 2018 (and the period prior to the issuance of our 2018 annual report) pursuant to Section 382. Therefore, it is possible that we have experienced an ownership change pursuant to Section 382. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. As a result, our ability to use our NOLs and research and development credit carryforwards to offset our U.S. federal taxable income and taxes, as applicable, may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, similar rules may apply and there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

We could be subject to changes in our tax rates, new tax legislation or additional tax liabilities.

The U.S. government has recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities. These changes include, among others, (i) a permanent reduction to the corporate income tax rate, (ii) a partial limitation on the deductibility of business interest expense, (iii) a shift of the U.S. taxation of multinational corporations from a tax on worldwide income to a territorial system (along with certain rules designed to prevent erosion of the U.S. income tax base) and (iv) a one-time tax on accumulated offshore earnings held in cash and illiquid assets, with the latter taxed at a lower rate. The overall impact of this tax reform is uncertain, and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the newly enacted federal tax law.

Our tax returns and other tax matters also are subject to examination by the U.S. Internal Revenue Service and other tax authorities and governmental bodies. We regularly assess the likelihood of an adverse outcome resulting from these examinations to determine the adequacy of our provision for taxes. We cannot guarantee the outcome of these examinations. If our effective tax rates were to increase, particularly in the U.S., or if the ultimate determination of our taxes owed is for an amount in excess of amounts previously accrued, our financial condition, operating results and cash flows could be adversely affected.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and, in particular, the description of our "Business" set forth in Item 1, the "Risk Factors" set forth in this Item 1A and our "Management's Discussion and Analysis of Financial Condition and Results of Operations" set forth in Item 7 contain or incorporate a number of forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including statements regarding:

- our estimates regarding anticipated operating losses, future revenue, expenses, capital requirements, uses and sources of cash and liquidity, including our anticipated revenue growth and cost savings;
- our ability to meet the financial covenants under our credit facilities;
- our ability to ensure that we have effective disclosure controls and procedures;
- our not realizing the full economic benefit from the Globus Transaction, including as a result of indemnification claims under the definitive agreement and the retention by us of certain liabilities associated with the international business, and our ability to meet our obligations under the Globus supply agreement;
- our ability to meet and potential liability from not meeting the payment obligations under the Orthotec settlement agreement;
- our ability to regain and maintain compliance with the quality requirements of the FDA;
- our ability to market, improve, grow, commercialize and achieve market acceptance of any of our products or any product candidates that we are developing or may develop in the future;
- our beliefs about the features, strengths and benefits of our products;
- our ability to continue to enhance our product offerings, outsource our manufacturing operations and expand the commercialization of our products, and the effect of our strategy;
- our expectations about the timing, costs and benefits of the restructuring and outsourcing of our manufacturing operations;
- our beliefs about the ability of our supplier relationships and quality processes to fulfill our production requirements;
- our ability to successfully integrate, and realize benefits from licenses and acquisitions;
- the effect of any existing or future federal, state or international regulations on our ability to effectively conduct our business;
- our estimates of market sizes and anticipated uses of our products;
- our business strategy and our underlying assumptions about market data, demographic trends, reimbursement trends and pricing trends;
- our ability to achieve profitability, and the potential need to raise additional funding;
- our ability to maintain an adequate sales network for our products, including to attract and retain independent distributors;
- our ability to enhance our U.S. distribution network;
- our ability to increase the use and promotion of our products by training and educating surgeons and our sales network;
- our ability to attract and retain a qualified management team, as well as other qualified personnel and advisors;
- our ability to enter into licensing and business combination agreements with third parties and to successfully integrate the acquired technology and/or businesses;
- our management team's ability to accommodate growth and manage a larger organization;
- our ability to protect our intellectual property, and to not infringe upon the intellectual property of third parties;

- the effects of the escalating cost of medical products and services and the effects of market demand, government regulation, third-party reimbursement policies and societal pressures on the healthcare industry and our business;
- our ability to meet or exceed the industry standard in clinical and legal compliance and corporate governance programs;
- our beliefs about our competitors and the principal competitive factors in our market and the effect of non-operative treatments on demand for our products;
- potential liability resulting from litigation;
- our beliefs about our employee relations;
- potential liability resulting from a governmental review of our business practices;
- our beliefs about the usefulness of the non-GAAP financial measures included in this Annual Report on Form 10-K;
- our beliefs with respect to our critical accounting policies and the reasonableness of our estimates and assumptions; and
- other factors discussed elsewhere in this Annual Report on Form 10-K or any document incorporated by reference herein or therein.

Any or all of our forward-looking statements in this Annual Report may turn out to be wrong. They can be affected by inaccurate assumptions by known or unknown risks and uncertainties. Many factors mentioned in our discussion in this Annual Report on Form 10-K will be important in determining future results. Consequently, no forward-looking statement can be guaranteed. Actual future results may vary materially from expected results.

We also provide a cautionary discussion of risks and uncertainties under “Risk Factors” in Item 1A of this Annual Report. These are factors that we think could cause our actual results to differ materially from expected results. Other factors besides those listed there could also adversely affect us.

Without limiting the foregoing, the words “believe,” “anticipate,” “plan,” “expect,” “may,” “could,” “would,” “seek,” “intend,” and similar expressions are intended to identify forward-looking statements. There are a number of factors and uncertainties that could cause actual events or results to differ materially from those indicated by such forward-looking statements, many of which are beyond our control, including the factors set forth under “Item 1A Risk Factors.” In addition, the forward-looking statements contained herein represent our estimate only as of the date of this filing and should not be relied upon as representing our estimate as of any subsequent date. While we may elect to update these forward-looking statements at some point in the future, we specifically disclaim any obligation to do so to reflect actual results, changes in assumptions or changes in other factors affecting such forward-looking statements, except as required by applicable law.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate office is located in Carlsbad, California. The table below provides selected information regarding our current material operating location.

Location	Use	Approximate Square Footage	Lease Expiration
Carlsbad, California	Corporate headquarters and product design	76,693	July 2021

Item 3. Legal Proceedings

We are and may become involved in various legal proceedings arising from our business activities. While the Company has no material accruals for pending litigation or claims for which accrual amounts are not disclosed in the Company’s consolidated financial statements, litigation is inherently unpredictable, and depending on the nature and timing of a proceeding, an unfavorable resolution could materially affect our future consolidated results of operations, cash flows or financial position in a particular period. We assess contingencies to determine the degree of probability and range of possible loss for potential accrual or disclosure in our consolidated financial statements. An estimated loss contingency is accrued in our consolidated financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Because litigation is inherently unpredictable and unfavorable resolutions could occur, assessing contingencies is highly subjective and requires judgments about future events. When

evaluating contingencies, we may be unable to provide a meaningful estimate due to a number of factors, including the procedural status of the matter in question, the presence of complex or novel legal theories, and/or the ongoing discovery and development of information important to the matters. In addition, damage amounts claimed in litigation against us may be unsupported, exaggerated or unrelated to reasonably possible outcomes, and as such are not meaningful indicators of our potential liability.

Refer to Note 6 of our Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for further information regarding the NuVasive, Inc. litigation.

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

Our common stock is traded on The NASDAQ Global Select Market under the symbol “ATEC.”

Stockholders

As of March 25, 2019, there were approximately 337 holders of record of an aggregate 46,847,652 outstanding shares of our common stock.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. In addition, our ability to pay dividends is currently restricted by the terms of the Amended Credit Facility with MidCap and the Term Loan with Squadron.

Issuer Purchases of Equity Securities

Under the terms of our 2016 Equity Incentive Plan and our Amended and Restated 2005 Employee, Director and Consultant Stock Plan, as amended, which we refer to collectively as the Stock Plans, and prior to the expiration of the Stock Plans in May 2026, we are permitted to award shares of restricted stock to our employees, directors and consultants. These shares of restricted stock are subject to a lapsing right of repurchase by us. We may exercise this right of repurchase in the event that a restricted stock recipient’s employment, directorship or consulting relationship with us terminates prior to the end of the vesting period. If we exercise this right, we are required to repay the purchase price paid by or on behalf of the recipient for the repurchased restricted shares. Repurchased shares are returned to the Stock Plans and are available for future awards under the terms of the Stock Plans. There were no shares of common stock repurchased during the years ended December 31, 2018 or 2017.

Item 6. Selected Financial Data

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this report include the identification of certain trends and other statements that may predict or anticipate future business or financial results that are subject to important factors that could cause our actual results to differ materially from those indicated. See “Item 1A Risk Factors” included elsewhere in this Annual Report on Form 10-K.

Overview

We are a medical technology company focused on the design, development, and advancement of technology for better surgical treatment of spinal disorders. We are dedicated to revolutionizing the approach to spine surgery. We have a broad product portfolio designed to address the majority of U.S. market for fusion-based spinal disorder solutions. We intend to drive growth by exploiting our collective spine experience and investing in the research and development to continually differentiate our solutions and improve spine surgery. We believe our future success will be fueled by introducing market-shifting innovation to the spine market, and we believe that we are well-positioned to capitalize on current spine market dynamics.

We market and sell our products in the U.S. through a network of independent distributors and direct sales representatives. An objective of our leadership team is to deliver increasingly consistent, predictable growth. To accomplish this, we have partnered more closely with new and existing distributors to create a more dedicated and loyal sales channel for the future. We have added, and intend to continue to add, new high-quality dedicated distributors to expand future growth. We believe this will allow us to reach an untapped market of surgeons, hospitals, and national accounts across the U.S., as well as better penetrate existing accounts and territories.

We have made significant progress in the transition of our sales channel since early 2017, driving the percent of sales contributed by our strategic distribution channel from approximately 59% for the year ended December 31, 2017 to 80% for the year ended December 31, 2018. Going forward, we intend to continue to relentlessly drive toward a fully exclusive network of independent and direct sales agents. Recent consolidation in the industry is facilitating the process, as large, seasoned agents are seeking opportunities to re-enter the spine market by partnering with spine-focused companies that have broad, growing product portfolios.

Sale of International Business

On September 1, 2016, we completed the sale of our international distribution operations and agreements, including our wholly-owned subsidiaries in Japan, Brazil, Australia, China and Singapore and substantially all of the assets of our other sales operations in the United Kingdom and Italy (“International Business”), to an affiliate of Globus (“Globus Transaction”). Following the closing of the Globus Transaction, we now operate in the U.S. market only and are restricted from marketing and selling our products in foreign markets pursuant to the terms and conditions, and for the time periods, set forth in the definitive documents related to the Globus Transaction.

Revenue and Expense Components

The following is a description of the primary components of our revenues and expenses:

Revenues. We derive our revenues primarily from the sale of spinal surgery implants used in the treatment of spine disorders. Spinal implant products include pedicle screws and complementary implants, interbody devices, plates, and tissue-based materials. Our revenues are generated by our direct sales force and independent distributors. Our products are requested directly by surgeons and shipped and billed to hospitals and surgical centers. Currently, most of our business is conducted with customers within markets in which we have experience and with payment terms that are customary to our business. We may defer revenues until the time of collection if circumstances related to payment terms, regional market risk or customer history indicate that collectability is not reasonably assured.

Cost of revenues. Cost of revenues consists of direct product costs, royalties, milestones and the amortization of purchased intangibles. Our product costs consist primarily of direct labor, overhead, and raw materials and components. The product costs of certain of our biologics products include the cost of procuring and processing human tissue. We incur royalties related to the technologies that we license from others and the products that are developed in part by surgeons with whom we collaborate in the product development process. Amortization of purchased intangibles consists of amortization of developed product technology.

Research and development. Research and development expense consists of costs associated with the design, development, testing, and enhancement of our products. Research and development expense also includes salaries and related employee benefits, research-related overhead expenses, fees paid to external service providers in both cash and equity, and costs associated with our Scientific Advisory Board and Executive Surgeon Panels.

Sales, general and administrative. Sales, general and administrative expense consists primarily of salaries and related employee benefits, sales commissions and support costs, depreciation of our surgical instruments, regulatory affairs, quality assurance costs, professional service fees, travel, medical education, trade show and marketing costs, insurance and legal expenses.

Litigation-related expenses. Litigation-related expenses are costs incurred for our ongoing litigation, primarily with NuVasive, Inc.

Transaction related expenses. Reflects the recognition of transaction expense incurred as part of the SafeOp acquisition.

Gain on settlement. Gain on settlement consists of a gain of approximately \$6.2 million for the year ended December 31, 2018 as a result of the settlement agreement with Elite Medical Holdings and Pac 3 Surgical, pursuant to which we made a cash payment of \$0.4 million as the final and total compensation under the collaboration and related amendment. The gain reflects the reversal of accrued obligations previously recorded under the collaboration.

Restructuring expenses. Restructuring expense consists of severance, social plan benefits and related taxes in connection with our ongoing cost rationalization efforts, including the termination of our manufacturing operations in California in 2017.

Loss on debt extinguishment. Loss on debt extinguishment is comprised of all amounts previously recorded as debt issuance costs related to the Globus facility that was repaid in full.

Total other income (expense). Total other income (expense) includes interest income, interest expense, changes in the fair value of the warrant liabilities, gains and losses from foreign currency exchanges and other non-operating gains and losses.

Income tax benefit. Income tax benefit from continuing operations primarily consists of release of the valuation allowance from the SafeOp acquisition, partially offset by state taxes.

Results of Operations

The first table below sets forth our statements of operations data for the periods presented. Our historical results are not necessarily indicative of the operating results that may be expected in the future. The amounts included for the year ended December 31, 2018 reflects results from our newly acquired subsidiary from the period of March 9, 2018 through December 31, 2018.

	Year Ended December 31,	
	2018	2017
(in thousands)		
Revenues:		
Revenue from U.S. products	\$ 83,656	\$ 86,925
Revenue from international supply agreement	8,038	14,814
Total revenues	91,694	101,739
Cost of revenues	28,457	33,517
Gross profit	63,237	68,222
Operating expenses:		
Research and development	9,984	4,920
Sales, general and administrative	72,509	69,959
Litigation-related expenses	5,683	308
Amortization of intangible assets	738	688
Transaction-related expenses	1,550	—
Gain on settlement	(6,168)	—
Restructuring expenses	1,381	2,206
Gain on sale of assets	—	(856)
Total operating expenses	85,677	77,225
Operating loss	(22,440)	(9,003)
Other income (expense):		
Interest and other expense, net	(7,139)	(7,615)
Loss on debt extinguishment	(590)	—
Gain on change in fair value of warrants	—	12,044
Total other income (expense)	(7,729)	4,429
Loss from continuing operations before taxes	(30,169)	(4,574)
Income tax (benefit)	(1,361)	(34)
Loss from continuing operations	(28,808)	(4,540)
Income (Loss) from discontinued operations, net of taxes	(167)	2,246
Net loss	(28,975)	(2,294)
Recognition of beneficial conversion feature - Series B Preferred Stock	(13,488)	—
Net loss attributable to common shareholders	<u>\$ (42,463)</u>	<u>\$ (2,294)</u>

	Year Ended December 31,	
	2018	2017
Revenues by source:	(in thousands)	
Revenue from U.S. products	\$ 83,656	\$ 86,925
Revenue from international supply agreement	8,038	14,814
Total revenues	<u>\$ 91,694</u>	<u>\$ 101,739</u>
Gross profit by source:		
Revenue from U.S. products	\$ 62,740	\$ 66,598
Revenue from international supply agreement	497	1,624
Total gross profit	<u>\$ 63,237</u>	<u>\$ 68,222</u>
Gross profit margin by source:		
Revenue from U.S. products	75.0%	76.6%
Revenue from international supply agreement	6.2%	11.0%
Total gross profit margin	69.0%	67.1%

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

Revenues. Revenues were \$91.7 million for the year ended December 31, 2018 compared to \$101.7 million for the year ended December 31, 2017, representing a decrease of \$10.0 million, or 9.8%.

Revenue from U.S. products was \$83.7 million for the year ended December 31, 2018 compared to \$86.9 million for the year ended December 31, 2017, representing a decrease of \$3.2 million, or 3.7%. The decrease in revenue for the year ended December 31, 2018 was attributed primarily to our decision to exit the stocking distributor model and terminate distributor relationships that are not representative of our long-term business strategy. While our U.S. product revenue declined for the year ended December 31, 2018 compared to the year ended December 31, 2017, revenues from our strategic distribution channel increased for the year ended December 31, 2018 as detailed below (in thousands):

	Year Ended December 31,		Increase (Decrease)	
	2018	2017	\$	%
U.S. revenues by distributor type:				
Strategic distribution	\$ 67,124	80% \$ 51,701	59%	\$ 15,423 30%
Legacy and terminated distribution	16,532	20% 35,224	41%	(18,692) -53%
Total U.S. revenues	<u>\$ 83,656</u>	<u>100% \$ 86,925</u>	<u>100%</u>	<u>\$ (3,269) -4%</u>

Revenue from international supply agreement, which is attributed to sales to Globus under which we supply our products for Globus' international customers, was \$8.0 million for the year ended December 31, 2018 compared to \$14.8 million for the year ended December 31, 2017, representing a decrease of \$6.8 million. We expect these revenues to continue to decrease over the next several quarters, as Globus continues to register its own products in international markets.

Cost of revenues. Total cost of revenues was \$28.5 million for the year ended December 31, 2018 compared to \$33.5 million for the year ended December 31, 2017, representing a decrease of \$5.0 million, or 14.9%.

Cost of revenue from U.S. products for the year ended December 31, 2018 increased to \$20.9 million compared to \$20.3 million for the year ended December 31, 2017. The increase is primarily due to an increase in excess and obsolescence expense as we are launching newly developed products and phasing out older, legacy products.

Cost of revenues from international supply agreement were \$7.5 million for the year ended December 31, 2018 compared to \$13.2 million for the year ended December 31, 2017, representing a decrease of \$5.7 million. These decreases were attributed to a reduction in sales volumes and related costs under the supply agreement with Globus.

Gross profit. Total gross profit was \$63.2 million for the year ended December 31, 2018 compared to \$68.2 million for the year ended December 31, 2017, representing a decrease of \$5.0 million, or 7.3%.

Gross profit margin from U.S. product revenue was 75.0% for the year ended December 31, 2018 compared to 76.6% for the year ended December 31, 2017. The decrease is attributable to an increase in excess and obsolescence expense as we are launching newly developed products and phasing out older products.

Gross profit margin from international supply agreement revenue was 6.2% for the year ended December 31, 2018 compared to 11.0% for the year ended December 31, 2017. The changes in gross margin from other revenues was primarily related to the impact of fixed minimum royalty costs product mix, and to a lesser extent, decrease in average selling price for certain products.

Research and development expense. Research and development expense increased \$5.1 million, or 104.1%, during the year ended December 31, 2018 compared to the year ended December 31, 2017. This increase was primarily related to the integration of the SafeOp technology into our product portfolio, including achievement of the first SafeOp milestone, an increase of personnel related costs as well as increased product development costs and related research expenses to support the alpha launch of our Kodiak and IdentiTi systems, which occurred in the fourth quarter of 2018. We expect research and development expenses to increase in future periods as we hire additional engineering and development talent, and continue to invest in our product pipeline.

Sales, general and administrative expense. Sales, general and administrative expense increased \$2.5 million, or 3.6%, during the year ended December 31, 2018 compared to the year ended December 31, 2017. The increase for the year ended December 31, 2018 was primarily related to expenses with our newly acquired business entity SafeOp, marketing efforts including additional headcount to support the alpha launch of our new products OsseoScrew, Kodiak and IdentiTi. Additionally, our stock-based compensation, which includes additional equity awards to our distributors as we continue to focus on expanding our dedicated sales channel, increased in 2018, partially offset by lower instruments depreciation. We expect our sales, general and administrative expenses to increase in absolute dollars in line with expected increase in our U.S. product revenue.

Litigation-related expenses. Litigation-related expenses of \$5.7 million for the year ended December 31, 2018 and \$0.3 million for the year ended December 31, 2017 are costs incurred for our ongoing litigation, primarily with NuVasive, Inc. We expect these expenses to decrease in future periods.

Amortization of acquired intangible assets. Amortization of acquired intangible assets was \$0.7 million for both the year ended December 31, 2018 and for the year ended December 31, 2017. This expense represents amortization in the period for intangible assets associated with general business assets, intellectual property, licenses and other assets obtained in acquisitions and licensing agreements.

Transaction-related expenses. Transaction-related expenses of \$1.6 million for the year ended December 31, 2018 are attributed to advisory and legal fees and other transaction costs incurred in connection with the SafeOp acquisition.

Gain on settlement. In February 2018, we reached a settlement agreement with Elite Medical Holdings and Pac 3 Surgical, pursuant to which we made a cash payment of \$0.4 million as the final and total compensation under a collaboration agreement and related amendment between the Company and these third parties. In addition, the parties agreed to release each other and waive any and all rights and claims arising from the collaboration agreement and amendment. We recorded a gain of approximately \$6.2 million for the year ended December 31, 2018, reflecting the reversal of accrued obligations previously recorded under the collaboration agreement.

Restructuring expense. Restructuring expense was \$1.4 million for the year ended December 31, 2018 compared to \$2.2 million for the year ended December 31, 2017. Beginning in late 2016 with the sale of our international business to Globus and continuing in 2018, we began a corporate initiative to rationalize our cost structure in line with our reduced operations and implemented a strategic repositioning of the Company, including the changeover of our senior leadership team, and have incurred related restructuring costs consisting primarily of severance and other personnel charges.

Gain on sale of assets. During the year ended December 31, 2017, we recorded a net gain of \$0.9 million pursuant to a sale of certain inventory and intellectual property to a third party for \$1.0 million in consideration, payable via a credit to future minimum royalties owed to the third party under an existing exclusive license agreement.

Interest and other expense, net. Interest and other expense, net, decreased \$0.5 million during the year ended December 31, 2018 compared to the year ended December 31, 2017, primarily due to lower average principal balances during 2018 due to the payoff of the MidCap Term Loan in August and the Globus facility in November, which had a higher interest rate compared to our Squadron Term Loan.

Loss on debt extinguishment. As part of the payoff of the Globus facility in the fourth quarter of 2018, the remaining balance of all amounts previously recorded as debt issuance costs of \$0.6 million were recorded as a loss on debt extinguishment.

Gain on change in fair value of warrants. Gain on change in fair value of warrants of \$12.0 million in 2017 represented the reduction of the fair value of the warrants issued to certain investors during the period when such warrants were temporarily classified as a liability in the fourth quarter of 2017 as we were potentially required to settle the warrants with cash during this time. On December 29, 2017, the potential to cash settlement was alleviated when two board members who are warrant holders entered into recusal agreements, pursuant to which they agreed to abstain from voting on any fundamental transaction so long as their warrants are outstanding. Accordingly, the warrants were re-classified to equity on December 29, 2017.

Income tax benefit. The income tax provision in continuing operations was a benefit of \$1.4 million for the year ended December 31, 2018, compared to less than \$0.1 million for the year ended December 31, 2017. The 2018 income tax benefit from continuing operations primarily consists of the release of the valuation allowance regarding the SafeOp acquisition, partially offset by state taxes. The 2017 income tax benefit from continuing operations primarily consists of the reversal of an uncertain tax position and the recognition of refundable federal minimum tax credits, partially offset by state taxes. ASC 740-20 requires total income tax expense or benefit to be allocated among continuing operations, discontinued operations, extraordinary items, other comprehensive income and items charged directly to shareholders' equity. This allocation is referred to as intra-period tax allocation. Accordingly, we are required to allocate the provision or benefit for income taxes between continuing operations and discontinued operations.

Recognition of beneficial conversion feature. The recognition of beneficial conversion feature of \$13.5 million is the calculated intrinsic value, which is measured as of the commitment date (i.e., the issuance date) of the Series B Preferred Stock, and required to be recorded as a discount in the Series B Preferred Stock with a corresponding entry to equity upon the Company obtaining stockholder approval of the transaction. Furthermore, due to the fact that the Series B Preferred Stock automatically converted into shares of the Company's common stock upon obtaining stockholder approval, the full discount in the Series B Preferred Stock that was created by the recognition of the beneficial conversion feature is fully accreted as a deemed dividend which increases the Company's accumulated deficit and net loss attributable to common shareholders.

Liquidity and Capital Resources

We have incurred significant net losses since inception and relied on our ability to fund our operations through revenues from the sale of our products, debt financings and equity financings, including our private placement in March 2018 ("2018 Private Placement"). As we have incurred losses, a successful transition to profitability is dependent upon achieving a level of revenues adequate to support our cost structure. This may not occur and, unless and until it does, we will continue to need to raise additional capital. At December 31, 2018, our principal sources of liquidity consisted of cash of \$29.1 million and accounts receivable (net) of \$15.1 million. We believe that our current available cash, combined with the availability of our expanded credit facility with Squadron Capital (described below) and draws on our revolving credit facility, will be sufficient to fund our planned expenditures and meet our obligations for at least 12 months following our financial statement issuance date.

Historically, our principal sources of cash have included customer payments from the sale of our products, proceeds from the issuance of common and preferred stock and proceeds from the issuance of debt. Our principal uses of cash have included cash used in operations, payments relating to purchases of surgical instruments, repayments of borrowings under the Amended Credit Facility, payments due under the Orthotec settlement agreement and acquisitions of businesses and intellectual property rights. We expect that our principal uses of cash in the future will be similar. We expect that, as our revenues grow, our sales and marketing, research and development expenses and our capital expenditures will continue to grow and, as a result, we will need to generate significant net revenues to achieve profitability. Operating losses and negative cash flows may continue for at least the next year as we continue to incur costs related to the execution of our operating plan and introduction of new products.

In March 2018, we entered into financing transactions to raise an aggregate of \$50 million, through a \$45.2 million private placement of Series B Convertible Preferred Stock and warrants exercisable for common stock, and a warrant exercise agreement with a holder of an existing warrant for an aggregate consideration of \$4.8 million, generating net proceeds of \$47.3 million. We paid \$15.1 million of the net proceeds to fund the cash portion of the purchase price for SafeOp.

On November 6, 2018, we closed the \$35.0 million Term Loan with Squadron, a provider of debt financing to growing companies in the orthopedic industry. Net proceeds of approximately \$34.1 million were used to retire our existing \$29.2 million term debt with Globus. The remainder of the proceeds are being used for general corporate purposes.

On March 27, 2019, we closed on an Expanded Credit Facility with Squadron for up to \$30 million in additional secured financing. This additional financing will be made available under our existing credit facility with Squadron. No amounts have been drawn on the Line of Credit as of its issuance date. Any amounts drawn will be used for general corporate purposes. The additional borrowings under the credit facility will mature concurrent with the current secured financing from Squadron and bear interest at LIBOR plus 8% per annum, subject to a 10% floor and a 13% ceiling. For any draws taken, interest-only payments are due monthly through May 2021, followed by principal payable in 29 equal monthly installments beginning June 2021 and a lump-sum payment payable at maturity in November 2023.

We may seek additional funds from public and private equity or debt financings, borrowings under new or existing debt facilities or other sources to fund our projected operating requirements. However, there is no guarantee that we will be able to obtain further financing, or do so on reasonable terms. If we are unable to raise additional funds on a timely basis, or at all, we would be materially adversely affected. As more fully described below, our debt agreements include traditional lending and reporting covenants, including a financial covenant that requires us to maintain a minimum fixed charge coverage ratio beginning in April 2020 and a minimum liquidity covenant of \$5.0 million effective through March 2020. Should at any time we fail to maintain compliance with these covenants, we will need to seek waivers or amendments to the debt agreements. If we are unable to secure such waivers or amendments, we may be required to classify our obligations under the debt agreements in current liabilities on our consolidated balance sheet. We may also be required to repay all or a portion of outstanding indebtedness under the debt agreements, which would require us to obtain further financing.

A substantial portion of our available cash funds is held in business accounts with reputable financial institutions. At times, however, our deposits, may exceed federally insured limits and thus we may face losses in the event of insolvency of any of the financial institutions where our funds are deposited. We did not hold any marketable securities as of December 31, 2018.

Amended Credit Facility, Squadron Credit Agreement and Other Debt

Our Amended Credit Facility with MidCap provides for a revolving credit commitment up to \$22.5 million. As of December 31, 2018, \$11.0 million was outstanding under the revolving line of credit. The term loan with MidCap was paid in full during the third quarter of 2018.

On March 8, 2018, we entered into a Seventh Amendment to the Amended Credit Facility to extend the date that the financial covenants of the Amended Credit Facility are effective from April 2018 to April 2019, and established a minimum liquidity covenant of \$5.0 million through March 31, 2019. Subsequently, on November 6, 2018, we entered into an Eighth Amendment to the Amended Credit Facility to extend the date that the financial covenants of the Amended Credit Facility are effective from April 2019 to April 2020, and extended the minimum liquidity covenant through March 2020. The Company was in compliance with the covenants under the Amended Credit Facility at December 31, 2018.

The revolving line of credit accrues interest at LIBOR plus 6.0%, reset monthly. At December 31, 2018, the revolving line of credit carried an interest rate of 8.35%. The borrowing base is determined based on the value of domestic eligible accounts receivable. As collateral for the Amended Credit Facility, MidCap has a first lien security interest in accounts receivable and a second lien on substantially all other assets. The Amended Credit Facility also includes several event of default provisions, such as payment default, insolvency conditions and a material adverse effect clause, which could cause interest to be charged at a rate which is up to five percentage points above the rate effective immediately before the event of default or result in MidCap's right to declare all outstanding obligations immediately due and payable.

On September 1, 2016, we entered into the Globus facility, pursuant to which Globus agreed to loan us up to \$30 million. We made an initial draw of \$25 million under the Globus facility with an additional draw of \$5 million made in the fourth quarter of 2016. In November 2018, the \$29.2 million outstanding was paid in full.

On November 6, 2018, we closed the \$35.0 million Term Loan with Squadron for net proceeds of approximately \$34.1 million, which were partially used to retire our existing \$29.2 million term debt with Globus noted above. The debt has a five-year maturity and bears interest at LIBOR plus 8% (10.5% as of December 31, 2018) per annum. The Agreement specifies a minimum interest rate of 10% and a maximum of 13% per year. Interest-only payments are due monthly through May 2021, followed by \$10 million in principal payable in 29 equal monthly installments beginning June 2021 and a \$25 million lump-sum payment payable at maturity in November 2023. As collateral for the Term Loan, Squadron has a first lien security interest in substantially all assets except for accounts receivable.

The Term Loan also includes several event of default provisions, such as payment default, insolvency conditions and a material adverse effect clause, which could cause interest to be charged at a rate which is up to five percentage points above the rate effective immediately before the event of default or result in Squadron's right to declare all outstanding obligations immediately due and payable. Furthermore, the credit agreement contains various covenants, including various negative covenants including a \$5 million minimum liquidity requirement through March 31, 2020. The minimum liquidity covenant will be replaced by a fixed charge ratio, pursuant to which operating cash to fixed charges (as defined) must equal at least 1:1 on a rolling 12-month basis, beginning April 2020. We were in compliance with the covenants under the credit agreement at December 31, 2018.

As of December 31, 2018, we have made \$36.2 million in Orthotec settlement payments and there remains an aggregate \$21.6 million of Orthotec settlement payments (including interest) to be paid by us.

Operating Activities

We used net cash of \$25.6 million from operating activities for the year ended December 31, 2018. During this period, net cash used in operating activities consisted of our net loss adjusted for non-cash adjustments including amortization, depreciation, stock-based compensation, provision for doubtful accounts, provision for excess and obsolete inventory, interest expense related to amortization of debt discount and issuance costs, and contingent consideration fair market value adjustment of \$15.9 million and working capital and other assets used cash of \$9.7 million.

Investing Activities

We used cash of \$21.7 million in investing activities for the year ended December 31, 2018, primarily for the acquisition of SafeOp of a net amount of \$15.1 million and the purchase of surgical instruments, computer equipment, furniture and fixture of \$6.5 million, the acquisition of intangible assets of \$0.4 million, net of \$0.3 million of cash received from sale of instruments and disposal of equipment.

Financing Activities

Financing activities provided net cash of \$53.9 million for the year ended December 31, 2018, primarily attributable to the 2018 Private Placement and warrant exercises, which provided net cash proceeds of \$51.9 million and the receipt of the Squadron Term Loan of \$34.1 million, net. We used cash to pay the remaining balance of our Globus facility along with other notes payable of \$32.5 million. Under the MidCap Amended Credit Facility, we made net borrowings under the lines of credit of \$0.5 million during the year ended December 31, 2018 and principal payments on notes payable and capital leases totaling \$0.1 million.

Contractual obligations and commercial commitments

Total contractual obligations and commercial commitments as of December 31, 2018 are summarized in the following table (in thousands):

	Payment Due by Year						
	Total	2019	2020	2021	2022	2023	Thereafter
Amended Credit Facility with MidCap	\$ 11,735	\$ 125	\$ —	\$ —	\$ 11,610	\$ —	\$ —
Squadron Term Loan	35,000	—	—	2,414	4,138	28,448	—
Convertible Notes Payable	3,000	3,000	—	—	—	—	—
Interest expense	23,461	5,437	5,380	5,304	4,909	2,431	—
Note payable for software agreements and insurance premiums	296	250	46	—	—	—	—
Capital lease obligations	145	34	37	37	37	—	—
Operating lease obligations	4,381	1,684	1,688	1,009	—	—	—
Litigation settlement obligations, gross ⁽²⁾	21,633	4,400	4,400	4,000	4,400	4,400	33
Guaranteed minimum royalty obligations	5,884	981	943	918	918	918	1,206
License agreement milestones ⁽¹⁾	2,250	700	650	250	450	—	200
Total	<u>\$107,785</u>	<u>\$ 16,611</u>	<u>\$ 13,144</u>	<u>\$ 13,932</u>	<u>\$ 26,462</u>	<u>\$ 36,197</u>	<u>\$ 1,439</u>

- (1) These commitments represent payments in cash, and are subject to attaining certain sales milestones which we believe are reasonably likely to be achieved beginning in 2019.
- (2) Represents gross payments due to Orthotec, LLC pursuant to a Settlement and Release Agreement, dated as of August 13, 2014, by and among the Company and its direct subsidiaries, including Alphatec Spine, Inc., Alphatec Holdings International C.V., Scient'x S.A.S. and Surgiview S.A.S.; HealthpointCapital, LLC, HealthpointCapital Partners, L.P., HealthpointCapital Partners II, L.P., John H. Foster and Mortimer Berkowitz III; and Orthotec, LLC and Patrick Bertranou. In September 2014, the Company and HealthpointCapital entered into an agreement for joint payment of settlement whereby HealthpointCapital is obligated to pay \$5 million of the settlement amount, with payments beginning in the fourth quarter of 2020 and continuing through 2021. See Note 13 of our Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for further information.

Real Property Leases

In January 2016, we entered into a lease agreement, or the Building Lease, for office, engineering, and research and development space in Carlsbad, California with the lease term through July 31, 2021. Under the Building Lease our monthly rent payable is approximately \$105,000 per month during the first year and increases by approximately \$3,000 each year thereafter.

Off-Balance Sheet Arrangements

As of December 31, 2018, we did not have any off-balance sheet arrangements.

Critical Accounting Policies and Estimates

Our discussion and analysis of our 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 U.S. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. On an on-going basis, we evaluate our estimates and assumptions, including those related to revenue recognition, allowances for accounts receivable, inventories and intangible assets, stock-based compensation and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumption conditions.

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

The Company recognizes revenue from products sales in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) Topic 606, *Revenue from Contracts with Customers* (“Topic 606”). The adoption of this guidance did not have a material impact on the Company’s consolidated financial statements. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Valuation of Intangible Assets

We assess the impairment of our intangible assets annually in December or whenever business conditions change and an earlier impairment indicator arises. This assessment requires us to make assumptions and judgments regarding the carrying value of these assets. These assets are considered to be impaired if we determine that their carrying value may not be recoverable based upon our assessment of certain events or changes in circumstances, including the following:

- a determination that the carrying value of such assets cannot be recovered through undiscounted cash flows;
- loss of legal ownership or title to the assets;
- significant changes in our strategic business objectives and utilization of the assets; or
- the impact of significant negative industry or economic trends.

If the assets are considered to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. Significant management judgment is required in estimating the fair value of our intangible assets.

Warrants to purchase common stock

Warrants are accounted for in accordance with the applicable accounting guidance provided in ASC 815 - *Derivatives and Hedging* as either derivative liabilities or as equity instruments depending on the specific terms of the agreements. Liability-classified instruments are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of derivative liabilities in the consolidated statements of operations. We estimate liability classified instruments using the Black Scholes model, which requires management to develop assumptions and inputs that have significant impact on such valuations.

During each reporting period, we evaluate changes in facts and circumstances that could impact the classification of warrants from liability to equity, or vice versa.

Stock-Based Compensation

We account for stock-based compensation under provisions which require that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. The amount of expense recognized during the period is affected by subjective assumptions, including estimates of our future volatility, the expected term for our stock options, the number of options expected to ultimately vest, and the timing of vesting for our share-based awards.

We use a Black-Scholes option-pricing model to estimate the fair value of our stock option awards. The calculation of the fair value of the awards using the Black-Scholes option-pricing model is affected by our stock price on the date of grant as well as assumptions regarding the following:

- Estimated volatility is a measure of the amount by which our stock price is expected to fluctuate each year during the expected life of the award. Our estimated volatility through December 31, 2018 was based on our actual historical volatility. An increase in the estimated volatility would result in an increase to our stock-based compensation expense.
- The expected term represents the period of time that awards granted are expected to be outstanding. Our estimated expected term through December 31, 2018 was calculated using a weighted-average term based on historical exercise patterns and the term from option grant date to exercise for the options granted within the specified date range. An increase in the expected term would result in an increase to our stock-based compensation expense.
- The risk-free interest rate is based on the yield curve of a zero-coupon U.S. Treasury bond on the date the stock option award is granted with a maturity equal to the expected term of the stock option award. An increase in the risk-free interest rate would result in an increase to our stock-based compensation expense.
- The assumed dividend yield is based on our expectation of not paying dividends in the foreseeable future.

We use historical data to estimate the number of future stock option forfeitures. Share-based compensation recorded in our consolidated statements of operations is based on awards expected to ultimately vest and has been reduced for estimated forfeitures. Our estimated forfeiture rates may differ from our actual forfeitures which would affect the amount of expense recognized during the period.

We account for stock option grants to non-employees under provisions which require that the fair value of these instruments be recognized as an expense over the period in which the related services are rendered.

Share-based compensation expense of awards with performance conditions is recognized over the period from the date the performance condition is determined to be probable of occurring through the time the applicable condition is met. Determining the likelihood and timing of achieving performance conditions is a subjective judgment made by management which may affect the amount and timing of expense related to these share-based awards. Share-based compensation is adjusted to reflect the value of options which ultimately vest as such amounts become known in future periods. As a result of these subjective and forward-looking estimates, the actual value of our share-based awards could differ significantly from those amounts recorded in our financial statements.

Stock-based awards with market conditions are valued using the Monte Carlo valuation technique which requires management to make significant estimates and assumptions that are not observable from the market. Stock based compensation for awards with both service and market conditions are recognized on a straight line basis over the longer of the derived service period or the requisite service period.

Income Taxes

We account for income taxes in accordance with provisions which set forth an asset and liability approach that requires the recognition of deferred tax assets and deferred tax liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Valuation allowances are established when necessary to reduce deferred tax assets to the amount that is more likely than not expected to be realized. In making such a determination, a review of all available positive and negative evidence must be considered, including scheduled reversal of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance.

We recognize interest and penalties related to uncertain tax positions as a component of the income tax provision.

Recent Accounting Pronouncements

See “Notes to Financial Statements - Note 2 - Recent Accounting Pronouncements” included elsewhere in this Annual Report on Form 10-K.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

Other outstanding debt consists of fixed rate instruments, including debt outstanding under the Amended Credit Facility with MidCap and the Term Loan with Squadron, notes payable and capital leases.

Our borrowings under our credit facilities expose us to market risk related to changes in interest rates. As of December 31, 2018, our outstanding floating rate indebtedness totaled \$46.0 million. The primary base interest rate is the LIBOR rate. Assuming the outstanding balance on our floating rate indebtedness remains constant over a year, a 100 basis point increase in the interest rate would decrease pre-tax income and cash flow by approximately \$0.5 million.

Item 8. Financial Statements and Supplementary Data

The consolidated financial statements and supplementary data required by this item are set forth at the pages indicated in Item 15.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

MANAGEMENT’S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Background

On March 8, 2018, we completed a private placement of equity securities to certain institutional and accredited investors, providing for the sale by us of newly designated Series B Convertible Preferred Stock, which shares of preferred stock were automatically converted into 14.3 million shares of our common stock upon approval by our stockholders. As the Series B Convertible Preferred Stock provided the holder the benefit to convert to shares of common stock, a beneficial conversion feature (“BCF”) with a calculated intrinsic fair value at issuance of \$13.5 million existed as of the date the shares of Series B Convertible Preferred Stock were able to be converted into shares of common stock. As the conversion was contingent upon shareholder approval, which occurred in May 2018, the BCF should have been recognized on the day the contingency was resolved.

This one-time, non-cash deemed dividend impacted net loss attributable to common stockholders and net loss per share for the three and six months ended June 30, 2018, the nine months ended September 30, 2018, and the year ended December 31, 2018. The error also impacted the amounts in accumulated deficit and additional paid in capital, but had no impact on total equity. We determined that the impact of this accounting error was not material to the financial statements for prior unaudited interim periods. We recorded the impact of the BCF in our audited financial statements as of and for the year ended December 31, 2018.

In connection with our review of the foregoing, we identified a lack of sufficient oversight and review to ensure the complete and proper application of U.S. GAAP as it relates to the impact of complex equity transactions on our financial statements as of June 30, 2018, September 30, 2018 and as of December 31, 2018.

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this report. Based on such evaluation, our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that our disclosure controls and procedures were not effective at a reasonable assurance level for the interim periods ended and as of June 30, 2018 and September 30, 2018 and as of December 31, 2018. This conclusion was based on the material weakness identified in our internal control over financial reporting related to our lack of sufficient oversight and review to ensure the complete and proper application of U.S. GAAP associated with complex equity transactions. We identified and reported this weakness to both the Audit Committee of our Board of

Directors. A material weakness existed as of December 31, 2018 that was remediated during the first quarter 2019 prior to filing this Form 10-K.

Internal Control Over Financial Reporting

Our management is responsible for establishing and maintain adequate internal control over financial reporting (as defined in Exchange Act Rules 13(a)—15(f)). Our management’s annual report on internal control over financial reporting is set forth below.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our Board of Directors, management and other personnel, 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.

Because of its inherent limitations, internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become ineffective because of changes in conditions or that the degree of compliance with established policies or procedures may deteriorate.

Our management, under the supervision of, our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018 using the framework set forth in the report entitled *Internal Control—Integrated Framework* published by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission. Management reviewed the results of this evaluation with the Audit Committee of our Board of Directors, and based on this evaluation, management identified deficiencies related to our review and accounting associated with significant non-routine transactions.

During the preparation process for our 2018 Annual Report on Form 10-K, we identified an error in our previously issued consolidated interim financial statements for the quarterly periods ended June 30, 2018 and September 30, 2018 related to the accounting for a beneficial conversion feature associated with our Series B Convertible Preferred Stock which converted into shares of common stock in May 2018. Specifically, management has concluded the material weakness in our internal control over financial reporting related to a lack of sufficient oversight and review to ensure the complete and proper application of U.S. GAAP associated with complex equity transactions.

Remediation of the Material Weakness during the first quarter 2019, prior to filing this Form 10-K

This material weakness related to a lack of sufficient oversight and review to ensure the complete and proper application of U.S. GAAP associated with complex equity transactions. To remediate the material weakness described above and to prevent similar deficiencies in the future, we added additional controls and procedures, including:

- Hiring of additional personnel, including an accounting manager and staff accountant, that allows for increased oversight of the accounting and finance processes and additional review of complex and non-routine transactions; and
- Re-design of internal controls to ensure more timely quarterly reviews of technical accounting positions documented by our staff and our independent external technical accounting consultants

Any actions we have taken or may take to remediate these deficiencies are subject to continued management review supported by testing, as well as oversight by the Audit Committee of our Board of Directors. We cannot assure you that material weaknesses or significant deficiencies will not occur in the future and that we will be able to remediate such weaknesses or deficiencies in a timely manner, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. See the related Risk Factor included in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

Except as described above, there has been no change to our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Concurrently with the adoption of an amendment of the Company's 2016 Equity Incentive Plan (the "Plan") to increase the annual per person limit on awards granted thereunder on October 25, 2018 disclosed in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, the Board of Directors of the Company (the "Board") ratified grants made to one individual in July 2018 (the "July Grants") that exceeded the annual per person limit as originally set forth under the Plan (the "October Resolutions"). By resolution on March 6, 2019, the Board clarified its actions in the October Resolutions to avoid any uncertainty related to its actions, resolving that, by approving the October Resolutions, the Board (1) ratified the July Grants, including the excess over the original limits, as of and effective on July 30, 2018; (2) ratified the amendment of the original limits under the Plan to the extent necessary to permit the ratification of the July Grants, including the excess over the original limits, in their entirety, as of and effective on July 30, 2018; and (3) approved an additional amendment to Section 3(c) of the Plan to increase the individual limit set forth therein to 1,250,000 shares, as of and effective on October 25, 2018.

The statutory notice under Section 204 of the Delaware General Corporation Law to the Company's stockholders is set forth in Exhibit 99.1 hereto and incorporated by reference herein.

On March 27, 2019, Alphatec Holdings, Alphatec Spine and SafeOp Surgical, as borrowers, and Squadron, as lender, entered into a First Amendment to Credit, Security and Guaranty Agreement, pursuant to which Squadron extended an additional \$30 million in draws available to us under our credit facility with Squadron beginning on March 27, 2019 through November 2023. In connection with the amendment of our credit facility with Squadron, we also entered into an Amended and Restated Note to effect the increase of the available borrowing. Any additional borrowings will be subject to the same terms as the credit agreement we entered into with Squadron in November 2018. No amounts have been drawn on the expanded credit facility as of its issuance date. Any amounts drawn will be used for general corporate purposes. The additional borrowings under the credit facility will mature concurrent with the current secured financing from Squadron and bear interest at LIBOR plus 8% per annum, subject to a 10% floor and a 13% ceiling. For any draws taken, interest-only payments are due monthly through May 2021, followed by principal payable in 29 equal monthly installments beginning June 2021 and a lump-sum payment payable at maturity in November 2023. At such time as the Company makes its first draw under the additional available borrowing, the Company will issue to Squadron warrants to purchase 4.8 million shares of the Company's common stock at an exercise price of \$2.17 per share. Upon issuance, the warrants will have a seven-year term and will be immediately exercisable.

In connection with the expansion of our credit facility with Squadron, on March 27, 2019 we also entered into a Ninth Amendment to Amended and Restated Credit, Security and Guaranty Agreement with MidCap to acknowledge and consent to the additional available borrowing under the Squadron credit facility.

The foregoing description does not purport to be complete and is qualified in its entirety by reference to the First Amendment to Credit, Security and Guaranty Agreement, and the Ninth Amendment to Amended and Restated Credit, Security and Guaranty Agreement, copies of which will be filed with the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2019.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to our Proxy Statement with respect to our 2019 Annual Meeting of Stockholders to be filed with the SEC within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

Item 15. Exhibits, Financial Statement Schedules

Item 15 (a) The following documents are filed as part of this Annual Report on Form 10-K:

(1) Financial Statements:

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Item 15(a)(3) Exhibits List

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
2.1	Purchase and Sale Agreement, dated as of July 25, 2016, by and between Alphatec Holdings, Inc. and Globus Medical Ireland, Ltd.		Form 8-K (Exhibit 2.1)	07/26/16	000-52024
2.2	First Amendment to Purchase and Sale Agreement, dated as of September 1, 2016, by and between Alphatec Holdings, Inc. and Globus Medical Ireland, Ltd.		Form 8-K (Exhibit 2.1)	09/08/16	000-52024
2.3	Second Amendment to Purchase and Sale Agreement and First Amendment to Product Manufacture and Supply Agreement, dated as of February 9, 2017, by and between Alphatec Holdings, Inc. and Globus Medical Ireland, Ltd.		Form 10-K (Exhibit 2.3)	03/31/17	000-52024
2.4	Agreement and Plan of Merger dated as of March 6, 2018, among Alphatec Holdings, Inc., Safari Merger Sub, Inc., SafeOp Surgical, Inc., the stockholders of the Company identified as Key Stockholders therein and Safari Holding Company, LLC, solely in its capacity as Stockholder Representative		Form 8-K (Exhibit 2.1)	03/12/18	000-52024
3.1	Amended and Restated Certificate of Incorporation of Alphatec Holdings, Inc.		Amendment No. 2 to Form S-1 (Exhibit 3.2)	04/20/06	333-131609
3.2	Amendment to the Certificate of Incorporation of Alphatec Holdings, Inc.		Form 8-K (Exhibit 3.1(B))	08/24/16	000-52024
3.3	Restated Bylaws of Alphatec Holdings, Inc.		Amendment No. 5 to Form S-1 (Exhibit 3.4)	05/26/06	333-131609
3.4	Form of Certificate of Designation of Preferences, Rights and Limitations of Series A convertible Preferred Stock of Alphatec Holdings, Inc.		Form 8-K (Exhibit 3.1)	03/23/17	000-52024
3.5	Form of Certificate of Designation of Preferences, Rights and Limitations of Series B convertible Preferred Stock of Alphatec Holdings, Inc.		Form 8-K (Exhibit 3.1)	03/12/18	000-52024

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
4.1	Form of Common Stock Certificate		Form 10-K (Exhibit 4.1)	03/20/14	333-131609
4.2	Corporate Governance Agreement, dated December 17, 2009, between the Company and certain shareholders of Scient'x Groupe S.A.S. and Scient'x S.A.		Form 8-K (Exhibit 10.1)	12/22/09	000-52024
4.3	Registration Rights Agreement, dated March 26, 2010, by and among Alphatec Holdings, Inc. and the other signatories thereto		Form 8-K (Exhibit 4.1)	03/31/10	000-52024
4.4	Form of Registration Rights Agreement		Form 8-K (Exhibit 4.2)	03/12/18	000-52024
4.5	Amended and Restated Registration Rights Agreement, dated April 16, 2018, by and among Alphatec Holdings, Inc. and the other signatories thereto		Form 8-K/A (Exhibit 4.1)	04/16/18	000-52024
4.6	Registration Rights Agreement, dated November 6, 2018, by and among Alphatec Holdings, Inc. and the other signatories thereto		Form S-3/A (Exhibit 4.5)	11/13/18	333-221085
4.7	Warrant with Silicon Valley Bank as the Warrant holder, dated December 16, 2011		Form 10-K (Exhibit 4.8)	03/05/12	000-52024
4.8	Form of Warrant to Purchase Common Stock issued to each of Deerfield Private Design Fund II, L.P., Deerfield Private Design International II, L.P., Deerfield Special Situations Fund, L.P. and Deerfield Special Situations International Master Fund, L.P. (collectively, "Deerfield") on each of March 17, 2014 and November 21, 2014.		Form 8-K (Exhibit 4.1)	03/19/14	000-52024
4.9	Form of Warrant issued to certain investors on March 28, 2017		Form 8-K (Exhibit 4.1)	03/23/17	000-52024
4.10	Form of Warrant issued to certain investors on December 28, 2017		Form 8-K (Exhibit 4.1)	10/02/17	000-52024
4.11	Form of Warrant issued to certain investors on March 8, 2018		Form 8-K (Exhibit 4.1)	03/12/18	000-52024
4.12	Form of Registration Rights Agreement		Form 8-K (Exhibit 4.2)	03/23/17	000-52024
4.13	Form of Warrant to Purchase Common Stock of Alphatec Holdings, Inc. issued to Patrick S. Miles		Form 8-K (Exhibit 4.1)	10/02/17	000-52024
4.14	Form of Warrant to Purchase Common Stock of Alphatec Holdings, Inc. issued in connection with financing dated November 6, 2018		Form S-3/A (Exhibit 4.11)	11/13/18	333-221085
4.15	Form of Merger Warrant		Form 8-K (Exhibit 4.3)	03/12/18	000-52024
4.16	Registration Rights Agreement between Alphatec Holdings, Inc., and Squadron Medical Finance Solutions LLC and Tawani Holdings LLC, dated November 6, 2018		Form S-3/A (Exhibit 4.5)	11/13/18	333-221085
10.1	Purchase Agreement dated as of October 2, 2017, between Alphatec Holdings, Inc. and Patrick Miles.		Form 8-K (Exhibit 10.1)	10/02/17	000-52024
10.2	Purchase Agreement dated as of October 2, 2017, between Alphatec Holdings, Inc. and Quentin Blackford.		Form 8-K (Exhibit 10.2)	10/02/17	000-52024

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.3	Securities Purchase Agreement, dated as of March 22, 2017, between Alphatec Holdings, Inc. and each purchaser named in the signature pages thereto		Form 8-K (Exhibit 10.1)	03/23/17	000-52024
10.4	Engagement Letter between Alphatec Holdings, Inc. and Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC		Form 8-K (Exhibit 10.2)	03/23/17	000-52024
10.5	Form of Support Agreement		Form 8-K (Exhibit 10.3)	03/23/17	000-52024
10.6	Securities Purchase Agreement dated as of March 8, 2018, between Alphatec Holdings, Inc. and each purchaser named in the signature pages thereto		Form 8-K (Exhibit 10.1)	03/12/18	000-52024
10.7	Form of Support Agreement		Form 8-K (Exhibit 10.2)	03/12/18	000-52024
10.8	Form of Note		Form 8-K (Exhibit 10.3)	03/12/18	000-52024
10.9	Warrant Exercise Agreement dated as of March 8, 2018, between Alphatec Holdings, Inc. and Armistice Capital Master Fund, Ltd.		Form 8-K (Exhibit 10.4)	03/12/18	000-52024
10.10	Amended and Restated Term Note, dated March 8, 2018, with Globus Medical, Inc.		Form 8-K (Exhibit 10.8)	03/12/18	000-52024
	<u>Real Property Lease Agreements</u>				
10.11	Lease Agreement by and between Alphatec Holdings, Inc. and Fenton Property Company., dated as of January 21, 2016		Form 10-K (Exhibit 10.2)	03/15/16	000-52024
	<u>Loan Agreements</u>				
10.12†	Amended and Restated Credit, Security and Guaranty Agreement dated August 30, 2013 by and among Alphatec Holdings, Inc., Alphatec Spine, Inc., Alphatec International LLC, Alphatec Pacific, Inc. and MidCap Funding IV, LLC		Form 10-Q/A (Exhibit 10.1)	10/21/15	000-52024
10.13†	First Amendment to Amended and Restated Credit, Security and Guaranty Agreement, dated March 17, 2014, with MidCap Funding IV, LLC as Administrative Agent and lender and other lenders from time to time a party thereto		Form 8-K/A (Exhibit 10.3)	10/21/15	000-52024
10.14†	Second Amendment to the Amended and Restated Credit, Security and Guaranty Agreement, dated July 10, 2015, with MidCap Funding IV Trust, as a lender and other lenders from time to time a party thereto		Form 10-Q (Exhibit 10.1)	11/03/15	000-52024
10.15†	Third Amendment to the Amended and Restated Credit, Security and Guaranty Agreement, dated March 11, 2016, with MidCap Funding IV Trust, as a lender and other lenders from time to time a party thereto		Form 10-Q (Exhibit 10.1)	05/06/16	000-52024
10.16†	Fourth Amendment to the Amended and Restated Credit, Security and Guaranty Agreement, dated August 9, 2016, with MidCap Funding IV Trust, as a lender and other lenders from time to time a party thereto		Form 10-K (Exhibit 10.6)	3/31/17	000-52024
10.17†	Consent and Fifth Amendment to the Amended and Restated Credit, Security and Guaranty Agreement, dated September 1, 2016 with MidCap Funding IV Trust, as a lender and other lenders from time to time a party thereto		Form 10-Q (Exhibit 10.3)	11/09/16	000-52024

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.18†	Sixth Amendment to the Amended and Restated Credit, Security and Guaranty Agreement, dated March 30, 2017, with MidCap Funding IV Trust, as a lender and other lenders from time to time a party thereto		Form 10-Q (Exhibit 10.1)	05/12/17	000-52024
10.19†	Seventh Amendment to Credit, Security and Guaranty Agreement, dated as of March 8, 2018, with MidCap Funding IV Trust, as a lender and other lenders from time to time a party thereto		Form 8-K (Exhibit 10.5)	03/12/18	000-52024
10.20	Eighth Amendment to Credit, Security and Guaranty Agreement, dated as of November 6, 2018, with MidCap Funding IV Trust, as a lender and other lenders from time to time a party thereto	X			
10.21	Amended and Restated Term Loan Note, dated July 10, 2015, with MidCap Funding IV Trust		Form 10-Q (Exhibit 10.3)	11/03/15	000-52024
10.22	Amended and Restated Revolving Loan Note, dated March 8, 2018, with MidCap Funding IV Trust		Form 8-K (Exhibit 10.6)	03/12/18	000-52024
10.23†	Credit, Security and Guaranty Agreement, dated September 1, 2016 with Globus Medical, Inc.		Form 10-Q (Exhibit 10.1)	11/09/16	000-52024
10.24†	First Amendment to the Credit, Security and Guaranty Agreement, dated March 30, 2017 with Globus Medical, Inc.		Form 10-Q (Exhibit 10.2)	05/12/17	000-52024
10.25†	Second Amendment to Credit, Security and Guaranty Agreement dated as of March 8, 2018, with Globus Medical, Inc.		Form 8-K (Exhibit 10.7)	03/12/18	000-52024
10.26	Credit, Security and Guaranty Agreement between Alphatec Holdings, Inc., Alphatec Spine, Inc. and SafeOp Surgical, Inc. and Squadron Medical Finance Solutions LLC, dated November 6, 2018	X			
10.27	Intercreditor Agreement between Alphatec Holdings, Inc., Alphatec Spine, Inc. and SafeOp Surgical, Inc. and Squadron Medical Finance Solutions LLC, dated November 6, 2018	X			
10.28	Term Note, dated November 6, 2018, with Squadron Medical Finance Solutions LLC	X			
<u>Agreements with Respect to Product Supply, Collaborations, Licenses, Research and Development</u>					
10.29†	Supply Agreement by and between Alphatec Spine, Inc. and Invibio, Inc., dated as of October 18, 2004 and amended by Letter of Amendment in respect of the Supply Agreement, dated as of December 13, 2004		Amendment No. 4 to Form S-1 (Exhibit 10.29)	05/15/06	333-131609
10.30†	Letter Amendment between Alphatec Spine, Inc. and Invibio, Inc., dated November 24, 2010		Form 10-Q (Exhibit 10.3)	05/06/11	000-52024
10.31†	Product Manufacture and Supply Agreement, dated September 1, 2016 with Globus Medical Ireland, Ltd.		Form 10-Q (Exhibit 10.2)	11/09/16	000-52024
<u>Agreements with Officers and Directors</u>					
10.32*	Employment Agreement with Jeffrey G. Black dated February 10, 2017		Form 10-Q (Exhibit 10.3)	05/12/17	000-52024
10.33*	Employment Agreement with Jon Allen dated October December 10, 2016		Form 10-Q (Exhibit 10.4)	05/12/17	000-52024
10.34*	Employment Agreement with Craig E. Hunsaker dated September 14, 2016		Form 10-Q (Exhibit 10.5)	05/12/17	000-52024

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.35*	Employment Agreement with Brian Snider dated February 27, 2017		Form 10-Q (Exhibit 10.6)	05/12/17	000-52024
10.36*	Employment Agreement by and among Patrick S. Miles, Alphatec Spine, Inc., and Alphatec Holdings, Inc., dated, dated October 2, 2017		Form 10-K (Exhibit 10.26)	03/09/18	000-52024
10.37*	Form of Indemnification Agreement entered into with each of the Company's non-employee directors		Form 10-Q (Exhibit 10.5)	05/05/09	000-52024
10.38*	Vesting Acceleration Agreement by and between Leslie H. Cross and Alphatec Holdings, Inc., dated June 15, 2017		Form 10-Q (Exhibit 10.11)	08/11/17	000-52024
10.39*	Vesting Acceleration Agreement by and between Stephen O' Neil and Alphatec Holdings, Inc., dated October 1, 2017		Form 8-K (Exhibit 10.3)	10/2/17	000-52024
	<u>Equity Compensation Plans</u>				
10.40*	Amended and Restated 2005 Employee, Director and Consultant Stock Plan		Form S-8 (Exhibit 99.1)	03/23/13	333-187190
10.41*	Amendment to the Amended and Restated 2005 Employee, Director and Consultant Stock Plan		Schedule 14A (Appendix B)	06/11/13	000-52024
10.42*	Amendment to the Alphatec Holdings, Inc. Amended and Restated 2005 Employee, Director and Consultant Stock Plan		Form 10-Q (Exhibit 10.1)	10/30/14	000-52024
10.43*	Form of Non-Qualified Stock Option Agreement issued under the Amended and Restated 2005 Stock Plan		Form 10-K (Exhibit 10.40)	03/05/13	000-52024
10.44*	Form of Incentive Stock Option Agreement issued under the Amended and Restated 2005 Stock Plan		Form 10-K (Exhibit 10.41)	03/05/13	000-52024
10.45*	Form of Restricted Stock Agreement issued under the Amended and Restated 2005 Stock Plan		Form 10-K (Exhibit 10.42)	03/05/14	000-52024
10.46*	Form of Performance-Based Restricted Unit Agreement issued under the Amended and Restated 2005 Employee, Director and Consultant Stock Plan, as amended.		Form 10-Q (Exhibit 10.2)	10/30/14	000-52024
10.47*	Amended and Restated 2007 Employee Stock Purchase Plan		Schedule 14A (Appendix C)	06/11/13	000-52024
10.48*	Amended and Restated 2007 Employee Stock Purchase Plan		Form 8-K/A (Exhibit 10.1)	06/22/17	000-52024
10.49*	Alphatec Holdings, Inc. 2016 Equity Incentive Plan		Form S-8 (Exhibit 10.1)	10/05/16	333-213981
10.50*	Amended and Restated 2007 Equity Stock Purchase Plan		Form 8-K/A (Exhibit 10.2)	06/22/17	000-52024
10.51*	Amended and Restated 2016 Equity Incentive Award Plan		Form 10-Q (Exhibit 10.1)	11/09/18	000-52024
10.52*	Alphatec Holdings, Inc. 2016 Employment Inducement Plan		Form S-8 (Exhibit 10.2)	10/05/16	333-213981
10.53*	First Amendment to the Alphatec Holdings, Inc. 2016 Employment Inducement Award Plan		Form S-8 (Exhibit 10.2)	12/12/16	333-215036
10.54	Second Amendment to the Alphatec Holdings, Inc. 2016 Employment Inducement Award Plan		Form S-8 (Exhibit 10.2)	03/31/17	333-217055

Exhibit Number	Exhibit Description	Filed with this Report	Incorporated by Reference herein from Form or Schedule	Filing Date	SEC File/Reg. Number
10.55*	Third Amendment to the Alphatec Holdings, Inc. 2016 Employment Inducement Award Plan, dated October 1, 2017.		Form 8-K (Exhibit 10.4)	10/2/17	000-52024
10.56*	Fourth Amendment to the Alphatec Holdings, Inc. 2016 Employment Inducement Award Plan, dated March 6, 2018.		Form 8-K (Exhibit 10.9)	03/12/18	000-52024
10.57*	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the Alphatec Holdings, Inc. 2016 Employment Inducement Award Plan		Form S-8 (Exhibit 10.3)	10/05/16	333-213981
10.58*	Form of Stock Option Grant Notice and Stock Option Agreement under the Alphatec Holdings, Inc. 2016 Employment Inducement Award Plan		Form S-8 (Exhibit 10.4)	10/05/16	333-213981
10.59*	Form of Performance Stock-Based Award Grant Notice and Performance Stock-Based Award Agreement under the Alphatec Holdings, Inc. 2016 Employment Inducement Award Plan		Form S-8 (Exhibit 10.5)	10/05/16	333-213981
<u>Settlement Agreements</u>					
10.60	Settlement and Release Agreement, dated as of August 13, 2014, by and among Alphatec Holdings, Inc. and its direct and indirect subsidiaries and affiliates, Orthotec, LLC, Patrick Bertranou and the other parties named therein		Form 10-Q (Exhibit 10.3)	10/30/14	000-52024
10.61	Separation and Release Agreement, dated December 31, 2018, between Alphatec Spine, Inc. and Alphatec Holdings, Inc. and Terry Rich	X			
10.62	Resignation and Transition Agreement, dated December 31, 2018, between Alphatec Holdings, Inc. and Terry Rich	X			
21.1	Subsidiaries of the Registrant and Wholly Owned Subsidiaries of the Registrant's Subsidiaries	X			
23.1	Consent of Independent Registered Public Accounting Firm	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	Certification pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X			
99.1	Notice of Ratification	X			
101.1	XBRL Instance Document**				
101.2	XBRL Taxonomy Extension Schema Document**				
101.3	XBRL Taxonomy Extension Calculation Linkbase Document**				
101.4	XBRL Taxonomy Extension Definition Linkbase Document**				
101.5	XBRL Taxonomy Extension Label Linkbase Document**				
101.6	XBRL Taxonomy Extension Presentation Linkbase Document**				

(*) Management contract or compensatory plan or arrangement.

(†) Confidential treatment has been granted by the Securities and Exchange Commission as to certain portions.

SIGNATURES

Pursuant to the requirements 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.

ALPHATEC HOLDINGS, INC.

Dated: March 29, 2019

By: /s/ Patrick S. Miles
Patrick S. Miles
Chairman and Chief Executive Officer
(principal executive officer)

Dated: March 29, 2019

By: /s/ Jeffrey G. Black
Jeffrey G. Black
Executive Vice President and Chief Financial Officer
(principal financial officer and principal accounting officer)

SIGNATURES AND POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Patrick S. Miles and Jeffrey G. Black, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that such attorneys-in-fact and agents or any of them, or his or her or their substitute or substitutes, may lawfully 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 and in the capacities and on the dates indicated.

Signature	Title	Date
<u>/S/ PATRICK S. MILES</u> Patrick S. Miles	Chairman and Chief Executive Officer (Principal Executive Officer)	March 29, 2019
<u>/S/ MORTIMER BERKOWITZ III</u> Mortimer Berkowitz III	Lead Director	March 29, 2019
<u>/S/ EVAN BAKST</u> Evan Bakst	Director	March 29, 2019
<u>/S/ QUENTIN BLACKFORD</u> Quentin Blackford	Director	March 29, 2019
<u>/S/ JASON HOCHBERG</u> Jason Hochberg	Director	March 29, 2019
<u>/S/ DAVID H. MOWRY</u> David H. Mowry	Director	March 29, 2019
<u>/S/ JAMES L.L. TULLIS</u> James L.L. Tullis	Director	March 29, 2019
<u>/S/ JEFFREY P. RYDIN</u> Jeffrey P. Rydin	Director	March 29, 2019
<u>/S/ DONALD A. WILLIAMS</u> Donald A. Williams	Director	March 29, 2019
<u>/S/ WARD W. WOODS</u> Ward W. Woods	Director	March 29, 2019

ALPHATEC HOLDINGS, INC.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of
Alphatec Holdings, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Alphatec Holdings, Inc. (“Company”) as of December 31, 2018 and 2017, and the related consolidated statements of operations, comprehensive loss, stockholders’ equity (deficit), and cash flows for each of the two years in the period ended December 31, 2018, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Adoption of New Accounting Standard

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for revenue from contracts with customers as a result of the adoption of Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* effective January 1, 2018, under the modified retrospective method.

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 the 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 audits 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 provides a reasonable basis for our opinion.

/s/ Mayer Hoffman McCann P.C.

We have served as the Company's auditor since 2017.
San Diego, California
March 29, 2019

ALPHATEC HOLDINGS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except par value data)

	December 31,	
	2018	2017
Assets		
Current assets:		
Cash	\$ 29,054	\$ 22,466
Accounts receivable, net	15,095	14,822
Inventories, net	28,765	27,292
Prepaid expenses and other current assets	2,030	1,767
Withholding tax receivable from officer	350	—
Current assets of discontinued operations	242	131
Total current assets	75,536	66,478
Property and equipment, net	13,235	12,670
Goodwill	13,897	—
Intangibles, net	26,408	5,248
Other assets	347	208
Noncurrent assets of discontinued operations	54	56
Total assets	\$ 129,477	\$ 84,660
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 4,399	\$ 3,878
Accrued expenses	22,316	22,246
Current portion of long-term debt	3,276	3,306
Current liabilities of discontinued operations	621	312
Total current liabilities	30,612	29,742
Long-term debt, less current portion	42,299	37,767
Other long-term liabilities	15,389	20,206
Redeemable preferred stock, \$0.0001 par value; 20,000 authorized at December 31, 2018 and 2017; 3,319 shares issued and outstanding at both December 31, 2018 and 2017	23,603	23,603
Commitments and contingencies		
Stockholders' equity (deficit):		
Series A convertible preferred stock, \$0.0001 par value; 15 shares authorized at December 31, 2018 and 2017, respectively; 4 shares issued and outstanding at December 31, 2018	—	—
Series B convertible preferred stock, \$0.0001 par value; 45 and 0 shares authorized at December 31, 2018 and 2017, respectively; 0 shares issued and outstanding at December 31, 2018	—	—
Common stock, \$0.0001 par value; 200,000 authorized; 43,368 and 19,857 shares issued and outstanding at December 31, 2018 and 2017, respectively	4	2
Treasury stock, 2 shares, at cost	(97)	(97)
Additional paid-in capital	523,525	436,803
Shareholder note receivable	(5,000)	(5,000)
Accumulated other comprehensive income	1,064	1,093
Accumulated deficit	(501,922)	(459,459)
Total stockholders' equity (deficit)	17,574	(26,658)
Total liabilities and stockholders' equity (deficit)	\$ 129,477	\$ 84,660

See accompanying notes to consolidated financial statements.

ALPHATEC HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,	
	2018	2017
Revenues:		
Revenue from U.S. products	\$ 83,656	\$ 86,925
Revenue from international supply agreement	8,038	14,814
Total revenues	91,694	101,739
Cost of revenues	28,457	33,517
Gross profit	63,237	68,222
Operating expenses:		
Research and development	9,984	4,920
Sales, general and administrative	72,509	69,959
Litigation-related expenses	5,683	308
Amortization of intangible assets	738	688
Transaction-related expenses	1,550	—
Gain on settlement	(6,168)	—
Restructuring expenses	1,381	2,206
Gain on sale of assets	—	(856)
Total operating expenses	85,677	77,225
Operating loss	(22,440)	(9,003)
Other income (expense):		
Interest and other expense, net	(7,139)	(7,615)
Loss on debt extinguishment	(590)	—
Gain on change of fair value of warrants	—	12,044
Total other income (expense)	(7,729)	4,429
Loss from continuing operations before taxes	(30,169)	(4,574)
Income tax (benefit)	(1,361)	(34)
Loss from continuing operations	(28,808)	(4,540)
Income (loss) from discontinued operations, net of applicable taxes	(167)	2,246
Net loss	(28,975)	(2,294)
Recognition of beneficial conversion feature - Series B Preferred Stock	(13,488)	—
Net loss attributable to common shareholders	\$ (42,463)	\$ (2,294)
(Loss) income per share, basic:		
Continuing operations	\$ (0.82)	\$ (0.36)
Discontinued operations	(0.00)	0.18
Net loss per share, basic	\$ (1.20)	\$ (0.18)
(Loss) income per share, diluted:		
Continuing operations	\$ (0.82)	\$ (1.25)
Discontinued operations	(0.00)	0.17
Net loss per share, diluted	\$ (1.20)	\$ (1.08)
Shares used in calculating basic net loss per share	35,315	12,788
Shares used in calculating diluted net loss per share	35,315	13,282

See accompanying notes to consolidated financial statements.

ALPHATEC HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,	
	2018	2017
Net loss	\$ (28,975)	\$ (2,294)
Foreign currency translation adjustments related to continuing operations	(29)	123
Comprehensive loss	<u>\$ (29,004)</u>	<u>\$ (2,171)</u>

See accompanying notes to consolidated financial statements.

ALPHATEC HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Common stock		Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Additional paid-in capital	Shareholder note receivable	Treasury stock	Accumulated other comprehensive income (loss)		Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Par Value	Shares	Par Value	Shares	Par Value				income	loss		
Balance at December 31, 2016	9,049	\$ 1	—	\$ —	—	\$ —	\$ 419,787	\$ (5,000)	\$ (97)	\$ 970	\$ (457,165)	\$ (41,504)	
Stock-based compensation	—	—	—	—	—	—	3,902	—	—	—	—	3,902	
Common and preferred stock and warrants issued in private placement, net of offering costs of \$1.7 million	1,810	1	15	—	—	—	17,117	—	—	—	—	17,118	
Conversion of preferred stock into common stock	4,964	—	(10)	—	—	—	—	—	—	—	—	—	
Issuance of common stock for employee stock purchase plan	128	—	—	—	—	231	—	—	—	—	—	231	
Shares issued for acquisition of intangible assets	285	—	—	—	—	473	—	—	—	—	—	473	
Common stock issued for vesting of restricted stock awards, net of shares repurchased for tax liability	183	—	—	—	—	—	—	—	—	—	—	—	
Common stock issued for warrant exercises	1,668	—	—	—	—	3,337	—	—	—	—	—	3,337	
Warrant derivative liability reclassified to equity due to exercise of warrants	—	—	—	—	—	2,311	—	—	—	—	—	2,311	
Issuance of common stock and warrants to board members	1,770	—	—	—	—	4,000	—	—	—	—	—	4,000	
Net change from reclassification of warrants to and from liability	—	—	—	—	—	(14,355)	—	—	—	—	—	(14,355)	
Foreign currency translation adjustments	—	—	—	—	—	—	—	—	—	123	—	123	
Balance at December 31, 2017	19,857	2	5	—	—	436,803	(5,000)	(97)	1,093	(2,294)	(459,459)	(26,658)	
Stock-based compensation	—	—	—	—	—	5,649	—	—	—	—	—	5,649	

Issuance of warrants in conjunction with Squadron Term Loan	—	—	—	—	—	1,708	—	—	—	1,708
Issuance and conversion of preferred stock into common stock, net of offering costs of \$2.6 million	14,986	2	(1)	—	—	42,608	—	—	—	42,610
Recognition of beneficial conversion feature - Series B Preferred Stock	—	—	—	—	—	13,488	—	—	(13,488)	—
Common stock issued for employee stock purchase plan and stock option exercises	258	—	—	—	—	666	—	—	—	666
Common stock issued for vesting of restricted stock awards, net of shares repurchased for tax liability	248	—	—	—	—	—	—	—	—	—
Common stock issued for warrant exercises, net of issuance costs of \$0.1 million	4,311	—	—	—	—	8,628	—	—	—	8,628
Issuance of common stock and warrants for the acquisition of SafeOp	3,265	—	—	—	—	12,529	—	—	—	12,529
Issuance of common stock for acquisition of SafeOp - Milestone 1	443	—	—	—	—	1,446	—	—	—	1,446
Foreign currency translation adjustments	—	—	—	—	—	—	—	(29)	—	(29)
Net loss	<u>43,368</u>	<u>\$ 4</u>	<u>\$ 4</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 523,525</u>	<u>\$ (5,000)</u>	<u>\$ (97)</u>	<u>\$ (28,975)</u>	<u>\$ 17,574</u>
Balance at December 31, 2018										

See accompanying notes to consolidated financial statements.

ALPHATEC HOLDINGS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,	
	2018	2017
Operating activities:		
Net loss	\$ (28,975)	\$ (2,294)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	6,789	7,481
Stock-based compensation	5,304	3,981
Amortization of debt discount and debt issuance costs	2,087	2,761
Provision (recovery) for doubtful accounts	164	(164)
(Recovery) provision for excess and obsolete inventory	4,743	2,542
Deferred income tax benefit	(1,405)	(36)
Gain on settlement	(6,168)	—
Gain on sale of assets	—	(856)
Loss on extinguishment of debt	590	—
Gain from change in estimated fair value of warrants	—	(12,044)
Loss on disposal of instruments	130	281
Accretion to contingent consideration	846	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(396)	4,153
Inventories, net	(6,024)	258
Prepaid expenses and other current assets	(268)	3,080
Other assets	(90)	348
Accrued expenses and other	1,677	(6,327)
Accounts payable	16	(2,592)
Deferred revenue	(261)	223
Other long-term liabilities	(4,367)	(9,524)
Net cash used in operating activities	<u>(25,608)</u>	<u>(8,729)</u>
Investing activities:		
Purchases of property and equipment	(6,514)	(7,596)
Cash paid for acquisition of SafeOp Surgical, Inc.	(15,103)	—
Cash paid for acquisition of intangible assets	(400)	—
Cash received from sale of equipment	348	1,101
Net cash used in investing activities	<u>(21,669)</u>	<u>(6,495)</u>
Financing activities:		
Proceeds from sale of stock, net	51,902	24,386
Borrowings under lines of credit	90,459	96,244
Repayments under lines of credit	(89,993)	(98,443)
Principal payments on capital lease obligations	(96)	(572)
Proceeds from issuance of term debt, net	34,077	—
Principal payments on term loan and notes payable	(32,464)	(3,794)
Net cash provided by financing activities	<u>53,885</u>	<u>17,821</u>
Effect of exchange rate changes on cash	(20)	276
Net increase in cash	6,588	2,873
Cash at beginning of year	22,466	19,593
Cash at end of year	<u>\$ 29,054</u>	<u>\$ 22,466</u>
Supplemental disclosure of cash flow information:		
Cash paid for interest	\$ 5,141	\$ 4,695
Cash paid for income taxes	\$ 134	\$ 107
Supplemental disclosure of noncash investing and financing activities:		
Issuance of warrants upon execution of term loan	\$ 1,708	\$ —
Common stock and warrants issued for the acquisition of SafeOp	\$ 12,529	\$ —
Common stock issued for achievement of SafeOp contingent consideration	\$ 1,446	\$ —
Purchases of property and equipment in accounts payable	\$ 940	\$ 436
Reclassification of warrant liabilities to equity	\$ —	\$ 14,355
Common stock issued for acquisition of intangible assets	\$ —	\$ 473
Capital lease additions included in property and equipment	\$ —	\$ 156
Subscription receivable	\$ —	\$ 300

See accompanying notes to consolidated financial statements.

ALPHATEC HOLDINGS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. The Company and Basis of Presentation

The Company

Alphatec Holdings, Inc. (the “Company”), through its wholly owned subsidiaries, Alphatec Spine, Inc. (“Alphatec Spine”) and SafeOp Surgical, Inc. (“SafeOp”), is a medical technology company that designs, develops, and markets technology for the treatment of spinal disorders associated with disease and degeneration, congenital deformities, and trauma. The Company markets its products in the U.S. via independent sales agents and a direct sales force.

On March 6, 2018, the Company and its newly-created wholly-owned subsidiary, Safari Merger Sub, Inc. (“Sub”), entered into an Agreement and Plan of Merger (the “Merger Agreement”) with SafeOp, a Delaware corporation, certain Key Stockholders of SafeOp and a Stockholder Representative. Pursuant to the Merger Agreement, a reverse triangular merger (the “Merger”) was consummated on March 8, 2018, in which Sub was merged into SafeOp, with SafeOp being the surviving corporation and a wholly-owned subsidiary of the Company. See Note 8 for further information.

On September 1, 2016, the Company completed the sale of its international distribution operations and agreements (collectively, the “International Business”) to Globus Medical Ireland, Ltd., a subsidiary of Globus Medical, Inc., and its affiliated entities (collectively “Globus”). As a result of this transaction, the International Business has been excluded from continuing operations for all periods presented in this Annual Report on Form 10-K and is reported as discontinued operations. See Note 4 for additional information on the divestiture of the International Business.

Basis of Presentation

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (“GAAP”) and include the accounts of the Company, Alphatec Spine and SafeOp. All intercompany balances and transactions have been eliminated in consolidation. The Company operates in one reportable business segment.

Liquidity

The Company’s existing working capital at December 31, 2018 is \$44.9 million (including cash of \$29.1 million) which includes the net proceeds of \$51.9 million received as of December 31, 2018 from the equity offering that closed on March 8, 2018 (see Note 10), warrant, employee stock purchase plan and stock option exercises, as well as the amendments to its debt facilities (see Note 5).

The Company has incurred significant net losses since inception and has relied on its ability to fund its operations through revenues from the sale of its products, equity financings and debt financings. As the Company has historically incurred losses, successful transition to profitability is dependent upon achieving a level of revenues adequate to support the Company’s cost structure. This may not occur and, unless and until it does, the Company will continue to need to raise additional capital. Operating losses and negative cash flows may continue for at least the next year as the Company continues to incur costs related to the execution of its operating plan and introduction of new products. Should the Company be unable to raise additional capital from outside sources, this will have a material adverse impact on its operations.

The Company’s Board approved annual operating plan projects that its existing working capital at December 31, 2018 along with the use of the Expanded Credit Facility with Squadron of \$30.0 million that closed on March 27, 2019 (see Note 16), allows the Company to fund its operations through at least one year subsequent to the date the financial statements are issued.

As more fully described in Note 5, the Company’s debt agreements include traditional lending and reporting covenants, including a financial covenant that requires the Company to maintain a minimum fixed charge coverage ratio beginning in April 2020 and a minimum liquidity covenant of \$5.0 million effective through March 2020. Should at any time the Company fail to maintain compliance with these covenants, the Company will need to seek waivers or amendments to the debt agreements. If the Company is unable to secure such waivers or amendments, it may be required to classify its obligations under the debt agreements in current liabilities on its consolidated balance sheet. The Company may also be required to repay all or a portion of outstanding indebtedness under the debt agreements, which would require the Company to obtain further financing. There is no assurance that the Company will be able to obtain further financing, or do so on reasonable terms.

Reclassification

Certain amounts in the consolidated financial statements included in our Form 10-K for the year ended December 31, 2017 have been reclassified to conform to current period's presentation. These reclassifications include the depreciation expense for surgical instruments, which was reclassified, to be consistent with industry practice, out of cost of revenues and into sales, general and administrative expense on the Company's consolidated statements of operations. This resulted in a reclassification of \$5.3 million and \$5.9 million of depreciation expense for the year ended December 31, 2018 and 2017, which was approximately 15% of total cost of revenues for each year. In addition, general and administrative expense for 2017 was combined into a single line item with sales and marketing expense for a new expense line titled "Sales, general and administrative expense" and litigation-related expenses primarily pertaining to the ongoing litigation with NuVasive, Inc. were classified out of selling, general and administrative expense on the Company's consolidated statement of operations for the years ended December 31, 2018 and 2017 and onto its own expense line item. None of the adjustments had any effect on the prior period net losses.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant items subject to such estimates and assumptions include the useful lives of property and equipment, intangibles, allowances for doubtful accounts, the valuation of share based liabilities, deferred tax assets, inventory, stock-based compensation, revenues, restructuring liabilities, income tax uncertainties, the acquired value of the SafeOp assets and liability acquired, contingent consideration related to the SafeOp acquisition and other contingencies.

Concentrations of Credit Risk and Significant Customers

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist primarily of cash and accounts receivable. The Company limits its exposure to credit loss by depositing its cash with established financial institutions. As of December 31, 2018, a substantial portion of the Company's available cash funds is held in business accounts. Although the Company deposits its cash with multiple financial institutions, its deposits, at times, may exceed federally insured limits.

The Company's customers are primarily hospitals, surgical centers and distributors, and no one single customer represented greater than 10 percent of consolidated revenues and accounts receivable for any of the periods presented. Credit to customers is granted based on an analysis of the customers' credit worthiness. Credit losses have not been significant.

Revenue Recognition

The Company recognizes revenue from product sales in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("Topic 606"). The adoption of this guidance did not have a material impact on the Company's consolidated financial statements. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

The Company derives its revenues primarily from the sale of spinal surgery implants used in the treatment of spine disorders. The Company sells its products primarily through its direct sales force and independent distributors. Revenue is recognized when control of the promised goods is transferred to the customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those goods. Transfer of control generally occurs when the Company receives the written acknowledgment that the product has been used in a surgical procedure or upon shipment to third-party customers who immediately accept title to such product.

The Company's accounts receivable generally have net 30-day payment terms. The Company generally does not allow returns of products that have been delivered. The Company offers standard quality assurance warranty on its products. As of December 31, 2018, accounts receivable related to products and services were \$15.1 million. For the year ended December 31, 2018, the Company had no material bad debt expense and there were no material contract assets, contract liabilities or deferred contract costs recorded on the consolidated balance sheet as of December 31, 2018.

Accounts Receivable, net

Accounts receivable are presented net of allowance for doubtful accounts. The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for a portion of receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the overall quality and age of those invoices not specifically reviewed. In determining the provision for invoices not specifically reviewed, the Company analyzes historical collection experience. If the historical data used to calculate the allowance provided for doubtful accounts does not reflect the Company's future ability to collect outstanding receivables or if the financial condition of customers were to deteriorate, resulting in impairment of their ability to make payments, an increase in the provision for doubtful accounts may be required.

Inventories, net

Inventories are stated at the lower of cost or net realizable value, with cost primarily determined under the first-in, first-out method. The Company reviews the components of inventory on a periodic basis for excess, obsolete and impaired inventory, and records a reserve for the identified items. The Company calculates an inventory reserve for estimated excess and obsolete inventory based upon historical turnover and assumptions about future demand for its products and market conditions. The Company's biologics inventories have an expiration based on shelf life and are subject to demand fluctuations based on the availability and demand for alternative implant products. The Company's estimates and assumptions for excess and obsolete inventory are reviewed and updated on a quarterly basis. Increases in the reserve for excess and obsolete inventory result in a corresponding increase to cost of revenues and establish a new cost basis for the part.

Property and Equipment, net

Property and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the related assets, generally ranging from three to seven years. Leasehold improvements and assets acquired under capital leases are amortized over the shorter of their useful lives or the remaining terms of the related leases.

Goodwill and Intangible Assets

The Company's goodwill represents the excess of the cost over the fair value of net assets acquired from its business combination with SafeOp. The determination of the value of goodwill and intangible assets arising from its business combination and asset acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired, including capitalized in-process research and development ("IPR&D"). Intangible assets acquired in a business combination that are used for in-process research and development activities are considered indefinite lived until the completion or abandonment of the associated research and development efforts. Upon reaching the end of the relevant research and development project, the Company will amortize the acquired IPR&D over its estimated useful life or expense the acquired in-process research and development should the research and development project be unsuccessful with no future alternative use.

Goodwill and IPR&D are not amortized; however, they are assessed for impairment using fair value measurement techniques on an annual basis or more frequently if facts and circumstance warrant such a review. The goodwill or IPR&D are considered to be impaired if the Company determines that the carrying value of the reporting unit or IPR&D exceeds its respective fair value.

The Company performs its annual impairment analysis by comparing the Company's estimated fair value, calculated from the Company's market capitalization, to its carrying amount. The Company's annual evaluation for impairment of goodwill consists of one reporting unit. The Company completed its most recent annual evaluation for impairment as of December 31, 2018 and determined that no impairment existed and, consequently, no impairment charge has been recorded during the year.

Intangible assets with a finite life, such as acquired technology, customer relationships, manufacturing know-how, licensed technology, supply agreements and certain trade names and trademarks, are amortized on a straight-line basis over their estimated useful life, ranging from one to twenty-year period. In determining the useful lives of intangible assets, the Company considers the expected use of the assets and the effects of obsolescence, demand, competition, anticipated technological advances, changes in surgical techniques, market influences and other economic factors. For technology based intangible assets, the Company considers the

expected life cycles of products which incorporate the corresponding technology. Trademarks and trade names that are related to products are assigned lives consistent with the period in which the products bearing each brand are expected to be sold.

The Company evaluates its intangible assets with finite lives for indications of impairment whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors that could trigger an impairment review include significant under-performance relative to expected historical or projected future operating results, significant changes in the manner of the Company's use of the acquired assets or the strategy for the Company's overall business or significant negative industry or economic trends. If this evaluation indicates that the value of the intangible asset may be impaired, the Company makes an assessment of the recoverability of the net carrying value of the asset over its remaining useful life. If this assessment indicates that the intangible asset is not recoverable, based on the estimated undiscounted future cash flows of the technology over the remaining amortization period, the Company reduces the net carrying value of the related intangible asset to fair value and may adjust the remaining amortization period.

Intangible assets with finite useful lives are amortized over their respective estimated useful lives and reviewed for indicators of impairment. The Company amortizes its intangible assets on a straight-line basis over a one to twenty-year period.

Impairment of Long-Lived Assets

The Company assesses potential impairment to its long-lived assets when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when the carrying amount of the long-lived assets is not recoverable if it exceeds the sum of the undiscounted cash flows expected to result from the use and eventual disposition of the asset. Any required impairment loss is measured as the amount by which the carrying amount of a long-lived asset exceeds its fair value and is recorded as a reduction in the carrying value of the related asset and a charge to operating results. There were no impairment charges in 2018 or 2017.

Warrants to Purchase Common Stock

Warrants are accounted for in accordance with the applicable accounting guidance as either derivative liabilities or as equity instruments depending on the specific terms of the agreements. Liability-classified instruments are recorded at fair value at each reporting period with any change in fair value recognized as a component of change in fair value of derivative liabilities in the consolidated statements of operations. The Company estimated liability classified instruments using the Black Scholes model, which required management to develop assumptions and inputs that have significant impact on such valuations. The Company periodically evaluates changes in facts and circumstances that could impact the classification of warrants.

The Company issued warrants to purchase shares of the Company's common stock in connection with a private placement transaction that closed on March 29, 2017. These warrants contain a feature that could require the transfer of cash in the event of a Fundamental Transaction, as defined in such warrants (other than a Fundamental Transaction not approved by the Company's Board of Directors). From March 29, 2017, the issuance date, to September 30, 2017, the warrant holders did not control the Company's Board of Directors, and therefore, since potential future cash settlement was deemed to be within the Company's control, the warrants were classified in stockholders' equity in accordance with the authoritative accounting guidance. As described in more detail in Note 10, beginning in fourth quarter of 2017, a majority of the Board of Directors was represented by warrant holders, and thus could control a vote on a Fundamental Transaction that could require the Company to transfer cash to settle the warrants. As a result, the warrants were classified as a liability during the period when the warrant holders had control of the Board of Directors, with changes in the fair value recorded in the consolidated statement of operations. The composition of the Board of Directors subsequently changed in the same fourth quarter of 2017 and allowed the warrants to again be classified within stockholders' equity. All new warrants issued in 2018 qualified for classification within stockholders' equity and, therefore, did not require liability accounting. As of December 31, 2018 and throughout the year ended December 31, 2018, all warrants are classified within stockholders' equity.

Fair Value Measurements

The carrying amount of financial instruments consisting of cash, trade accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses, accrued compensation and current portion of long-term debt included in the Company's consolidated financial statements are reasonable estimates of fair value due to their short maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, management believes the fair value of long-term debt approximates its carrying value.

Authoritative guidance establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

- Level 1: Observable inputs such as quoted prices in active markets;
- Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and
- Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The Company does not maintain any financial assets that are considered to be Level 1, Level 2 or Level 3 instruments as of December 31, 2018. The fair value of the contingent consideration liability assumed in the SafeOp acquisition is recorded as part of the purchase price consideration of the acquisition. The contingent consideration related to the SafeOp acquisition is classified within Level 3 of the fair value hierarchy as the Company is using a probability-weighted income approach, utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate related to the risks of the expected cash flows attributable to the milestones.

The following table provides a reconciliation of liabilities measured at fair value using significant unobservable inputs (Level 3) for the year ended December 31, 2017 and 2018 (in thousands):

	Level 3 Liabilities
Balance at December 31, 2016	\$ —
Transfer from equity	29,413
Changes in fair value	(12,044)
Exercises	(2,311)
Transfer to equity	(15,058)
Balance at December 31, 2017	—
Contingent consideration liability recorded upon acquisition of SafeOp	3,200
Settlement of milestone #1	(1,446)
Change in fair value measurement	846
Balance at December 31, 2018	<u>\$ 2,600</u>

The common stock warrant liabilities for the year ended December 31, 2017 were measured at fair value using the Black-Scholes option pricing valuation model. The assumptions used in the Black-Scholes option pricing valuation model for the common stock warrant liabilities were: (a) a risk-free interest rate based on the rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the remaining contractual term of the warrants; (b) an assumed dividend yield of zero based on the Company's expectation that it will not pay dividends in the foreseeable future; (c) an expected term based on the remaining contractual term of the warrants; and (d) an expected volatility based upon the Company's historical volatility over the remaining contractual term of the warrants.

Research and Development

Research and development expense consists of costs associated with the design, development, testing, and enhancement of the Company's products. Research and development costs also include salaries and related employee benefits, research-related overhead expenses, fees paid to external service providers. Research and development costs are expensed as incurred.

Transaction-related Expenses

The Company expensed certain costs related to the SafeOp acquisition, which primarily include third-party advisory and legal fees.

Litigation-related Expenses

Litigation-related expenses are costs incurred for the ongoing litigation, primarily with NuVasive, Inc. See Note 6 for further information.

Leases

The Company leases its facilities and certain equipment and vehicles under operating leases, and certain equipment under capital leases. For facility leases that contain rent escalation or rent concession provisions, the Company records the total rent payable during the lease term on a straight-line basis over the term of the lease. The Company records the difference between the rent paid and the straight-line rent within accrued expenses in the accompanying consolidated balance sheets.

Product Shipment Cost

Product shipment costs are included in sales and marketing expense in the accompanying consolidated statements of operations. Product shipment costs totaled \$2.5 million and \$2.3 million for the years ended December 31, 2018 and 2017, respectively.

Stock-Based Compensation

The Company accounts for stock-based compensation under provisions which require that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. The amount of expense recognized during the period is affected by subjective assumptions, including estimates of the future volatility of the Company's stock price, the expected term for its stock options, the number of options expected to ultimately vest, and the timing of vesting for the Company's share-based awards.

The Company uses a Black-Scholes option pricing valuation model to estimate the fair value of its stock option awards. The calculation of the fair value of the awards using the Black-Scholes option pricing model is affected by the Company's common stock price on the date of grant as well as assumptions regarding the following:

- Estimated volatility is a measure of the amount by which the Company's common stock price is expected to fluctuate each year during the expected life of the award. The Company's estimated volatility through December 31, 2018 was based on a weighted-average volatility of its actual historical volatility over a period equal to the expected life of the awards.
- The expected term represents the period of time that awards granted are expected to be outstanding. Through December 31, 2018, the Company calculated the expected term using a weighted-average term based on historical exercise patterns and the term from option date to full exercise for the options granted within the specified date range.
- The risk-free interest rate is based on the yield curve of a zero-coupon U.S. Treasury bond on the date the stock option award is granted with a maturity equal to the expected term of the stock option award.
- The assumed dividend yield is based on the Company's expectation of not paying dividends in the foreseeable future.

The Company used historical data to estimate the number of future stock option forfeitures. Stock-based compensation recorded in the Company's consolidated statement of operations is based on awards expected to ultimately vest and has been reduced for estimated forfeitures. The Company's estimated forfeiture rates may differ from its actual forfeitures which would affect the amount of expense recognized during the period.

The Company accounts for stock option grants to non-employees in accordance with provisions which require that the fair value of these instruments be recognized as an expense over the period in which the related services are rendered.

Stock-based compensation expense of awards with performance conditions is recognized over the period from the date the performance condition is determined to be probable of occurring through the time the applicable condition is met. Determining the likelihood and timing of achieving performance conditions is a subjective judgment made by management which may affect the amount and timing of expense related to these share-based awards. Share-based compensation is adjusted to reflect the value of options which ultimately vest as such amounts become known in future periods.

Stock-based awards with market conditions are valued using the Monte Carlo valuation technique which requires management to make significant estimates and assumptions that are not observable from the market. Stock based compensation for awards with both service and market conditions are recognized on a straight line basis over the longer of the derived service period or the requisite service period.

Valuation of Stock Option Awards

The weighted average assumptions used to compute the stock-based compensation costs for the stock options granted during the years ended December 31, 2018 and 2017 are as follows:

	Year Ended December 31,	
	2018	2017
Risk-free interest rate	2.85%	2.01%
Expected dividend yield	—	—
Weighted average expected life (years)	6.08	6.02
Volatility	78.54%	78.52%

Stock-Based Compensation Costs

The compensation cost that has been included in the Company's consolidated statement of operations for all stock-based compensation arrangements is detailed as follows (in thousands):

	Year Ended December 31,	
	2018	2017
Cost of revenues	\$ 73	\$ 40
Research and development	482	206
Sales, general and administrative	4,749	3,735
Total	<u>\$ 5,304</u>	<u>\$ 3,981</u>

Income Taxes

The Company accounts for income taxes in accordance with provisions which set forth an asset and liability approach that requires the recognition of deferred tax assets and deferred tax liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. In making such determination, a review of all available positive and negative evidence must be considered, including scheduled reversal of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance.

The Company recognizes interest and penalties related to uncertain tax positions as a component of the income tax provision.

Beneficial Conversion Feature – Series B Preferred Stock

In March 2018, the Company completed a private placement of equity securities to certain institutional and accredited investors, providing for the sale by the Company of newly designated Series B Convertible Preferred Stock, which shares of preferred stock were automatically converted into 14.3 million shares of our common stock upon approval by the Company's stockholders. As the Series B Convertible Preferred Stock provided the holder the benefit to convert to shares of common stock, a beneficial conversion feature ("BCF") with a calculated intrinsic fair value at issuance of \$13.5 million existed as of the date the shares of Series B Convertible Preferred Stock were able to be converted into shares of common stock. This one-time, non-cash deemed dividend impacts net loss attributable to common stockholders and net loss per share on the Company's consolidated statement of operations for the year ended December 31, 2018.

Net Loss per Share

Basic earnings per share ("EPS") is calculated by dividing the net income or loss available to common stockholders by the weighted average number of shares of common stock outstanding for the period without consideration for common stock equivalents. Diluted EPS is computed by dividing the net income or loss available to common stockholders by the weighted average number of shares of common stock outstanding for the period and the weighted average number of dilutive common stock equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, common stock subject to repurchase by the Company, common stock issuable upon conversion of preferred shares, options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted earnings per share when their effect is dilutive.

The following table sets forth the computation of basic and diluted loss per share (in thousands, except per share data):

	Year Ended December 31,		
	2018	2017	
	Net loss attributable to common shareholders	Continuing operations	Discontinued operations
Numerator:			
Net (loss) income, basic	\$ (42,463)	\$ (4,540)	\$ 2,246
Change in fair value of warrants	—	12,044	—
Net (loss) income, diluted	\$ (42,463)	\$ (16,584)	\$ 2,246
Denominator:			
Weighted average common shares outstanding	35,402	12,827	12,827
Weighted average unvested common shares subject to repurchase	(87)	(39)	(39)
Weighted average common shares outstanding - basic	35,315	12,788	12,788
Dilutive impact of warrants	—	494	494
Weighted average common shares outstanding - diluted	35,315	13,282	13,282
Basic net (loss) income per share	<u>\$ (1.20)</u>	<u>\$ (0.36)</u>	<u>\$ 0.18</u>
Diluted net (loss) income per share	<u>\$ (1.20)</u>	<u>\$ (1.25)</u>	<u>\$ 0.17</u>

The anti-dilutive securities not included in diluted net loss per share were as follows calculated on a weighted average basis (in thousands):

	Year Ended December 31,	
	2018	2017
Options to purchase common stock	330	3,156
Warrants to purchase common stock	1,860	1,204
Series A convertible preferred stock	2,141	3,829
Unvested restricted stock awards	87	39
Convertible notes	761	—
	<u>5,179</u>	<u>8,228</u>

Recent Accounting Pronouncements

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, as modified by subsequently issued ASUs 2015-14, 2016-08, 2016-10, 2016-12 and 2016-20 (collectively “ASU 2014-09”). ASU 2014-09 superseded existing revenue recognition standards with a single model unless those contracts are within the scope of other standards. The revenue recognition principle in ASU 2014-09 is that an entity should recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company adopted the new standard effective January 1, 2018 using the modified retrospective approach applied to those contracts which were not completed as of January 1, 2018. Results for reporting periods beginning after January 1, 2018 are presented under ASU 2014-09, while prior period amounts are not adjusted and continue to be reported in accordance with the historic accounting under ASC 605. The adoption of ASU 2014-09 did not have a material cumulative impact on the Company’s consolidated financial statements as of January 1, 2018.

In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, which eliminates the diversity in practice related to the classification of certain cash receipts and payments in the statement of cash flows, by adding or clarifying guidance on eight specific cash flow issues. The guidance is effective for annual and interim reporting periods in fiscal years beginning after December 15, 2017, with early adoption permitted. The amendments in this update should be applied retrospectively to all periods presented, unless deemed impracticable, in which case, prospective application is permitted. The adoption did not have a material cumulative impact on the Company’s consolidated financial statements.

In January 2017, the FASB issued ASU 2017-01, *Clarifying the Definition of a Business*, which was created to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This guidance provides a screen to determine whether an integrated set of assets and activities is a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The guidance is effective for annual and interim reporting periods in fiscal years beginning after December 15, 2017. The Company followed this guidance for its acquisition of SafeOp during the first quarter of 2018, which was deemed to qualify as a business.

In May 2017, the FASB issued ASU 2017-09, *Compensation-Stock Compensation*, to provide clarity and reduce both 1) diversity in practice and 2) cost and complexity when applying the guidance in Topic 718 to a change in the terms or conditions of a share-based payment award. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under Topic 718. The amendments in ASU 2017-09 are effective for fiscal and interim reporting periods in fiscal years beginning after December 15, 2017. Early adoption is permitted, including adoption in any interim period. The amendments in ASU 2017-09 should be applied prospectively to an award modified on or after the adoption date. The adoption did not have a material cumulative impact on the Company's consolidated financial statements.

In July 2017, the FASB issued ASU 2017-11, *Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815); (Part I) Accounting for Certain Financial Instruments with Down Round Features. (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Non-Controlling Interests with a Scope Exception*. The ASU allows companies to exclude a down round feature when determining whether a financial instrument (or embedded conversion feature) is considered indexed to the entity's own stock. As a result, financial instruments (or embedded conversion features) with down round features may no longer be required to be classified as liabilities. A company will recognize the value of a down round feature only when it is triggered and the strike price has been adjusted downward. For equity-classified freestanding financial instruments, such as warrants, an entity will treat the value of the effect of the down round, when triggered, as a dividend and a reduction of income available to common shareholders in computing basic earnings per share. For convertible instruments with embedded conversion features containing down round provisions, entities will recognize the value of the down round as a beneficial conversion discount to be amortized to earnings. The guidance in ASU 2017-11 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, and the guidance is to be applied using a full or modified retrospective approach. The Company early adopted the guidance in conjunction with the 2018 Private Placement. As no instruments with down round protection were held prior to the 2018 Private Placement, a cumulative effect change was not recognized upon adoption.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which expands the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should 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 guidance is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company early adopted the guidance during the second quarter of 2018. The adoption did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which changes several aspects of the accounting for leases, including the requirement that all leases with durations greater than twelve months be recognized on the balance sheet. The guidance is effective for annual and interim reporting periods in fiscal years beginning after December 15, 2018. Although the Company is in the process of finalizing the impact of adoption of the ASU on its consolidated financial statements, the Company will elect the optional transition method to account for the impact of the adoption with a cumulative-effect adjustment in the period of adoption and will not restate prior periods. The Company expects to elect certain practical expedients permitted under the transition guidance. The Company will record a right-of-use asset and liability upon adoption of the guidance pertaining to its long-term real estate lease for its corporate facilities. The Company is currently finalizing its review of contracts and may identify additional embedded leases and additional amounts to be recorded.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other*, which eliminates the requirement to calculate the implied fair value of goodwill to measure a goodwill impairment charge. Instead, entities will record an impairment charge based on the excess of a reporting unit's carrying amount over its fair value. The standard has tiered effective dates, starting in 2020 for calendar-year public business entities that meet the definition of an SEC filer. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. The Company is in the process of determining the impacts the adoption will have on its consolidated financial statements as well as whether to early adopt the new guidance.

3. Balance Sheet Details

Accounts Receivable, net

Accounts receivable consist of the following (in thousands):

	December 31,	
	2018	2017
Accounts receivable	\$ 15,291	\$ 15,328
Less allowance for doubtful accounts	(196)	(506)
Accounts receivable, net	<u>\$ 15,095</u>	<u>\$ 14,822</u>

Inventories, net

Inventories consist of the following (in thousands):

	December 31,	
	2018	2017
Raw materials	\$ 5,813	\$ 4,969
Work-in-process	952	502
Finished goods	40,165	37,933
	46,930	43,404
Less reserve for excess and obsolete	(18,165)	(16,112)
Inventories, net	<u>\$ 28,765</u>	<u>\$ 27,292</u>

Property and Equipment, net

Property and equipment consist of the following (in thousands except for useful lives):

	Useful lives (in years)	December 31,	
		2018	2017
Surgical instruments	4	\$ 54,848	\$ 53,198
Machinery and equipment	7	5,971	5,503
Computer equipment	3	3,104	3,500
Office furniture and equipment	5	1,155	2,794
Leasehold improvements	various	1,765	1,714
Construction in progress	n/a	92	336
		66,935	67,045
Less accumulated depreciation and amortization		(53,700)	(54,375)
Property and equipment, net		<u>\$ 13,235</u>	<u>\$ 12,670</u>

Total depreciation expense was \$6.0 million and \$6.6 million for the years ended December 31, 2018 and 2017, respectively. At December 31, 2018 and 2017, assets recorded under capital leases of \$0.4 million were included in the machinery and equipment balance. Amortization of assets under capital leases is included in depreciation expense.

Intangible Assets, net

In conjunction with the acquisition of SafeOp in March 2018, the Company recorded \$21.6 million of new intangible assets. See Note 8 for further information regarding the acquisition. Intangible assets, net consist of the following (in thousands, except as indicated):

	Remaining Avg. Useful lives (in years)	December 31,	
		2018	2017
Developed product technology	10	\$ 26,976	\$ 13,876
Intellectual property	—	1,004	1,004
License agreements	1	5,064	5,738
Trademarks and trade names	—	792	732
Customer-related	5	7,458	7,458
Distribution network	4	4,027	4,027
In process research and development	19	8,800	—
		54,121	32,835
Less accumulated amortization		(27,713)	(27,587)
Intangible assets, net		<u>\$ 26,408</u>	<u>\$ 5,248</u>

Total expense related to amortization of intangible assets was \$0.8 million and \$0.9 million for the years ended December 31, 2018 and 2017, respectively.

Future amortization expense related to intangible assets as of December 31, 2018 is as follows (in thousands):

Year Ending December 31,	
2019	\$ 1,566
2020	1,890
2021	1,890
2022	1,890
2023	1,890
Thereafter	17,282
Total	<u>\$ 26,408</u>

Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2018	2017
Commissions and sales milestones	\$ 3,594	\$ 3,360
Payroll and payroll related	3,222	2,968
Litigation settlement obligation	4,400	4,400
Professional fees	2,637	1,484
Royalties	1,354	1,269
Restructuring and severance accruals	710	520
Taxes	(3)	246
Guaranteed collaboration compensation, current	—	4,485
Interest	261	376
Acquisition related - contingent consideration	2,600	—
Other	3,541	3,138
Total accrued expenses	<u>\$ 22,316</u>	<u>\$ 22,246</u>

4. Discontinued Operations

In connection with the sale of the International Business, the Company entered into a product manufacture and supply agreement (the “Supply Agreement”) with Globus, pursuant to which the Company supplies to Globus certain of its implants and

instruments (the “Products”), previously offered for sale by the Company in international markets at agreed-upon prices for a minimum term of three years, with the option for Globus to extend the term for up to two additional twelve month periods subject to Globus meeting specified purchase requirements. In accordance with authoritative guidance, sales to Globus are reported under continuing operations as the Company has continuing involvement under the Supply Agreement.

During the year ended December 31, 2018, the Company recorded \$8.0 million in revenue and \$7.5 million in cost of revenue from the Supply Agreement in continuing operations and during the year ended December 31, 2017, the Company recorded \$14.4 million in revenue and \$12.1 million in cost of revenue in the continuing operations. General and administrative expenses pertaining to discontinued operations on the Company’s consolidated statements of operations were immaterial for the years ended December 31, 2018 and 2017.

In addition, on September 1, 2016, the Company entered into a five-year term credit, security and guaranty agreement with Globus (the “Globus Facility Agreement”), as further described in Note 5, pursuant to which Globus agreed to loan the Company up to \$30 million, subject to the terms and conditions set forth in the Globus Facility Agreement, as amended. In November 2018, the Globus facility was paid in full.

5. Debt

MidCap Facility Agreement

The Company’s Amended Credit Facility with MidCap provides for a revolving credit commitment up to \$22.5 million and provided for a term loan commitment up to \$5 million. As of December 31, 2018, \$11.0 million was outstanding under the revolving line of credit and the term loan was paid in full. The principal balance outstanding under the revolving line of credit is due in December 2022.

Amounts outstanding under the revolving line of credit accrues interest at the London Interbank Offered Rate (“LIBOR”) plus 6.0%, reset monthly. At December 31, 2018, the revolving line of credit carried an interest rate of 8.35%, with interest payable monthly. The borrowing base is determined based on the value of domestic eligible accounts receivable. As collateral for the Amended Credit Facility, MidCap has a first lien security interest in accounts receivable and a second lien on substantially all other assets.

At December 31, 2018, \$1.3 million remains as unamortized debt discount related to the Amended Credit Facility on the consolidated balance sheet, which will be amortized over the remaining term of the Amended Credit Facility.

The Amended Credit Facility also includes several event of default provisions, such as payment default, insolvency conditions and a material adverse effect clause, which could cause interest to be charged at a rate which is up to five percentage points above the rate effective immediately before the event of default or result in MidCap’s right to declare all outstanding obligations immediately due and payable.

On March 8, 2018, the Company entered into a Seventh Amendment to the Amended Credit Facility to extend the date that the financial covenants of the Amended Credit Facility are effective from April 2018 to April 2019, and established a minimum liquidity covenant of \$5.0 million effective through March 2019. On November 6, 2018, the Company entered into the Eighth Amendment to the Amended Credit Facility to extend the date that the financial covenants of the Amended Credit Facility are effective from April 2019 to April 2020, and extended the minimum liquidity covenant through March 2020. The Company was in compliance with the covenants under the Amended Credit Facility at December 31, 2018.

Globus Facility Agreement

On September 1, 2016, the Company and Globus entered into the Globus Facility Agreement, pursuant to which Globus loaned the Company \$30 million, subject to the terms and conditions set forth in the Globus Facility Agreement. On November 7, 2018, the Company repaid in full all amounts outstanding and due under the Globus Facility Agreement. The Company made a final payment of \$29.2 million to Globus, consisting of outstanding principal and accrued interest. All amounts previously recorded as debt issuance costs were recorded as a loss on debt extinguishment on the Company's consolidated statement of operations for the year ended December 31, 2018.

Squadron Credit Agreement

On November 6, 2018, the Company closed a \$35 million Term Loan with Squadron, a provider of debt financing to growing companies in the orthopedic industry. Net proceeds of approximately \$34.1 million were used to retire the Company's existing \$29.2 million term debt with Globus. The remainder of the proceeds will be used for general corporate purposes.

The debt has a five-year maturity and bears interest at LIBOR plus 8% (10.5% as of December 31, 2018) per annum. The Agreement specifies a minimum interest rate of 10% and a maximum of 13% per year. Interest-only payments are due monthly through May 2021, followed by \$10 million in principal payable in 29 equal monthly installments beginning June 2021 and a \$25 million lump-sum payment payable at maturity in November 2023. As collateral for the Term Loan, Squadron has a first lien security interest in substantially all assets except for accounts receivable.

The credit agreement also includes several event of default provisions, such as payment default, insolvency conditions and a material adverse effect clause, which could cause interest to be charged at a rate which is up to five percentage points above the rate effective immediately before the event of default or result in Squadron's right to declare all outstanding obligations immediately due and payable. Furthermore, the credit agreement contains various covenants, including monthly compliance certifications and compliance with government regulations and maintenance of insurance, and prohibitions against certain specified actions, including acquiring any new equipment financings over a specified amount. The credit agreement also contains various negative covenants including a \$5 million minimum liquidity requirement through March 31, 2020. The minimum liquidity covenant will be replaced by a fixed charge ratio, pursuant to which operating cash to fixed charges (as defined) must equal at least 1:1 on a rolling 12-month basis, beginning April 2020. The Company was in compliance with the covenants under the credit agreement at December 31, 2018.

In connection with the financing, the Company issued warrants to Squadron to purchase 845,000 shares of common stock at an exercise price of \$3.15 per share. The warrants have a seven-year term and are immediately exercisable. See Note 10 for further detail on the warrants.

The debt is recorded at its carrying value of \$32.4 million, net of issuance costs, including all amounts paid to third parties to secure the debt and the fair value of the warrants issued. The debt issuance costs are being amortized into interest expense over the five-year term utilizing the effective interest rate method.

In March 2019, the Company closed on an Expanded Credit Facility with Squadron for up to \$30 million in additional secured financing. See Note 16 for further information.

Other Debt Agreements

The Company has one outstanding capital lease arrangement as of December 31, 2018. The lease bears interest at an annual rate of 6.4% and is due in monthly principal and interest installments, collateralized by the related equipment, and matures in December 2022.

Long-term debt consists of the following (in thousands):

	December 31,	
	2018	2017
Amended Credit Facility and Term Loan with MidCap	\$ 11,010	\$ 12,674
Globus Facility Agreement	—	30,000
Squadron Term Loan	35,000	—
Notes payable	296	200
Convertible note	3,000	—
Total	49,306	42,874
Add: capital leases	126	222
Less: debt discount	(3,857)	(2,023)
Total	45,575	41,073
Less: current portion of long-term debt	(3,276)	(3,306)
Total long-term debt, net of current portion	<u>\$ 42,299</u>	<u>\$ 37,767</u>

Principal payments on debt are as follows as of December 31, 2018 (in thousands):

Year Ending December 31,	
2019	\$ 3,250
2020	47
2021	2,414
2022	15,148
2023 and thereafter	28,447
Total	49,306
Add: capital lease principal payments	126
Less: debt discount	(3,857)
Total	45,575
Less: current portion of long-term debt	(3,276)
Long-term debt, net of current portion	<u>\$ 42,299</u>

6. Commitments and Contingencies

Leases

The Company occupies approximately 76,000 square feet of office, engineering, and research and development space in Carlsbad, California. Monthly rent is approximately \$111,000 per month for the year ended December 31, 2018 and increases by approximately \$3,000 per month each year through expiration of the lease on July 31, 2021.

The Company also leases certain equipment under operating leases which expire on various dates through 2021, and certain equipment under a capital lease that expires in 2022.

Future minimum annual lease payments under the Company's operating and capital leases are as follows (in thousands):

Year ending December 31,	Operating	Capital
2019	\$ 1,684	\$ 34
2020	1,688	37
2021	1,009	37
2022	—	37
2023 and thereafter	—	—
	4,381	145
Less: amount representing interest		(19)
Present value of minimum lease payments		126
Current portion of capital leases		(34)
Capital leases, less current portion		<u>\$ 92</u>

Rent expense under operating leases for each of the years ended December 31, 2018 and 2017 was \$1.4 million.

Litigation

The Company is and may become involved in various legal proceedings arising from its business activities. While management is not aware of any litigation matter that in and of itself would have a material adverse impact on the Company's consolidated results of operations, cash flows or financial position, litigation is inherently unpredictable, and depending on the nature and timing of a proceeding, an unfavorable resolution could materially affect the Company's future consolidated results of operations, cash flows or financial position in a particular period. The Company assesses contingencies to determine the degree of probability and range of possible loss for potential accrual or disclosure in the Company's consolidated financial statements. An estimated loss contingency is accrued in the Company's consolidated financial statements if it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. Because litigation is inherently unpredictable and unfavorable resolutions could occur, assessing contingencies is highly subjective and requires judgments about future events. When evaluating contingencies, the Company may be unable to provide a meaningful estimate due to a number of factors, including the procedural status of the matter in question, the presence of complex or novel legal theories, and/or the ongoing discovery and development of information important to the matters. In addition, damage amounts claimed in litigation against the Company may be unsupported, exaggerated or unrelated to reasonably possible outcomes, and as such are not meaningful indicators of the Company's potential liability.

On February 13, 2018, NuVasive, Inc. filed suit against the Company in the United States District Court for the Southern District of California, alleging that certain of the Company's products (including components of the Battalion™ Lateral System), infringe, or contribute to the infringement of, U.S. Patent Nos. 7,819,801, 8,355,780, 8,439,832, 8,753,270, 9,833,227 (entitled "Surgical access system and related methods"), U.S. Patent No. 8,361,156 (entitled "Systems and methods for spinal fusion"), and U.S. Design Patent Nos. D652,519 ("Dilator") and D750,252 ("Intervertebral Implant"). NuVasive is seeking unspecified monetary damages and a court injunction against future infringement by the Company.

On March 8, 2018, the Company moved to dismiss NuVasive's claims of infringement of its design patents on the grounds that those allegations fail to state a cognizable legal claim. On May 14, 2018, the Court ruled that NuVasive had failed to state a plausible claim for infringement of the asserted design patents and granted the Company's motion to dismiss those claims with prejudice, as any further amendment would be futile. The Company filed its answer, affirmative defenses and counterclaims to NuVasive's remaining claims on May 21, 2018.

On March 26, 2018, NuVasive moved for a preliminary injunction, which, on March 27, 2018, the Court denied without prejudice for failure to comply with the Court's chambers rules. On April 5, 2018, NuVasive again moved for a preliminary injunction. The Court held a hearing on the matter, having been fully briefed, on June 21, 2018. On July 10, 2018, the Court ruled that NuVasive had failed to establish either likelihood of success on the merits of its remaining claims or that it would suffer irreparable harm in the absence of a preliminary injunction. Accordingly, the Court denied NuVasive's motion for preliminary injunction.

On September 13, 2018, NuVasive filed an Amended Complaint for Patent Infringement, asserting additional infringement claims of U.S. Patent Nos. 9,924,859, 9,974,531 and 8,187,334. The Company filed its answer, affirmative defenses and counterclaims to NuVasive's claims on October 12, 2018. On October 26, 2018, NuVasive moved to dismiss the Company's counterclaims that NuVasive intentionally had misled the Patent Office as a means of obtaining certain patents asserted against the Company. On January 30, 2019, the Court denied NuVasive's motion as to all but one of the Company's counterclaims. The Court granted NuVasive's motion with respect to one counterclaim, but granted the Company leave to amend its counterclaim to cure the dismissal. The Company amended that counterclaim on February 14, 2019. On February 28, 2019, NuVasive moved to dismiss the amended counterclaim. A hearing on the matter is set for April 4, 2019.

On December 13, 2018, the Company filed a petition with the Patent Trial and Appeal Board ("PTAB") challenging the validity of certain claims of U.S. Patent No. 8,361,156. On December 21, 2018, the Company filed a similar petition with PTAB challenging the validity of certain claims of U.S. Patent No. 8,187,334. The Company expects the PTAB to issue its decisions on the matters in the second half of 2019. On February 6, 2019, upon joint motion of the parties, the Court stayed all proceedings in this matter pending PTAB's determination of whether to institute *inter partes* review of the asserted claims of the two patents at issue and vacated the trial date. The Company anticipates that the stay of proceedings will remain in effect until at least July 2019.

The Company believes that the allegations lack merit and intends to vigorously defend all claims asserted. It is impossible at this time to assess whether the outcome of this proceeding will have a material adverse effect on the Company consolidated results of operations, cash flows or financial position. Therefore, in accordance with authoritative accounting guidance, the Company has not recorded any accrual for a contingent liability associated with this legal proceeding based on its belief that a liability, while possible, is not probable and any range of potential future charge cannot be reasonably estimated at this time.

Indemnifications

In the normal course of business, the Company enters into agreements under which it occasionally indemnifies third-parties for intellectual property infringement claims or claims arising from breaches of representations or warranties. In addition, from time to time, the Company provides indemnity protection to third-parties for claims relating to past performance arising from undisclosed liabilities, product liabilities, environmental obligations, representations and warranties, and other claims. In these agreements, the scope and amount of remedy, or the period in which claims can be made, may be limited. It is not possible to determine the maximum potential amount of future payments, if any, due under these indemnities due to the conditional nature of the obligations and the unique facts and circumstances involved in each agreement.

In October 2017, NuVasive filed a lawsuit in Delaware Chancery Court against Mr. Miles, the Company's Chairman and CEO, who was a former officer and board member of NuVasive. The Company itself was not initially a named defendant in this lawsuit; however, on June 28, 2018, NuVasive amended its complaint to add the Company as a defendant. As of December 31, 2018, the Company has not recorded any liability on the consolidated balance sheet related to this matter. On October 12, 2018, the Delaware Court ordered that NuVasive begin advancing legal fees for Mr. Miles' defense in the lawsuit, as well as Mr. Miles' legal fees incurred in pursuing advancement of his fees, pursuant to an indemnification agreement between NuVasive and Mr. Miles.

Royalties

The Company has entered into various intellectual property agreements requiring the payment of royalties based on the sale of products that utilize such intellectual property. These royalties primarily relate to products sold by Alphatec Spine and are based on fixed fees or calculated either as a percentage of net sales or on a per-unit sold basis. Royalties are included on the accompanying consolidated statements of operations as a component of cost of revenues. As of December 31, 2018, the Company is obligated to pay guaranteed minimum royalty payments under these agreements of approximately \$5.9 million through 2023 and beyond.

7. Orthotec Settlement

On September 26, 2014, the Company entered into a Settlement and Release Agreement, dated as of August 13, 2014, by and among the Company and its direct subsidiaries, including Alphatec Spine, Inc., Alphatec Holdings International C.V., Scient'x S.A.S. and Surgiview S.A.S.; HealthpointCapital, LLC, HealthpointCapital Partners, L.P., HealthpointCapital Partners II, L.P., John H. Foster and Mortimer Berkowitz III; and Orthotec, LLC and Patrick Bertranou, (the "Settlement Agreement"). Pursuant to the Settlement Agreement, the Company agreed to pay Orthotec, LLC \$49.0 million in cash, including initial cash payments totaling \$1.75 million, which the Company previously paid in March 2014, and an additional lump sum payment of \$15.75 million, which the Company previously paid in April 2014. The Company agreed to pay the remaining \$31.5 million in 28 quarterly installments of \$1.1 million and one additional quarterly installment of \$0.7 million, commencing October 1, 2014. The payments set forth above are guaranteed by Stipulated Judgments held against the Company, HealthpointCapital Partners, L.P., HealthpointCapital Partners II, L.P., HealthpointCapital, LLC, John H. Foster and Mortimer Berkowitz III and, in the event of a default, will be entered and enforced against these entities and/or individuals in that order. In September 2014, the Company and HealthpointCapital entered into an agreement for joint payment of settlement whereby HealthpointCapital has agreed to contribute \$5 million to the \$49 million settlement amount. The \$5 million is classified within stockholders' equity on the Company's consolidated balance sheet due to the related party nature with HealthpointCapital and its affiliates. See Note 13 for further information.

As of December 31, 2018, the Company has made installment payments in the aggregate of \$36.2 million, with a remaining outstanding balance of \$21.6 million (including interest). The Company has the right to prepay the amounts due without penalty. The unpaid amounts due accrue interest at the rate of 7% per year until paid in full. The accrued but unpaid interest will be paid in quarterly installments of \$1.1 million (or the full amount of the accrued but unpaid interest if less than \$1.1 million) following the full payment of the \$31.5 million in quarterly installments described above. No interest will accrue on the accrued interest. The Settlement Agreement provides for mutual releases of all claims in the Orthotec, LLC v. Surgiview, S.A.S, et al. matter in the Superior Court of California, Los Angeles County and all other related litigation matters involving the Company and its directors and affiliates.

8. Acquisition of SafeOp Surgical, Inc.

On March 8, 2018, the Company acquired SafeOp, a privately-held provider of neuromonitoring technology designed to enable effective intra-operative nerve health assessment. At the time of acquisition SafeOp had FDA 510(k) approval for a somatosensory evoked potential (“SSEP”) monitoring technology. The Company has developed a product that will allow for both free run and triggered specific recording of muscle activity, also known as Electromyography (“EMG”). The Company received FDA clearance for SafeOp’s EMG technology in February 2019 to complement the SSEP solution, and anticipates commercialization of the combined technology solution in mid-2019. In addition to expanding the Company’s market presence in lateral spine surgery, the Company believes that the SafeOp solution will allow it to integrate neuromonitoring into its broader product portfolio and accelerate the transition to procedural integration of the entire portfolio.

The Merger was accounted for using the acquisition method of accounting. The following unaudited pro forma results of operations assume that the Company acquired SafeOp on January 1, 2018 and 2017, respectively (in thousands).

	Year Ended December 31,	
	2018	2017
Revenue	\$ 91,694	\$ 101,981
Loss from continuing operations	(29,493)	(8,776)
Net loss	<u>\$ (28,975)</u>	<u>\$ (6,530)</u>
Net loss per share, basic and diluted	<u>\$ (0.69)</u>	<u>\$ (0.35)</u>

The unaudited pro forma information presented above is not necessarily indicative of either the results of operations that would have occurred had the acquisition of SafeOp been effective on January 1, 2018 or 2017, respectively, or of the Company’s future results of operations.

The results of operations for SafeOp have been included in the Company’s financial results since the acquisition date. For the year ended December 31, 2018, the Company’s total net revenues were not materially impacted from the Merger and net loss increased by \$2.8 million due to SafeOp’s operating expenses.

Under the term of the definitive merger agreement, the Company agreed to pay \$15.1 million in cash and agreed to issue 3,265,132 shares of common stock. The Company paid the full \$15.1 million in cash consideration during the year ended December 31, 2018. On March 8, 2018, the Company issued 2,975,209 shares of common stock valued at \$9.8 million, based on the closing share price of \$3.30, and issued an additional 115,621 shares of common stock during the second quarter of 2018 and the remaining 174,302 shares of common stock during the third quarter of 2018.

The Company also issued \$3 million in convertible notes that were convertible into a total of 987,578 shares, which included total interest incurred, of common stock and issued warrants to purchase 2.2 million shares of common stock at an exercise price of \$3.50 per share. The convertible notes matured on March 9, 2019 and were settled in cash. Shares of common stock are issuable upon achievement of post-closing milestones as described further below.

The total purchase price is presented below (in thousands):

Cash paid	\$ 15,103
Common stock issued	10,879
Note	3,000
Warrants	1,650
Contingent consideration issued or issuable	3,200
Total	<u>\$ 33,832</u>

The Company has measured the identifiable assets and liabilities assumed at their acquisition date fair values separately from goodwill. The intangible assets acquired includes the EPAD tradename, in-process research and development (“IPR&D”) for the EMG technology, and the developed technology for SSEP. The fair value of the EPAD tradename was determined to be \$60,000 with an estimated useful life of one year. The IPR&D for the EMG technology is considered to have an indefinite life until the development is completed (i.e. once FDA clearance is obtained), at which point the Company will determine the intangible asset’s estimate useful life. The developed SSEP technology has an estimated fair value of \$13.1 million with an estimated useful life of 20 years. The Company has not presented any measurement period adjustments to the purchase price or the allocation detailed below for the year ended December 31, 2018 due to their immaterial nature.

The allocation of the purchase price to the assets acquired and liabilities assumed based on their fair values, is as follows (in thousands):

<i>Assets acquired:</i>	
Accounts receivable	\$ 40
Inventory	192
Prepaid expenses and other current assets	89
Total current assets	<u>\$ 321</u>
Property and equipment, net	20
Other long-term assets	5
IPR&D	8,400
EPAD Tradename	60
Developed Technology	13,100
Total assets	<u>\$ 21,906</u>
<i>Liabilities assumed:</i>	
Accounts payable	\$ 55
Accrued expenses	148
Deferred tax liability	1,768
Total liabilities	<u>\$ 1,971</u>
Goodwill	<u>13,897</u>
Total consideration transferred	<u><u>\$ 33,832</u></u>

The purchase price exceeded the fair value of the net tangible and identifiable intangible assets acquired from SafeOp. As a result, the Company recorded goodwill in connection with the Merger. Specifically, the goodwill recorded as part of the Merger includes the assembled workforce and synergies associated with the combined entity. The goodwill is not expected to be deductible for tax purposes.

As a result of the Merger, for the year ended December 31, 2018, the Company incurred \$1.6 million in total transaction costs which, in accordance with authoritative accounting guidance, were expensed as incurred.

The Company agreed to issue additional shares of common stock for up to \$4.3 million upon achievement of post-closing milestones (the “Contingent Consideration”). The first milestone included payment of up to \$1.4 million due 10 days after submission of an application for Regulatory Approval (as that term is defined in the Merger Agreement) for an indication for regulatory clearance for use of a product that includes specifically recording of muscle activity (EMG). During the third quarter of 2018, the first milestone was achieved and the Company issued 443,421 shares of common stock as payment. The second milestone includes a payment of up to \$2.9 million in common stock due 10 days after the receipt of Regulatory Approval from any Regulatory Authority (as those terms are defined in the Merger Agreement) for an indication for use of a product that includes specifically EMG. During the first quarter of 2019, the second milestone was achieved and the Company issued 886,843 shares of common stock as payment. The Contingent Consideration is recorded as a liability and measured at fair value using a probability-weighted income approach, utilizing significant unobservable inputs including the probability of achieving each of the potential milestones and an estimated discount rate related to the risks of the expected cash flows attributable to the milestones. The material factors that may impact the fair value of the Contingent Consideration, and therefore, this liability, are the probabilities of achieving the related milestones and the discount rate. Significant increases or decreases in any of the probabilities of success would result in a significantly higher or lower fair value, respectively. The fair value of the Contingent Consideration, and the associated liability relating to the Contingent Consideration at each reporting date, will be re-assessed with the changes in fair value reflected in earnings. For the year ended December 31, 2018, the fair value for the Contingent Consideration increased by \$0.8 million due to the proximity of the achievement of the milestones. The amount was recorded within research and development expense on the consolidated statement of operations, with a corresponding increase in the liability on the Company’s consolidated balance sheet.

9. Sale of Assets

On May 5, 2017, the Company entered into an agreement to sell certain inventory and intellectual property to a third party for \$1.0 million in consideration, payable via a credit to future minimum royalties owed to the third party under an existing exclusive license agreement between the parties. The Company recorded a net gain on sale of assets of \$0.9 million which is included under operating expenses on the Company’s consolidated statement of operations.

10. Equity

Redeemable preferred stock

The Company issued shares of redeemable preferred stock in connection with its initial public offering in June 2006. As of December 31, 2018 and 2017, the redeemable preferred stock carrying value was \$23.6 million and there were 20 million shares of redeemable preferred stock authorized. The redeemable preferred stock is not convertible into common stock but is redeemable at \$9.00 per share, (i) upon the Company's liquidation, dissolution or winding up, or the occurrence of certain mergers, consolidations or sales of all or substantially all of the Company's assets, before any payment to the holders of the Company's common stock, or (ii) at the Company's option at any time. Holders of redeemable preferred stock are generally not entitled to vote on matters submitted to the stockholders, except with respect to certain matters that will affect them adversely as a class, and are not entitled to receive dividends. The carrying value of the redeemable preferred stock was \$7.11 per share at December 31, 2018 and 2017. The redeemable preferred stock is presented separately from stockholders' deficit in the consolidated balance sheets and any adjustments to its carrying value up to its redemption value of \$9.00 per share are reported as a dividend.

Series A Convertible Preferred Stock

In March 2017, the Company completed a private placement (the "2017 Private Placement") with certain institutional and accredited investors, including certain directors, executive officers and employees of the Company (collectively, the "Purchasers"), providing for the sale by the Company of 1,809,628 shares of the Company's common stock at a purchase price of \$2.00 per share and 15,245 shares of newly designated Series A Convertible Preferred Stock at a purchase price of \$1,000 per share (which shares were convertible into approximately 7,622,372 shares of common stock).

The 2017 Private Placement generated aggregate gross proceeds to the Company of approximately \$18.9 million. The Series A Convertible Preferred Stock are entitled to dividends on an as-if-converted basis in the same form as any dividends actually paid on shares of common stock or other securities. Except as otherwise required by law, the holders of Series A Convertible Preferred Stock have no right to vote on matters submitted to a vote of the Company's stockholders. Without the prior written consent of 75% of the outstanding shares of Series A Convertible Preferred Stock, the Company may not: (a) alter or change adversely the powers, preferences or rights given to the Series A Convertible Preferred Stock or alter or amend the Certificate of Designation for the Series A Convertible Preferred Stock, (b) amend the Company's certificate of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Convertible Preferred Stock, (c) increase the number of authorized shares of Series A Convertible Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. In the event of the dissolution and winding up of the Company, the proceeds available for distribution to the Company's stockholders shall be distributed *pari passu* among the holders of the shares of common stock and Series A Convertible Preferred Stock, *pro rata* based upon the number of shares held by each such holder, as if the outstanding shares of Series A Convertible Preferred Stock were convertible, and were converted, into shares of common stock.

During the years ended December 31, 2018 and 2017, 1,274 and 9,927 shares of Series A Preferred Stock were converted into 636,997 and 4,963,702 shares of common stock. As of December 31, 2018, there were 4,043 shares of Series A Convertible Preferred Stock outstanding, which are convertible into 2,021,673 shares of common stock. See Note 16 for information regarding Series A conversions that occurred during the first quarter of 2019.

2017 Warrants

In connection with the 2017 Private Placement, the Company issued warrants to purchase up to 9,432,000 shares of the Company's common stock at an exercise price of \$2.00 per share (the "2017 Common Stock Warrants"). The Company also issued warrants to purchase common stock to the exclusive placement agents for the issuance ("the 2017 Banker Warrants"). The 2017 Banker Warrants were for the purchase of up to an aggregate of 471,600 shares of the Company's common stock with substantially the same terms as the 2017 Common Stock Warrants, except that they have an exercise price equal \$2.50 per share.

The 2017 Common Stock Warrants and the 2017 Banker Warrants (collectively, the "2017 Warrants") expire on June 15, 2022.

The 2017 Warrants, are exercisable for cash. The exercise price is subject to adjustment in the case of stock dividends or other distributions on shares of common stock or any other equity or equity equivalent securities payable in shares of common stock, stock splits, stock combinations, reclassifications or similar events affecting the Company's common stock, and also, subject to limitations, upon any distribution of assets, including cash, stock or other property to the Company's stockholders.

Prior to exercise, holders of the 2017 Warrants do not have any of the rights of holders of the common stock purchasable upon exercise, including voting rights; however, the holders of the 2017 Warrants have certain rights to participate in distributions or dividends paid on the Company's common stock to the extent set forth in the respective warrant agreements.

The 2017 Warrants may not be exercised by the holder to the extent that the holder, together with its affiliates, would beneficially own, after such exercise more than 4.99% of the shares of the Company's common stock then outstanding (subject to the right of the holder to increase or decrease such beneficial ownership limitation upon notice to us, provided that such limitation cannot exceed 9.99%) and provided that any increase in the beneficial ownership limitation shall not be effective until 61 days after such notice is delivered.

If the Company effects a fundamental transaction, then upon any subsequent exercise of any 2017 Warrants, the holder thereof shall have the right to receive, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of the successor's or acquiring corporation's common stock or of the Company's common stock, if the Company is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock into which the 2017 Warrants were exercisable immediately prior to such fundamental transaction. In addition, in the event of a fundamental transaction (other than a fundamental transaction not approved by the Company's Board of Directors), the Company or any successor entity shall, at the holder's option, purchase the holder's 2017 Warrants for an amount of cash equal to the value of the 2017 Warrants as determined in accordance with the Black Scholes option pricing model. A fundamental transaction as described in the 2017 Warrants generally includes any merger with or into another entity, sale of all or substantially all of the Company's assets, tender offer or exchange offer, reclassification of the Company's common stock or the consummation of a transaction whereby another entity acquires more than 50% of the Company's outstanding voting stock.

Based on the terms of the 2017 Warrants, the Company may be required to settle such warrants with cash upon a fundamental transaction, as defined. Since potential future cash settlement is deemed to be within the Company's control, the 2017 Warrants are classified in stockholders' equity in accordance with the authoritative accounting guidance.

In conjunction with the 2018 Private Placement described further below, a holder of 2.4 million 2017 Warrants exercised all of its 2017 Warrants at the original exercise price of \$2.00 per warrant in exchange for the issuance of additional warrants. As a result of the warrant exercise, the Company received gross proceeds of \$4.8 million during the year ended December 31, 2018.

During the year ended December 31, 2018, excluding the \$4.8 million described above, the Company received proceeds of approximately \$4.0 million in connection with the exercise of approximately 1.9 million of 2017 Common Stock Warrants. During the year ended December 31, 2017, the Company received proceeds of approximately \$3.3 million in connection with the exercise of approximately 1.7 million of Common Stock Warrants. As of December 31, 2018, there were 3,757,000 shares of 2017 Common Stock Warrants outstanding.

During the year ended December 31, 2018, 304,182 of the 2017 Banker Warrants were exercised for total cash proceeds upon exercise of \$0.8 million during the period. No 2017 Banker Warrants were exercised during the year ended December 31, 2017. A total of 167,418 of the 2017 Banker Warrants remained outstanding as of December 31, 2018.

Series B Convertible Preferred Stock

On March 8, 2018, the Company completed the 2018 Private Placement to certain institutional and accredited investors, including certain directors and executive officers of the Company, providing for the sale by the Company at a purchase price of \$1,000 per share, 45,200 of newly designated Series B Convertible Preferred Stock, which shares of preferred stock were automatically converted into 14,349,236 shares of the Company's common stock upon approval by the Company's stockholders at the 2018 annual meeting of stockholders held in May 2018, and warrants to purchase up to 12,196,851 shares of common stock at an exercise price of \$3.50 per share (the "2018 Common Stock Warrants"). The 2018 Common Stock Warrants became exercisable following stockholder approval at the 2018 annual meeting of stockholders, are subject to certain ownership limitations in certain cases, and expire five years after the date of such stockholder approval. The gross proceeds from the 2018 Private Placement were approximately \$45.2 million.

Pursuant to the terms of the purchase agreement entered into in connection with the 2018 Private Placement, from the date of the stockholder approval of the 2018 Private Placement, or May 17, 2018, through the first anniversary of the effective date of the resale registration statement related to the 2018 Private Placement, or May 11, 2019, if the Company issues any shares of common stock or common stock equivalents, subject to certain permitted exceptions, at a price below the conversion price on the date stockholder approval was obtained (a "Dilutive Issuance"), the Company is required to issue an additional number of shares of common stock to the purchasers in the 2018 Private Placement in amount equal the number of shares of common stock such purchasers would have received if the Dilutive Issuance occurred prior to the date the Company's stockholders approved the 2018 Private Placement.

2018 Warrants

The 2018 Common Stock Warrants (the "2018 Warrants"), are exercisable for cash or by cashless exercise. The exercise price of the 2018 Warrants is subject to adjustment in the case of stock dividends or other distributions on shares of common stock or any other equity or equity equivalent securities payable in shares of common stock, stock splits, stock combinations, reclassifications or similar events affecting the Company's common stock, and also, subject to limitations, upon any distribution of assets, including cash, stock or other property to the Company's stockholders.

Prior to the exercise, holders of the 2018 Warrants do not have any of the rights of holders of the common stock purchasable upon exercise, including voting rights; however, the holders of the 2018 Warrants have certain rights to participate in distributions or dividends paid on the Company's common stock to the extent set forth in the 2018 Warrants.

Some of the 2018 Warrants may not be exercised by the holder to the extent that the holder, together with its affiliates, would beneficially own, after such exercise more than 4.99% of the shares of the Company's common stock then outstanding (subject to the right of the holder to increase or decrease such beneficial ownership limitation upon notice to us, provided that such limitation cannot exceed 9.99%) and provided that any increase in the beneficial ownership limitation shall not be effective until 61 days after such notice is delivered.

If the Company effects a fundamental transaction, then upon any subsequent exercise of any 2018 Warrants, the holder thereof shall have the right to receive, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of the successor's or acquiring corporation's common stock or of the Company's common stock, if the Company is the surviving corporation, and any additional consideration receivable as a result of such fundamental transaction by a holder of the number of shares of common stock into which the 2018 Warrants were exercisable immediately prior to such fundamental transaction. A fundamental transaction as described in the 2018 Warrants generally includes any merger with or into another entity, sale of all or substantially all of the Company's assets, tender offer or exchange offer, reclassification of the Company's common stock or the consummation of a transaction whereby another entity acquires more than 50% of the Company's outstanding voting stock.

In addition to the 12,196,851 warrants issued in the 2018 Private Placement, the Company issued 1,800,000 warrants to an existing holder with identical terms to the 2018 Warrants, including the exercise price of \$3.50.

All the 2018 Warrants were deemed to qualify for equity classification under authoritative accounting guidance.

Warrants

A summary of all outstanding warrants is as follows:

	Number of Warrants	Strike Price
2017 Common Stock Warrants	3,757,000	\$ 2.00
2017 Banker Warrants	167,418	\$ 2.50
2018 Common Stock Warrants	13,996,851	\$ 3.50
Merger Warrants	2,200,000	\$ 3.50
Executive	1,327,434	\$ 5.00
Squadron Capital	845,000	\$ 3.15
Other	7,812	\$ 19.20
Total	<u>22,301,515</u>	

In December 2011, in connection with the third amendment to the Company's former credit facility with the Silicon Valley Bank ("SVB"), finance charges totaling \$0.2 million were waived in exchange for the issuance to SVB of warrants to purchase 7,812 shares of the Company's common stock. The warrants are immediately exercisable, can be exercised through a cashless exercise, have an exercise price of \$19.20 per share and have a 10-year term.

As mentioned above, the Company issued Common Stock Warrants in connection with the private placement financing in March 2017 and March 2018. The warrants expire on the fifth anniversary of the date on which they were first exercisable. Further, as described in Note 8, the Company issued warrants in conjunction with the acquisition of SafeOp.

In December 2017 the Company issued warrants to Mr. Miles, the Company's Chairman and Chief Executive Officer, to purchase 1,327,434 shares of the Company's common stock for \$5 per share. The warrants have a five-year term. The warrants issued to Mr. Miles were accounted for as share based compensation, and the fair value of the warrants of approximately \$1.4 million were recognized in full in the statement of operations for the year ended December 31, 2017 as the warrants were immediately vested upon issuance. The following inputs were used to estimate the fair value of warrants issued to Mr. Miles: risk free interest rate of 1.9%, volatility of 99.5%, expected term of 2.3 years and dividend yield of 0%.

As further described in Note 5, in connection with the debt financing with Squadron, the Company issued warrants to purchase 845,000 shares of common stock at an exercise price of \$3.15 per share. The warrants have a seven-year term and are immediately exercisable. In accordance with authoritative accounting guidance, the warrants classified for equity treatment upon issuance and were recorded as a debt discount to the face of the debt liability based on a relative fair value basis to be amortized into interest expense over the life of the debt agreement. As the warrants provide for partial price protection that allow for a reduction in the price in the event of a lower per share priced issuance, the warrants were valued utilizing a Monte Carlo simulation that considers the probabilities of future financings. The Monte Carlo model simulates the present value of the potential outcomes of future stock prices of the Company over the seven-year life of the warrants. The projection of stock prices is based on the risk-free rate of return and the volatility of the stock price of the Company and correlates future equity raises based on the probabilities provided.

11. Stock Benefit Plans and Stock-Based Compensation

In the third quarter of 2016, the Company adopted its 2016 Equity Incentive Plan (the “2016 Plan”), which replaced the Company’s 2005 Employee, Director and Consultant Stock Plan. On October 25, 2018, the Company’s Board of Directors adopted an amendment to the Company’s 2016 Equity Incentive Award Plan. The 2016 Plan allows for the grant of options, restricted stock, restricted stock unit awards and performance unit awards to employees, directors, and consultants of the Company. Upon its adoption, the 2016 Plan had 1,083,333 shares of common stock reserved for issuance. The Board of Directors determines the terms of the grants made under the 2016 Plan. Options granted under the 2016 Plan expire no later than ten years from the date of grant (five years for incentive stock options granted to holders of more than 10% of the Company’s voting stock). Options generally vest over a four-year period and may be immediately exercisable upon a change of control of the Company. The exercise price of incentive stock options may not be less than 100% of the fair value of the Company’s common stock on the date of grant. The exercise price of any option granted to a 10% stockholder may be no less than 110% of the fair value of the Company’s common stock on the date of grant. At December 31, 2018, 711,933 shares of common stock remained available for issuance under the 2016 Plan. The 2016 Plan will expire in May 2026.

On October 4, 2016, the Company’s Board of Directors adopted the 2016 Employment Inducement Award Plan (the “Inducement Plan”). The Inducement Plan allows for the grant of options, restricted stock, restricted stock unit awards and performance unit awards to new employees of the Company by granting an award to such new employee as an inducement for such new employee to begin employment with the Company. As of December 31, 2018 the Inducement Plan had 188,356 shares of common stock reserved for issuance, which may only be granted to an employee who has not previously been an employee or member of the board of directors of the Company. The terms of the Inducement Plan are substantially similar to the terms of the Company’s 2016 Plan with two principal exceptions: (i) incentive stock options may not be granted under the Inducement Plan; and (ii) the annual compensation paid by the Company to specified executives will be deductible only to the extent that it does not exceed \$1.0 million. Under the Inducement Plan, the Company granted \$0.8 million of value Performance Restricted Share Units (“PRSUs”) in 2016. The PRSUs will vest in a dollar amount representing between 0% to 250% of the target value upon the earlier of September 14, 2019 or a change in control of the Company. The actual payout amount will be based on the Company’s market capitalization on the vesting date and the fair-market value of the Company’s common stock on such vesting date and will be paid in shares of the Company’s common stock.

The 2016 Plan and the Inducement Plan are collectively referred to as the Plans.

Stock Options

A summary of the Company’s stock option activity under the Plans and related information is as follows (in thousands, except as indicated and per share data):

	Shares	Weighted average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2017	3,156	\$ 4.31	8.28	\$ 1,841
Granted	2,298	\$ 2.88		
Exercised	(14)	\$ 1.81		
Forfeited	(758)	\$ 4.12		
Outstanding at December 31, 2018	4,682	\$ 3.64	8.46	\$ 919
Options vested and exercisable at December 31, 2018	1,249	\$ 6.34	6.77	\$ 341
Options vested and expected to vest at December 31, 2018	4,230	\$ 3.73	8.40	\$ 861

The weighted-average grant-date fair value per share of stock options granted during the years ended December 31, 2018 and 2017 was \$2.00 and \$1.36, respectively. The aggregate intrinsic value of options at December 31, 2018 is based on the Company's closing stock price on the last business day of 2018 of \$2.29 per share.

As of December 31, 2018, there was \$5.1 million of unrecognized compensation expense for stock options which is expected to be recognized on a straight-line basis over a weighted average period of approximately 2.98 years.

Restricted Stock Awards and Units

The following table summarizes information about the restricted stock awards, restricted stock units and performance-based restricted units activity (in thousands, except as indicated and per share data):

	Shares	Weighted average grant date fair value	Weighted average remaining recognition period (in years)
Unvested at December 31, 2017	2,000	\$ 3.41	2.78
Awarded	1,924	\$ 2.87	
Vested	(278)	\$ 4.00	
Forfeited	(376)	\$ 4.31	
Unvested at December 31, 2018	<u>3,270</u>	<u>\$ 2.94</u>	<u>2.55</u>

The weighted average fair value per share of awards granted during the years ended December 31, 2018 and 2017 was \$2.87 and \$2.96, respectively.

As of December 31, 2018, there was \$7.2 million of unrecognized compensation expense for restricted stock awards and units which is expected to be recognized on a straight-line basis over a weighted average period of approximately 2.55 years.

Termination and Settlement of Elite Medical Holdings and Pac 3 Surgical Collaboration Agreement

In February 2018, the Company reached a settlement agreement with Elite Medical Holdings and Pac 3 Surgical, pursuant to which the Company made a cash payment of \$0.4 million as the final and total compensation under the original agreement. In addition, the parties agreed to release each other and waive any and all rights and claims arising from the original agreement. The Company recorded a gain of approximately \$6.2 million during the year ended December 31, 2018, reflecting the reversal of accrued obligations previously recorded under the collaboration.

2017 Distributor Inducement Plan

In December 2017, the Board of Directors approved and adopted the 2017 Distributor Inducement Plan which authorizes the Company to issue to distributors restricted shares of common stock of the Company and/or warrants to purchase the Company's common stock. The warrants are issuable with an exercise price equal to the fair market value of the common stock on the date of issuance. Each warrant and common stock issuance is subject to a time-based or net sales-based vesting provision. The Board of Directors authorized the grant of up to 1,000,000 shares of common stock under the 2017 Distributor Inducement Plan. As of December 31, 2018, 0.3 million warrants and 17,000 shares of common stock were earned under the 2017 Distributor Inducement Plan. Total expense for the plan was \$0.2 million for the year ended December 31, 2018.

In December 2017, the Board of Directors also authorized grant of warrants to purchase 50,000 of the Company's common stock, and 75,000 restricted stock units to a distributor. These warrants and restricted stock units are subject to time based and net sales based vesting conditions.

2017 Development Services Plan

In December 2017, the Board of Directors approved and adopted the 2017 Development Services Plan which authorizes the Company to enter into Development Services Agreements with third-party individuals or entities whereby, upon the achievement of certain Company financial and commercial revenue milestones, future royalty payments for product and/or intellectual property development work may be paid in either cash or restricted shares of Company common stock at the option of the developer. Each

common stock issuance would be subject to net sales-based vesting provisions and satisfaction of applicable laws and market regulations regarding the issuance of restricted shares to such developers. The Board of Directors authorized the grant of up to 3,000,000 shares of common stock under the 2017 Development Services Plan. As of December 31, 2018, 2.3 million have been designated under the 2017 Development Services Plan, but no common stock elections, grants or cash payouts have been made as of December 31, 2018.

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance consists of the following (in thousands):

	December 31, 2018
Stock options outstanding	4,682
Unvested restricted stock awards	3,270
Employee stock purchase plan	226
Series A convertible preferred stock	2,022
Convertible notes	988
Warrants outstanding	22,302
Distributor and Development Services plans	4,000
Merger contingently issuable	887
Authorized for future grant under the Plans	1,061
	<u>39,438</u>

12. Income Taxes

The components of the pretax income (loss) from continuing operations are presented in the following table (in thousands):

	Year Ended December 31,	
	2018	2017
U.S. Domestic	\$ (30,169)	\$ (4,536)
Foreign	—	(38)
Pretax loss from operations	<u>\$ (30,169)</u>	<u>\$ (4,574)</u>

The components of the (benefit) provision for income taxes from continuing operations are presented in the following table (in thousands):

	Year Ended December 31,	
	2018	2017
Current income tax (benefit) provision:		
Federal	\$ (64)	\$ (102)
State	86	101
Foreign	4	3
Total current	<u>26</u>	<u>2</u>
Deferred income tax benefit:		
Federal	(1,140)	(36)
State	(247)	—
Total deferred	<u>(1,387)</u>	<u>(36)</u>
Total income tax benefit	<u>\$ (1,361)</u>	<u>\$ (34)</u>

The provision for income taxes differs from the amount of income tax determined by applying the applicable U.S. statutory federal income tax rate to pretax income (loss) from continuing operations as a result of the following differences:

	December 31,	
	2018	2017
Federal statutory rate	21.00%	35.00%
Adjustments for tax effects of:		
State taxes, net	0.47%	7.40%
Stock-based compensation	(4.29)%	(16.10)%
Foreign taxes	—	(1.20)%
Tax law change	—	(459.10)%
Fair market value adjustments	(0.59)%	92.10%
Other permanent adjustments	(0.56)%	(1.30)%
Tax rate adjustment	—	19.10%
Uncertain tax positions	0.30%	4.90%
NOL expiration	—	(21.80)%
Other	(1.57)%	—
Valuation allowance	(10.25)%	341.80%
Effective income tax rate	<u>4.51%</u>	<u>0.80%</u>

Significant components of the Company's deferred tax assets and liabilities as of December 31, 2018 and 2017 are as follows (in thousands):

	December 31,	
	2018	2017
Deferred tax assets:		
Accruals and reserves	\$ 1,133	\$ 1,783
Income tax credit carryforwards	3,150	3,182
Interest	1,351	(126)
Inventory	4,959	4,302
Legal settlement	4,693	6,881
Net operating losses	45,092	34,376
Stock-based compensation	1,182	1,542
Total deferred tax assets	61,560	51,940
Valuation allowance	(46,578)	(42,236)
Total deferred tax assets, net of valuation allowance	14,982	9,704
Deferred tax liabilities:		
Property and equipment	(21)	1,249
Goodwill and intangibles	(1,972)	3,945
Investment in foreign partnership	(13,370)	(14,859)
Total deferred tax liabilities	(15,363)	(9,665)
Net deferred tax assets (liabilities)	<u>\$ (381)</u>	<u>\$ 39</u>

The realization of deferred tax assets is dependent on the Company's ability to generate sufficient taxable income in future years in the associated jurisdiction to which the deferred tax assets relate. As of December 31, 2018, a valuation allowance of \$46.6 million has been established against the net deferred tax assets as realization is uncertain. During the years ended December 31, 2018 and 2017, the federal and state valuation allowances collectively increased by \$4.3 million and decreased by \$13.8 million, respectively.

In determining the need for a valuation allowance, the Company considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies, and recent financial performance. Based on the review of all positive and negative evidence, including a three-year cumulative pre-tax loss, the Company determined that a full valuation allowance should be recorded against its definite life deferred tax assets. As a result of the acquisition of SafeOp, the Company recorded an indefinite life deferred tax liability reduced to the extent of indefinite life deferred tax assets related to net operating loss and interest expense carryforward.

At December 31, 2018, the Company has unrecognized tax benefits of \$4.3 million of which \$3.9 million will affect the effective tax rate if recognized when the Company no longer has a valuation allowance offsetting its deferred tax assets.

The following table summarizes the changes to unrecognized tax benefits (in thousands):

	Year ended December 31,	
	2018	2017
Unrecognized tax benefit at the beginning of the year	4,440	9,331
(Deduction) additions based on tax positions related to the current year	—	(1,981)
Additions based on tax positions related to the prior year	—	—
Reductions as a result of lapse of applicable statute of limitations	(106)	(551)
Reductions as a result of tax rate changes	—	(236)
Reductions as a result of foreign exchange rates and other	—	(2,123)
Unrecognized tax benefits at the end of the year	<u>\$ 4,334</u>	<u>\$ 4,440</u>

The Company and its subsidiaries are subject to federal income tax as well as income tax of multiple state and foreign jurisdictions. With few exceptions, the Company is no longer subject to income tax examination by tax authorities in major jurisdictions for years prior to 2014. However, to the extent allowed by law, the taxing authorities may have the right to examine prior periods where net operating losses and tax credits were generated and carried forward and make adjustments up to the amount of the carryforwards. The Company is not currently under examination by the Internal Revenue Service, foreign or state and local tax authorities.

The Company recognizes interest and penalties related to uncertain tax positions as a component of the income tax provision. As of December 31, 2018, there were no accrued interest and penalties.

At December 31, 2018, the Company had federal and state net operating loss carryforwards of \$172.2 million and \$106.7 million, respectively, expiring at various dates beginning in 2018 through 2038. Net operating losses generated in years ending after December 31, 2017 can be carried forward indefinitely for federal and some states. At December 31, 2018, the Company had federal and state research and development tax credit carryforwards of \$3.4 million and \$3.1 million, respectively. The federal research and development tax credits expire at various dates beginning in 2018 through 2038, while the state credits do not expire. Utilization of the net operating loss and tax credit carryforwards may become subject to annual limitations due to ownership change limitations that could occur in the future as provided by Section 382 of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), as well as similar state provisions. These ownership changes may limit the amount of the net operating loss and tax credit carryforwards that can be utilized annually to offset future taxable income.

The Tax Cuts and Jobs Act ("Act") was enacted on December 22, 2017. The tax impact of the Act was estimated in the year ended December 31, 2017. This mainly included the corporate tax rate reduction from 35% to 21% which resulted in a remeasurement of deferred tax assets which was fully offset by a full valuation allowance. The tax impact of the Act has not materially changed in the year ending December 31, 2018.

13. Related Party Transactions

In July 2016, the Company entered into a forbearance agreement with HealthpointCapital, LLC, HealthpointCapital Partners, L.P., and HealthpointCapital Partners II, L.P. (collectively, "HealthpointCapital"), pursuant to which HealthpointCapital, on behalf of the Company, paid \$1.0 million of the \$1.1 million payment due and payable by the Company to Orthotec on July 1, 2016 and agreed to not exercise its contractual rights to seek an immediate repayment of such amount. Pursuant to this forbearance agreement, the Company repaid this amount in September 2016. The Company and HealthpointCapital also entered into an agreement for joint payment of settlement whereby HealthpointCapital has agreed to contribute \$5 million to the \$49 million Orthotec settlement amount.

During the second quarter of 2018, HealthpointCapital Partners, L.P., and HealthpointCapital Partners II, L.P. distributed its holdings in the Company's common stock to its limited partners. As a result, the fund is no longer a shareholder of the Company as of December 31, 2018. The \$5 million receivable from HealthpointCapital, LLC continues to be classified within stockholders' equity on the Company's consolidated balance sheet due to the related party nature with HealthpointCapital affiliates.

Certain of the Company's board of directors and senior management participated in the March 2017 and 2018 private placements.

Included on the consolidated balance sheet as of December 31, 2018 is a \$0.3 million officer receivable for settlement of a tax liability related to the vesting of restricted common stock. A corresponding liability for the same amount is also included on the consolidated balance sheet within the accrued expenses line item. Subsequent to December 31, 2018, the amounts were settled and remitted to settle the tax liability.

14. Retirement Plan

The Company maintains an employee savings plan that qualifies as a deferred salary arrangement under Section 401(k) of the Internal Revenue Code. Under the savings plan, participating employees may contribute a portion of their pre-tax earnings, up to the Internal Revenue Service annual contribution limit. Additionally, the Company may elect to make matching contributions into the savings plan at its sole discretion of up to 4% of each individual's compensation. Matching contributions vest after one year of service. The Company's total contributions to the 401(k) plan were \$0.6 million and \$0.2 million for the years ended December 31, 2018 and 2017, respectively.

15. Restructuring Activities

In connection with the sale of the International Business (described in Note 4), the Company terminated employment agreements with several executive officers, including the chief executive officer and the chief financial officer, and commenced an employee headcount reduction program. In conjunction with the restructuring program, the Company recorded restructuring expenses related to severance liabilities and post-employment benefits. A rollforward of the accrued restructuring liability is presented below (in thousands):

Balance at January 1, 2018	\$	520
Accrued restructuring charges		1,381
Payments		(1,191)
Balance at December 31, 2018	\$	<u>710</u>

All activities and costs are expected to be completed during 2019.

Additionally, on July 6, 2015, the Company announced a restructuring of its manufacturing operations in California in an effort to improve its cost structure. The restructuring included a reduction in workforce and closing the California manufacturing facility in 2017. Additionally, the Company recorded restructuring expenses related to severance and post-employment benefits in the year ended December 31, 2017 related to its U.S. workforce reduction in connection with the Globus Transaction. The Company incurred expenses of \$2.2 million during the year ended December 31, 2017 related to these restructuring activities. There was no expense attributed to these transactions for the year ended December 31, 2018.

16. Subsequent Event

Series A Conversions

During the first quarter of 2019, an additional 3,715 shares of Series A Convertible Preferred Stock were converted into 1,857,586 shares of common stock. As of March 1, 2019, there were 328 shares of Series A Convertible Preferred Stock outstanding, which are convertible into 164,087 shares of common stock.

Expanded Credit Facility with Squadron

On March 27, 2019, the Company closed on an Expanded Credit Facility with Squadron for up to \$30 million in additional secured financing. This additional financing will be made available under the Company's existing credit facility with Squadron. No amounts have been drawn on the Line of Credit as of its issuance date. Any amounts drawn will be used for general corporate purposes. The additional borrowings under the credit facility will mature concurrent with the current secured financing from Squadron and bear interest at LIBOR plus 8% per annum, subject to a 10% floor and a 13% ceiling. For any draws taken, interest-only payments are due monthly through May 2021, followed by principal payable in 29 equal monthly installments beginning June 2021 and a lump-sum payment payable at maturity in November 2023.

At such time as the Company makes its first draw under the Expanded Credit Facility, the Company will issue to Squadron warrants to purchase 4.8 million shares of the Company's common stock at an exercise price of \$2.17 per share. The warrants will have a seven-year term and will be immediately exercisable upon issuance.

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