UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

[Mark One]

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

For the fiscal year ended December 31, 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 001-38242

ORTHOPEDIATRICS CORP.

(Exact name of registrant as specified in its charter)

Delaware	**26-1761833**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
2850 Frontier Drive **Warsaw, Indiana**	**46582**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (574) 268-6379

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

Title of Each Class	Name of each exchange on which registered
Common Stock, $0.00025 par value per share	The NASDAQ Stock Market

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

None

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

check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [ ] No [X]

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

Indicate by check mark 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 [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. Large accelerated filer [ ] Accelerated filer[ ] Non-accelerated filer [X] Small Reporting Company [X] Emerging Growth Company [X]

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 to Section 7(a)(2)(B) of the Securities Act. [X]

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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $182.2 million as of the last business day of the registrant's most recently completed second fiscal quarter (June 30, 2018), based upon the closing sale price for the registrant's common stock on that day as reported by the NASDAQ Global Select Market. Shares of common stock held by each officer and director of the registrant on June 30, 2018 have been excluded in that such persons may be deemed to be affiliates.

As of March 6, 2019, the registrant had 14,677,200 outstanding shares of common stock, $0.00025 par value per share.

FORWARD-LOOKING STATEMENTS

The Company from time to time includes forward-looking statements in its oral and written communication. The Company may include forward-looking statements in filings with the SEC, such as its Annual Reports on Form 10-K and its Quarterly Reports on Form 10-Q, in other written materials and oral statements made by senior management to analysts, investors, representatives of the media and others. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, current and prospective products, product approvals, research and development costs, prospective collaborations, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The Company intends these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and the Company is including this statement for purposes of these safe harbor provisions.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other similar expressions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this report. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

These forward-looking statements are subject to significant risks, assumptions and uncertainties, including, among other things, those discussed in Item 1A, “RISK FACTORS”.

Because of these and other uncertainties, the Company’s actual future results may be materially different from the results indicated by these forward-looking statements. In addition, the Company’s past results of operations do not necessarily indicate its future results.

PART I

ITEM 1. BUSINESS

GENERAL

OrthoPediatrics Corp. (the "Company") is a Delaware corporation, headquartered in Warsaw, Indiana, and organized in November 2007. The Company's Common Stock is traded on NASDAQ's Global Market System under the symbol KIDS. OrthoPediatrics Corp. is a medical device company committed to designing, developing and marketing anatomically appropriate implants and devices for children with orthopedic conditions, giving pediatric orthopedic surgeons and caregivers the ability to treat children with technologies specifically designed to meet their needs. Initially organized as an Indiana limited liability company on August 31, 2006, OrthoPediatrics Corp. was converted to a Delaware corporation on November 30, 2007. We sell our specialized products, including PediLoc®, PediPlates®, Cannulated Screws, PediFlex™ nail, PediNail™, PediLoc® Tibia, ACL Reconstruction System, Locking Cannulated Blade, Locking Proximal Femur, RESPONSE™ Spine, Bandloc and Pediguard and Pediatric Nailing Platform | Femur, to various hospitals and medical facilities throughout the United States and various international markets. We currently use a contract manufacturing model for the manufacturing of implants and related surgical instrumentation.

In early 2017, we expanded operations and established legal entities in the United Kingdom (UK), Australia and New Zealand permitting us to sell under an agency model direct to local hospitals in these countries. Operations began in the United Kingdom on April 3, 2017, in Australia on May 1, 2017 and New Zealand on July 1, 2017. In September 2018, we further expanded operations in Canada selling direct to local hospitals.

In December 2018, the Company completed a secondary offering of shares of common stock, in which it sold 1,725,000 shares at an offering price of $27.00 per share raising a total of $43.4 million in net proceeds after deducting underwriting commissions and offering expenses.

Our controlling investor is Squadron Capital ("Squadron"), a family office firm headquartered near Hartford, Connecticut.

All intercompany transactions are eliminated in the consolidated financial statements.

As of December 31, 2018, the Company had consolidated total assets of $112.1 million, consolidated total liabilities of $30.4 million and stockholders' equity of $81.7 million. As of December 31, 2018, the Company and its subsidiaries had 80 full-time equivalent employees.

AVAILABLE INFORMATION

The Company makes its Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, available on its website under the Investor Relations tab at www.orthopediatrics.com without charge, as soon as reasonably practicable, after such reports are electronically filed with, or furnished to, the Securities and Exchange Commission. The SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including the Company. Those filings are accessible on the SEC's website at *http://www.sec.gov*.

The Company

We are the only global medical device company focused exclusively on providing a comprehensive trauma and deformity correction, scoliosis and sports medicine product offering to the pediatric orthopedic market in order to improve the lives of children with orthopedic conditions. We design, develop and commercialize innovative orthopedic implants and instruments to meet the specialized needs of pediatric surgeons and their patients, who we believe have been largely neglected by the orthopedic industry. We currently serve three of the largest categories in this market. We estimate that the portion of this market that we currently serve represents a $2.5 billion opportunity globally, including over $1.1 billion in the United States.

Historically, there have been a limited number of implants and instruments specifically designed for the unique needs of children. As a result, pediatric orthopedic surgeons often improvise with adult implants repurposed for use in children, resort to freehand techniques with adult instruments and use implants that can be difficult to

remove after being temporarily implanted. These improvisations may lead to undue surgical trauma and morbidity.

We address this unmet market need and sell the broadest product offering specifically designed for children with orthopedic conditions. We currently market 26 surgical systems that serve three of the largest categories within the pediatric orthopedic market: (i) trauma and deformity, (ii) scoliosis and (iii) sports medicine procedures. Our products have proprietary features designed to:

- protect a child's growth plates;
- fit a wide range of pediatric anatomy;
- enable earlier surgical intervention;
- enable precise and reproducible surgical techniques; and
- ease implant removal.

We believe our innovative products promote improved surgical accuracy, increase consistency of patient outcomes and enhance surgeon confidence in achieving high standards of care. In the future, we expect to expand our product offering to address additional categories of the pediatric orthopedic market, such as active growing implants for early onset scoliosis, limb length discrepancies and other orthopedic trauma and deformity applications.

Our global sales organization focuses exclusively on pediatric orthopedics. Our organization has a deep understanding of the unique nature of children's clinical conditions and surgical procedures as well as an appreciation of the tremendous sense of responsibility pediatric orthopedic surgeons feel for the children whom parents have entrusted to their care. We provide these surgeons with dedicated support, both in and out of the operating room. As of December 31, 2018, our U.S. sales organization consisted of 33 independent sales agencies employing more than 130 sales representatives. Increasingly, these sales agencies are making us the anchor line in their businesses or representing us exclusively. Sales from such sales agencies represented 75% and 76% of our revenue in 2018 and 2017, respectively. Outside of the United States, our sales organization consisted of 35 independent distributors and five independent sales agencies in 39 countries. In addition, beginning in 2017, we began to supplement the use of distributors with direct sales programs in select international markets where we work through sales agencies that are paid a commission. These new arrangements are expected to generate an increase in revenue and gross margin.

We collaborate with pediatric orthopedic surgeons in developing new surgical systems that improve the quality of care. We have an efficient product development process that relies upon teams of engineers, commercial personnel and surgeon advisors. Since inception, our average clearance time with the U.S. Food and Drug Administration, or the FDA, has been 93 days, which we believe is less than half of the average approval time for all medical devices over the past five years. This is due in part to the impact of the Pediatric Medical Device Safety and Improvement Act of 2007, which encourages pediatric medical device research and development and aids the FDA in tracking the number and types of medical devices approved specifically for children. We believe our products are characterized by stable pricing, few reimbursement issues and attractive gross margins.

We believe clinical education is critical to advancing the field of pediatric orthopedics. Cumulatively, we are the largest financial contributor to the five primary pediatric orthopedic surgical societies that conduct pediatric clinical education and research. We are a major sponsor of continuing medical education, or CME, courses in pediatric spine and pediatric orthopedics, which are focused on fellows and young surgeons. In 2018, we conducted more than 250 training workshops. We believe these workshops help surgeons recognize our commitment to their field. We believe our commitment to clinical education has helped to increase our account presence while promoting familiarity with our products and loyalty among fellows and young surgeons.

We have established a corporate culture built on the cause of improving the lives of children with orthopedic conditions. We believe our higher corporate purpose captures the imagination of our employees and makes them committed to doing everything better, faster and at lower cost. This culture allows us to attract and retain talented, high-performing individuals.

We have grown our revenue from approximately $10.2 million for the year ended December 31, 2011 to $57.6 million for the year ended December 31, 2018, reflecting a growth rate each year of at least 20%. For the years ended December 31, 2018, 2017 and 2016, our revenue was $57.6 million, $45.6 million and $37.3 million, respectively. As of December 31, 2018, our accumulated deficit was $115.1 million.

We believe we have a history of efficient capital utilization, and we intend to scale our business model by continuing to implement the successful strategy that has sustained our growth. This strategy includes increasing investment in consigned implant and instrument sets in the United States and select international markets, expanding our innovative product line by leveraging our efficient product development process, strengthening our global sales and distribution infrastructure, broadening our commitment to clinical education and research and deepening our culture of continuous improvement. Due to the high concentration of pediatric orthopedic surgeons in comparatively few hospitals, we believe we can accelerate the penetration of our addressable market in a capital-efficient manner and further strengthen our position as the category leader in pediatric orthopedics. The primary challenges to maintaining our growth in a market that has not historically relied on age-specific implants and instruments have been insufficient implant/instrument sets and overcoming older surgeons' familiarity with repurposing adult implants for use in children. Our efforts in surgeon training, collaboration and marketing address the inertia of using repurposed adult products, particularly with younger surgeons.

Industry Overview

Children Have Unique Skeletal Characteristics

Children are not just small adults. Their skeletal anatomy and physiology differs significantly from adults, which affects the way in which children with orthopedic conditions are managed surgically. These differences include:

- Children's Bones Are Smaller. Children's bones are significantly smaller than adult bones. Bone size and strength increases rapidly during childhood and adolescence.

- Children's Bones Are Growing. Children's bones contain growth plates, or physes, that consist of developing cartilage tissue at the end of the bone, enabling skeletal growth. Bones grow lengthwise from the ends of the growth plates until skeletal maturity is reached and the growth plates close. As this occurs, some bones fuse together, reducing the 270 bones children have at birth to 206 bones by adulthood. Injury to the growth plates, including fracture or surgical trauma, can lead to growth arrest and subsequent deformity.

- The Composition and Vasculature of Children's Bones Is Unique. Children's bones are more porous and respond to injury and infection differently than adult bones. Children also have blood vessels that supply oxygen and nutrients to bones as they grow, which disappear when the growth plates close and the child reaches adulthood. Trauma to these blood vessels during surgery may cut off blood supply to the bone, resulting in death of the bone tissue.

- Children's Bones Change Shape as They Grow. Children's bones are more curved than adult bones. As children grow into adulthood, their bones change shape. For example, the curvature of the femur decreases up to 30% as a child matures.

- Complex Disorders in Children Pose Unique Clinical Challenges. Complex disorders such as cerebral palsy, scoliosis, brittle bone disease and hip disorders can pose significant challenges for surgical treatment. The most common such disorder is cerebral palsy, which affects approximately 500,000 children under the age of 18 in the United States and approximately three out of every 1,000 live births. Spastic cerebral palsy is the most common form, making up the majority of all cerebral palsy cases. Spastic cerebral palsy can produce skeletal deformities such as curvature of the spine, hip dislocation, gait abnormalities and other conditions involving joints and bones. Children suffering from these disorders often require multiple surgeries into adulthood.

We believe the challenges resulting from the unique characteristics of children's skeletal anatomy and physiology, as well as the complex disorders affecting them, are best addressed by the use of implants and instruments specifically designed for the treatment of children.

Pediatric Orthopedic Surgeons Are Generalists

Unlike orthopedic surgeons focused on treating adults, pediatric orthopedic surgeons are, for the most part, generalists treating a wide range of congenital, developmental and traumatic orthopedic conditions, including limb and spine deformities, gait abnormalities, bone and joint infections, sports injuries and orthopedic trauma cases. Accordingly, they generally represent a single call point for our broad range of pediatric orthopedic implants and instruments. In 2018, there were more than 1,400 members of POSNA, as compared to approximately 33,400 practicing orthopedic surgeons in the United States focused on the treatment of adults. The number of fellowships in pediatric orthopedics continues to grow. As generalists, these surgeons have a deep understanding of the unique nature of children's clinical conditions and surgical procedures. We believe they feel a tremendous sense of responsibility for the children whom parents have entrusted to their care.

Market Opportunity

We currently serve a portion of the pediatric orthopedic implant market that we estimate represents a $2.5 billion opportunity globally, including over $1.1 billion in the United States. The chart below provides the estimated sizes of the four categories of our U.S. addressable market opportunity, based on third-party data (including data compiled by IMS Health, Inc. and Life Science Intelligence, Inc. in studies that we commissioned) regarding the number of procedures performed in 2015 and our average revenue per procedure or, in the case of smart implants, our estimated average revenue per procedure based on industry data.

	Trauma and Deformity	Scoliosis	Sports Medicine	Smart Implants
U.S. Pediatric Orthopedic Implant Market	$401 Million	$285 Million	$116 Million	$299 Million

We estimate that the United States represented approximately 55% of the total global orthopedic implant market, both adult and pediatric, and that this geographic segmentation similarly applies to the global pediatric orthopedic implant market.

Overviews of the three categories of the trauma and deformity, scoliosis and sports medicine markets that we currently serve, and the smart implant market that we are planning to enter, are as follows:

Trauma and Deformity

Trauma and deformity procedures involve placing metal plates and screws on the outside of the bone or long nails inside the canal of the bone, known as flexible and rigid intramedullary nails, to stabilize fractures and allow them to heal. Trauma and deformity procedures also include osteotomies, or surgical cutting of the bone, and the use of metal implants to correct angular bone deformities or limb length discrepancies.

Scoliosis

Scoliosis procedures involve the use of spinal implants, such as pedicle screws and rods, to correct curvature of the spine as a result of scoliosis, trauma or tumors.

Sports Medicine

Sports medicine procedures include reconstruction of the anterior cruciate ligament, or ACL, and medial patellofemoral ligament, or MPFL. These reconstruction procedures refer to the replacement of the ACL or MPFL ligaments, as applicable, with a surgical tissue graft to restore function to the knee after injury. According to Life Science Intelligence, Inc., in a study that we commissioned, approximately 29% of ACL reconstruction procedures completed in the United States in 2015 were in patients under the age of 18. The vast majority of these procedures were performed in ambulatory surgery centers.

Smart Implants

We are developing a new generation of adjustable implant systems, which we refer to as our Active Growing Implants, which will utilize a mechanized motor and are adjustable at the time of implantation and non-invasively over the course of treatment to accommodate the clinical needs of patients with early onset scoliosis and limb length discrepancies, or LLDs, as they heal, grow and age.

Early onset scoliosis refers to severe spinal deformities in skeletally immature patients under the age of ten. Despite its low incidence rate, early onset scoliosis is a challenging health issue and can lead to significant morbidity.

LLDs can occur for a variety of reasons, including congenital deformities and previous injury to the bone. Larger LLDs often result in debilitating pain and difficulty to walk.

High Procedural Concentration in Trauma and Deformity and Scoliosis

According to IMS Health, Inc., 3,425 hospitals performed pediatric trauma and deformity or scoliosis procedures in the United States in 2015. Only 268 of these hospitals performed 62% of all pediatric trauma and deformity and scoliosis procedures. Further, of these hospitals, 62 are children's hospitals and performed 21% of all pediatric trauma and deformity and scoliosis procedures. We believe that this high concentration of pediatric trauma and deformity and scoliosis procedures and our focused sales organization will enable us to address the pediatric orthopedic surgery market in a capital-efficient manner.

In the future, we expect to expand our market opportunity by addressing additional categories of the pediatric orthopedic market, such as craniomaxilloacial, elbow, proximal humerus, pelvis and other sports-related injuries.

Our Exclusive Focus on Pediatric Orthopedic Surgery

We believe we are the only company that has committed the resources necessary to create a global sales and product development infrastructure focused on the pediatric orthopedic implant market. Our goal is to build an enduring company committed to addressing this market's unmet needs.

Only Commercial Infrastructure Dedicated to Pediatric Orthopedic Surgeons

- Dedicated Sales Support to Pediatric Orthopedic Surgeons. Our sales and marketing personnel provide dedicated sales support to pediatric orthopedic surgeons, both in and out of the operating room, to guide them through the optimal selection and use of implants and instruments to achieve desired clinical outcomes.

- Participation of Pediatric Orthopedic Surgeons in New Product Development. With the assistance of our Chief Medical Officer, or CMO, a highly respected former pediatric orthopedic surgeon, we engage with pediatric orthopedic surgeons to understand their clinical needs and develop new implants, instruments and surgical techniques that will allow them to better serve their patients. We also respond to surgeons' requests for customized implants and instruments to improve their workflows and enhance their clinical outcomes.

- Leading Supporter of Pediatric Orthopedic Surgical Societies and Clinical Education. Cumulatively, we donate more than any of our competitors to the five primary pediatric orthopedic surgical societies that conduct pediatric clinical education and research. In 2018, we conducted more than 250 training workshops focused on fellows and surgeons early in their careers. We believe our commitment to clinical education advances pediatric orthopedic surgery and increases our account presence, while promoting familiarity with our products and loyalty among fellows and young surgeons. We aspire to be viewed as the partner of pediatric orthopedic surgeons around the world.

Our Competitive Strengths

We believe our focus and experience in pediatric orthopedic surgery, combined with the following principal competitive strengths, will allow us to continue to grow our sales and expand our market opportunity.

- Exclusive Focus on Pediatric Orthopedics. We were founded with the mission of improving the lives of children with orthopedic conditions, a patient population which we believe has been largely neglected by the orthopedic industry. We believe we are the first diversified orthopedic company to focus exclusively on the pediatric market. Our core competencies are the development and commercialization of innovative products and technologies specifically designed to address the unmet clinical needs of pediatric orthopedic patients and satisfy the demands of the surgeons who treat them. We have developed and sell the broadest product

offering specifically designed for pediatric orthopedic patients. We believe we are the only orthopedic company to have established a robust pediatric-focused infrastructure, including product development and a dedicated global commercial organization. We believe our exclusive focus on pediatric orthopedics has generated strong brand equity in the pediatric orthopedic surgeon community.

- Comprehensive Portfolio of Innovative Orthopedic Products Designed Specifically for Children. We have developed a comprehensive portfolio of implants and instruments specifically designed to treat children with orthopedic conditions. Last year, we estimate that our products were used in surgeries for 20,000 children. We currently market 26 surgical systems consisting of more than 5,000 stock keeping units, which address pediatric trauma and deformity, scoliosis and sports medicine procedures. Our products include features that provide specific advantages for pediatric orthopedic surgeons and their patients, such as surgical instrumentation specifically designed for use in children, proper anatomical sizes and contouring, and proprietary designs that address the unique skeletal anatomy and physiology of a growing child. Our broad product offering has made us, within the three categories of the market that we currently serve, the only provider of comprehensive solutions to pediatric orthopedic surgeons, who for the most part are generalists performing a wide range of orthopedic surgeries. Since inception, our average clearance time with the FDA has been 93 days, which we believe is less than half of the average approval time for all medical devices over the past five years. This is due in part to the impact of the Pediatric Medical Device Safety and Improvement Act of 2007, which encourages pediatric medical device research and development and aids the FDA in tracking the number and types of medical devices approved specifically for children.

- Partnership with Pediatric Orthopedic Surgeons and Pediatric Surgical Societies. We have devoted significant time and resources to developing deep relationships with pediatric orthopedic surgeons and supporting clinical education to advance the practice of pediatric orthopedic medicine. We believe we are the only orthopedic company with a non-founding former pediatric orthopedic surgeon serving as CMO. This enables us to engage and collaborate with thought-leading surgeons and academic institutions around the world in order to develop products and technologies specifically designed to meet the needs of pediatric orthopedic surgeons and their patients. Our dedication to the pediatric orthopedic community is evidenced by our leading support of the five major pediatric orthopedic surgical societies that conduct pediatric clinical education and research. In 2018, we conducted more than 250 training workshops focused on fellows and surgeons early in their careers. We are a major sponsor of CME courses in pediatric spine and pediatric orthopedics. We believe collaborating with pediatric orthopedic surgeons has helped to promote familiarity with our products and loyalty among fellows and surgeons early in their careers.

- Scalable Business Model. Our ability to identify and respond quickly to the needs of pediatric orthopedic surgeons and their patients is central to our culture and critical to our continued success. As of December 31, 2018, our U.S. sales organization consisted of 33 independent sales agencies employing more than 130 sales representatives. Outside of the United States, we work with 35 independent distributors and 5 independent sales agencies in 39 countries, and have begun to supplement the use of distributors with direct sales programs in select international markets. We estimate that 62% of U.S. pediatric trauma and deformity and scoliosis procedures in 2015 were performed in only 268 hospitals. We believe that this high concentration of procedures and our focused sales organization will enable us to address the pediatric orthopedic surgery market in a capital-efficient manner. In addition, we believe our exclusive focus on hospitals that perform pediatric orthopedic surgery will allow us to grow our revenue while leveraging investment in a smaller number of consigned implant and instrument sets. As we continue to broaden our product offering, we believe the scalability of our business model will allow us simultaneously to increase our reach, deepen our relationships with pediatric orthopedic surgeons and help us to achieve significant returns on our investments in implant and instrument sets, product development and commercial infrastructure.

- Unique Culture: A Different Kind of Orthopedic Company. We have established a results-oriented, people-focused corporate culture dedicated to improving the lives of children with orthopedic conditions. Our senior management team provides engaging leadership and believes

that the only hierarchy is that of good ideas, which can come from everywhere in our company. Our Trauma and Deformity and Scoliosis product categories are each led by a vice president, who chairs a business team composed of representatives from research and development, quality and regulatory, operations, sales and finance functions. These teams meet frequently and make decisions regarding new products, inventory builds and promotional activities, thus enhancing our agility and the speed of decision making. We believe this culture allows us to attract and retain talented, high performing professionals. We believe our focus and commitment to pediatric orthopedics has also enhanced our reputation among pediatric orthopedic surgeons as the only diversified orthopedic company focused on their field.

We believe that our exclusive focus on pediatric orthopedic surgery, our comprehesive product portfolio, our collaborations with surgeons, our scalable business model and our engaging culture are all sources of significant competitive advantage. We believe these sources of competitive advantage provide us with the means to expand and defend our position as category leader and constitute barriers to entry that would require significant time, focus, and investment for a competitor to overcome.

Our Strategy

Our goal is to continue to enhance our leadership in the pediatric orthopedic surgery market and thereby improve the lives of children with orthopedic conditions. To achieve this goal, we have implemented a strategy that has five elements:

- Increase Investment in Consigned Implant and Instrument Sets to Accelerate Revenue Growth. We intend to increase our investment in implant and instrument sets consigned to hospitals in the United States and select international markets to satisfy market demand and accelerate our product sales worldwide. Due to the high concentration of pediatric orthopedic surgeons in comparatively few hospitals, we believe we can accelerate the penetration of our addressable market efficiently.

- Capitalize on Our Efficient Product Development Process to Expand Our Innovative Products. We have a track record of introducing innovative products that meet the clinical needs of pediatric orthopedic surgeons and their patients. We believe many of these products are becoming the standard of care in pediatric orthopedic surgery, and we intend to increase our investment in research and development of new products to 10% of sales. We aim to surround our customers with all the important surgical systems they need to do their work, and our product pipeline includes a number of new systems and product line extensions. We aspire to launch at least one new surgical system and multiple product line extensions in our trauma and deformity and scoliosis businesses each year for the foreseeable future. We intend to leverage our market knowledge and our relationships with leading pediatric orthopedic surgeons to continue developing innovative technologies and bringing them to market quickly. We believe broadening our product offering will strengthen our position as the comprehensive solution provider for pediatric orthopedic surgeons, deepen our relationships with existing customers, lead to the acquisition of new customers and enhance our reputation.

- Strengthen Our Global Sales and Distribution Infrastructure. We believe there is significant opportunity for us to leverage our exclusive focus on pediatric orthopedic surgery and expand our market penetration and share. We intend to continue investing in our global sales and distribution organization by increasing the number and upgrading the quality of our independent sales agencies and distributors through recruitment, adding clinical and sales training programs. Starting in 2017, we also began to supplement our use of independent distributors with direct sales programs in the United Kingdom, Ireland, Australia and New Zealand. In 2018, we further expanded our international sales program in Canada. In these markets, we work through sales agencies that are paid a commission, and we consign sets to hospitals, ship replacement products, bill and collect receivables. This is expected to generate an increase in revenue and gross margin. Many experienced sales agencies and distributors have been impacted by ongoing consolidation in the orthopedic industry and, as a result, we believe are eager to adopt new product lines like ours. We believe these continued investments will strengthen our relationships with pediatric orthopedic surgeons, expand our presence in the hospitals where pediatric orthopedic surgery is performed and leverage our proprietary technologies to enhance the field of pediatric orthopedic surgery.

- Deepen Our Partnerships With Pediatric Orthopedic Surgeons Through Clinical Education and Research. We want pediatric orthopedic surgeons to view us as their partner in advancing the field of pediatric orthopedic surgery. Beyond working with them to develop innovative products, we intend to deepen our partnership with surgeons by leveraging the experience of our senior management team, including our CMO, to expand our clinical education programs and partnerships with teaching hospitals, sponsor surgical workshops for residents and fellows and support worthwhile clinical research projects. We believe our commitment to clinical education and research enables us to advance the practice of pediatric orthopedic surgery and provides surgeons with access to sophisticated training in pediatric orthopedics that is not available through traditional residents' training programs. We believe these efforts will continue to promote familiarity with our products and loyalty among fellows and young surgeons and generate new product ideas that will contribute to growth, enhance our competitive position and expand our market opportunity.

- Continue to Develop an Engaging Culture of Continuous Improvement. We believe that culture can be a company's most powerful source of competitive advantage. Cultures are unique, cannot be reverse-engineered and are impossible to duplicate. We have established a corporate culture that is results-oriented and people-focused. It is built on the cause of improving the lives of children with orthopedic conditions. We believe our higher corporate purpose captures the hearts and minds of our employees and empowers them to be committed to doing everything better, faster and at lower cost. We intend to continue developing this engaging culture of continuous improvement with the goal of building a different kind of orthopedic company: one that is committed to children, works with distributors as partners and aims to address the market's unmet needs.

Our Product Portfolio

We have developed a comprehensive portfolio of implants and instruments specifically designed to treat children with orthopedic conditions within the three categories of the pediatric orthopedic market that we currently serve. We currently market 26 surgical systems that address pediatric trauma and deformity, scoliosis and sports medicine/other procedures. Many of our products are available in a variety of sizes and configurations to address a wide range of patient conditions and surgical requirements. These surgical systems are summarized below.

Trauma and Deformity

Our trauma and deformity product line includes more than 1,800 implants and bone fixation devices for the femur, tibia and upper extremities. Our global revenue from this category for the year ended December 31, 2018 was $39.7 million, or 69% of total revenue, which represented growth of 21% over the prior year. Global revenue from this category for the years ended December 31, 2017 and 2016 was $32.8 million and $26.8 million or 72% and 72% of total revenue, respectively.

Scoliosis

Our scoliosis product category includes our RESPONSE™ systems for treating spinal deformity in children, the BandLoc 5.5mm/6.0mm sub-laminar banding system, and FIREFLY® Pedicle Screw Navigation Guides. Our global revenue from this category for the year ended December 31, 2018 was $16.7 million, or 29% of total revenue, which represented growth of 44% over the prior year. Global revenue from this category for the years ended December 31, 2017 and 2016 was $11.6 million and $9.3 million or 25% and 25% of total revenue, respectively.

Sports Medicine/Other

Our sports medicine/other product category primarily includes our ACL and MPFL Reconstruction system. Our global revenue from this category for the year ended December 31, 2018 was $1.2 million, or 2% of total revenue, which represented a reduction of 3% over the prior year. Global revenue from this category for the years ended December 31, 2017 and 2016 was $1.2 million and $1.1 million or 3% and 3% of total revenue, respectively.

Our revenue is typically higher in the summer months and holiday periods, driven by higher sales of our trauma and deformity and scoliosis products, which is influenced by the higher incidence of pediatric surgeries during these periods due to recovery time provided by breaks in the school year.

Product Pipeline

We have three product development objectives: (i) develop innovative new systems that enable new surgical procedures, advance the field of pediatric orthopedics and allow us to focus on categories of the pediatric orthopedic market we are not currently addressing such as active growing implants for early onset scoliosis and limb length discrepancies, other sports-related injuries, patient-specific templates for spine surgical procedures and other orthopedic trauma and deformity applications; (ii) build-out our portfolio of current products with line extensions that allow these systems to be used in more types of surgeries; and (iii) make improvements to our current implants and instruments that reduce their cost and improve their effectiveness. We have a large number of new product ideas under development, and we aspire to launch one new surgical system and multiple line extensions and product improvements every year.

We have a deep pipeline of new systems that are currently under development, including the following projects.

Bandloc Duo

In the first quarter 2019, we launched Bandloc Duo, the latest enhancement to our Bandloc 5.5/6.mm system. This system allows a pedicle-sparing, band passage technique for treating a wide variety of complex spine pathologies, including scoliosis.

Cannulated Screws

In the second quarter 2019, we will launch a significantly expanded line of cannulated screws with a wide array of sizes, lengths, and thread designs.

PediFoot

By mid-2019 we will launch the first pediatric-specific foot system. PediFoot will treat four of the most comon foot deformities, including clubfoot, flatfoot, cavus foot and hallus valgus.

SCFE

In late 2019, we will launch a system to treat slipped capital femoral ephiphysis. This system will consist of a line of implants and enhanced instrumentation to treat this common injury to the ball of the upper femur.

PNP | Tibia

In late 2019, we will launch the Pediatric Nailing Platform | Tibia, which will utilize the same enhanced instrumentation in the PNP | Femur system, which was introduced in 2018. This system will treat deformities and traumatic injuries of the tibia.

RESPONSE™ Neuromuscular

In mid-2019, we will launch the RESPONSE™ Neuromuscular system which will provide surgeons with additional implants to our RESPONSE™ systems to treat the complex deformities associated with neuromuscular scoliosis.

Small Stature BandLoc System

We are developing a hybrid small stature sub-lamina polyester banding system that will accept either a 4.5mm, 4.75mm or 5.0mm cobalt chrome or titanium rod. The tulip profile will be consistent with the Small Stature RESPONSE™ system now under development but with a smaller band. This system is currently being tested with the goal of a 510(k) submission to the FDA by early 2019 and market introduction in 2019.

Osteogenesis Imperfecta Nail System

Brittle bone disease poses a number of challenges for orthopedic surgeons. We are developing a passive growing nail that will maximize rotational stability, addressing the primary deficiency of the product that has historically been used to perform this surgery. This system is currently in late-stage development with the goal of a 510(k) submission to the FDA by early 2019.

Active Growing Implants

We are developing a new generation of adjustable implant systems, which we refer to as our Active Growing Implants. Our Active Growing Implants will utilize a non-magnetic power source of significantly greatly strength and control than the current technology and will be adjustable at the time of implantation and non-invasively over the course of treatment to accommodate the changing clinical needs of patients as they heal, grow and age. We are developing our Active Growing Implants for the treatment of early onset scoliosis and limb length discrepancies. We believe these products will be a natural complement to our current product offering. While we have an active program underway in the development of these systems, the dates of completion, 510(k) submission to the FDA and market introduction are uncertain at this time.

Spine Tethering

Spine tethering is an emerging procedure in which one side of the spine is secured while the other side is able to continue growing, thus enabling the spine's curvature to self-correct. This procedure is now being performed using an adult lumbar fixation device. Because the procedure does not fuse the spine, it is reversible and has been used in patients as young as the age of 10. We are pursuing technology that is pediatric-specific and will be combined with purpose-built instruments to facilitate placement. We have an active program underway to develop this technology and instrumentation with the goal of market introduction in 2020. However, the regulatory requirements of this technology are uncertain at this time.

Research and Product Development

We seek to leverage our considerable experience in pediatric orthopedics to develop innovative implants and instruments that serve the unmet needs of pediatric orthopedic surgeons and their patients. Some of our product designs leverage our exclusive rights to the Hamann-Todd Collection of the Cleveland Natural History Museum, the world's largest pediatric osteological collection.

We have made significant investments in product development personnel and infrastructure, and we believe that ongoing research and development efforts are essential to our success. Our culture of continuous improvement challenges us to develop better products efficiently and at lower cost. New products are developed by teams of engineers, commercial personnel and surgeon advisors, who work closely together through the design, prototype and market-testing phases of a product's development.

Our clinical and regulatory affairs personnel support our product design teams to facilitate regulatory clearances and market registrations. Since inception, our average clearance time with the FDA has been 93 days, which we believe is less than half of the average approval time for all medical devices over the past five years. This is in part due to the impact of the Pediatric Medical Device Safety and Improvement Act of 2007, which encourages pediatric medical device research and development and aids the FDA in tracking the number and types of medical devices approved specifically for children.

Sales and Marketing

We believe we are the only orthopedic company with a robust pediatric-focused infrastructure, including a dedicated global commercial organization. As of December 31, 2018, our U.S. sales organization consisted of 33 independent sales agencies employing more than 130 sales representatives. Increasingly, these sales agencies are making us the anchor line in their businesses or representing us exclusively. Sales from such agencies represented 75% of our revenue in 2018 and 76% in 2017.

Outside of the United States, our sales organization consisted of 35 independent stocking distributors and five independent sales agencies in 39 countries, including the largest markets in the European Union, Latin America and the Middle East, as well as South Africa, Australia and Japan. We believe our distributors are well regarded by pediatric orthopedic surgeons in their respective markets. To support our international distribution organization,

we have hired a number of regional market managers, whose product and clinical expertise deepens our relationships with both surgeons and our distributors. In the near term, we expect to selectively expand the number of international markets we serve, as well as to deepen our penetration of important existing markets such as Brazil and Japan. In 2017, we began to supplement our use of independent distributors with direct sales programs in the United Kingdom, Ireland, Australia and New Zealand. In 2018, we began selling direct in Canada. In these markets, we work through sales agencies that are paid a commission. We consign sets to hospitals, ship replacement products, bill and collect receivables. These new arrangements are expected to generate an increase in revenue and gross margin. We plan to continue to make similar transitions in select international markets that we believe would benefit from a sales agency model.

We have developed intensive training programs for our global sales organization. We expect our sales agencies and distributors to continue to deepen their knowledge of pediatric clinical conditions, surgical procedures and our products, thus increasing their effectiveness. Our domestic and international sales representatives are usually present in the operating room during surgeries in which our products are used. We believe the clinical expertise of our global sales organization and their presence both in and out of the operating room will enable them to increase pediatric orthopedic surgeons' confidence in using our products, deepen their relationships with existing customers and lead to the acquisition of new customers.

Global Pediatric Orthopedic Surgeon Involvement, Education and Training

We are dedicated to the cause of improving the lives of children with orthopedic conditions. We want pediatric orthopedic surgeons throughout the world to view us as their partner in advancing their field. Therefore, we utilize surgeon input when developing products and clinical education programs. These efforts are aided by our CMO, a highly respected former pediatric orthopedic surgeon. Our entire organization, including our senior executive team and sales representatives, maintains an extensive network of contacts with pediatric orthopedic surgeons. These relationships help us understand clinical needs, respond quickly to customer ideas and support new developments in the field of pediatric orthopedics.

We are committed to advancing pediatric orthopedic care by supporting clinical education. We support local, regional and national educational courses, intensive hands-on training programs and product-based workshops that enable surgeons to practice surgical procedures using our products. In 2018, we conducted more than 250 training workshops focused on fellows and surgeons early in their careers. We are also a major sponsor of CME courses in pediatric spine and pediatric orthopedics. In 2018 and 2017, we sponsored the third and fourth Annual International Children's Spine Symposium, respectively, each of which was held in Orlando, Florida, and we prepared the second and third Annual Pediatric Orthopedic Surgical Techniques Course, respectively, each of which was held at The Medical Education and Research Institute in Memphis, Tennessee. We also sponsor the annual Akron Pediatric Orthopedic Residents Review Course for over 100 residents from hospitals across the Midwest and the first annual PediOrthoWest resident review program that attracted more than 30 residents from hospitals in Northern California. We have a growing commitment to the clinical research performed by surgeons. This commitment ranges from providing our products for clinical outcome studies to providing advanced research grants.

Cumulatively, we are the largest financial contributor to the five primary pediatric orthopedic surgical societies that conduct pediatric clinical education and research: the Pediatric Orthopedic Society of North America, the International Pediatric Orthopedic Symposium, the European Pediatric Orthopedic Society, the American Academy for Cerebral Palsy and Developmental Medicine and the Pediatric Research in Sports Medicine Society. Additionally, we are a sponsor of the two major spine deformity organizations, the Scoliosis Research Society and the International Meeting on Advanced Spine Techniques. We are also the founding and leading sponsor of the Pediatric Research in Sports Medicine Society. Our support of these organizations demonstrates our commitment to the clinical training and research these organizations sponsor. We believe this support enhances our reputation as the category leader in pediatric orthopedics.

Additionally, during 2018, we funded the OrthoPediatrics Foundation for Education and Research ("Foundation") as a 501(c)3 public charity. The Foundation is led by the Company's Chief Medical Officer and a board composed of nine eminent pediatric orthopedic educators. The Foundation channels OrthoPediatrics' clinical education funding together with contributions from the general public to support non-commerical education programs and clinical research.

Manufacturing and Suppliers

Our products are manufactured to our specifications by third-party suppliers who meet our manufacturer qualification standards. Our third-party manufacturers meet FDA and other country-specific quality standards, supported by our internal specifications and procedures. We believe these manufacturing relationships allow us to work with suppliers who have well-developed specialized competencies, minimize our capital investment, control costs and shorten cycle times, all of which we believe allow us to compete with larger volume manufacturers of orthopedic implants. We work closely with our suppliers with a goal of ensuring our inventory needs are met while maintaining high quality and reliability.

All of our device contract manufacturers are required to be ISO 13485 certified and are registered establishments with the FDA. Our internal quality management group conducts comprehensive on-site inspection audits of our suppliers to ensure they meet FDA and other country-specific requirements, as necessary. In addition, we and our suppliers are subject to periodic unannounced inspections by U.S. and international regulatory authorities to ensure compliance with quality regulations.

We do not have long-term supply contracts, nor do our suppliers require guaranteed minimum purchases. In most cases, we have redundant manufacturing capabilities for each of our products. To date, we have not experienced any difficulty obtaining the materials necessary to meet demand for our products, and we believe manufacturing capacity is sufficient to meet global market demand for our products for the foreseeable future.

Intellectual Property

Our success depends upon our ability to protect our intellectual property. We rely on a combination of intellectual property rights, including patents, trade secrets, copyrights and trademarks, as well as customary confidentiality and other contractual protections. We own numerous issued patents and pending patent applications that relate to our technology. As of December 31, 2018, we owned 12 issued U.S. patents and 14 issued foreign patents and we had 19 pending U.S. patent applications and 16 foreign patent applications. As of December 31, 2018, two of our U.S. issued patents have pending continuation or divisional applications in process which may provide additional intellectual property protection if issued as U.S. patents. Our issued U.S. patents expire between 2024 and 2035, subject to payment of required maintenance fees, annuities and other charges. As of December 31, 2018, we owned eleven U.S. trademark registrations and four pending U.S. trademark applications, as well as 24 registrations in other jurisdictions worldwide.

We also rely upon trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. We protect our proprietary rights through a variety of methods, including confidentiality agreements and proprietary information agreements with suppliers, employees, consultants and others who may have access to proprietary information.

Competition

The orthopedic industry is competitive, subject to rapid technological change and significantly affected by new product introductions and market activities of other participants. Our currently marketed products are, and any future products we commercialize will be, subject to competition. We believe the principal competitive factors in our markets include:

- improved outcomes for medical conditions;
- acceptance by orthopedic surgeons;
- ease of use and reliability;
- acceptance by the patient community;
- product price;
- availability of implant-specific instrument sets;
- effective marketing and distribution; and

- speed to market.

We have competitors in each of our three product categories, including the DePuy Synthes Companies (a subsidiary of Johnson & Johnson), Medtronic plc and Smith & Nephew plc. We believe we have the broadest product offering across these categories relative to these competitors. Our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, are cost effective and are safe and effective. They also require a dedicated selling organization that is viewed by pediatric orthopedic surgeons as a consultative resource that can attend surgery.

Employees

As of December 31, 2018, we employed 80 full-time employees, 17 of whom were engaged in research and development and 24 of whom were engaged in sales and marketing. None of our employees are subject to a collective bargaining agreement, and we consider our employee relations to be good.

Government Regulation

Our products and our operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. Our products are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act ("FDCA"), as implemented and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, import, export, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed domestically are safe and effective for their intended uses and otherwise meet the requirements of the FDCA.

In addition to U.S. regulations, we are subject to a variety of regulations in other jurisdictions governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA clearance or approval for a product, we must obtain authorization before commencing clinical trials or obtain marketing authorization or approval of our products under the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials or commercialize our products in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA clearance or approval.

FDA Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification or PMA approval. Under the FDCA, medical devices are classified into one of three classes — Class I, Class II or Class III — depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device.

These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents. While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life-sustaining, life-supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to the FDA's premarket notification and clearance process in order to be commercially distributed. Our currently marketed products are Class II or unclassified devices subject to 510(k) clearance.

510(k) Marketing Clearance Pathway

Our current products are subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a predicate device already on the market. 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) process. The FDA's 510(k) clearance process usually takes from nine to twelve months, but may take significantly longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the "de novo" process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) marketing clearance or, depending on the modification, a de novo classification or PMA approval. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k) or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications today are accomplished by a manufacturer documenting the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for every change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or PMA approval is obtained. Also, in these circumstances, we may be subject to significant regulatory fines or penalties.

The FDA is currently considering proposals to reform its 510(k) marketing clearance process, 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 in July 2014, published a new guidance document governing the review process for the clearance of medical devices. Specifically, the FDA has adopted new practices related to the acceptance of 510(k) applications which could place a higher standard on data and evidence provided to the FDA and a reduced ability to definitionally (i.e. same intended use, same technological characteristics) consider other devices as potential predicates. The FDA intends these reform actions to improve the efficiency and transparency of the 510(k) clearance process, as well as bolster patient safety. In addition, as part of 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.

Post-Market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions

on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;

- the federal Physician Sunshine Act and various state and foreign laws on reporting remunerative relationships with healthcare customers;

- the federal Anti-Kickback Statute (and similar state laws) prohibiting, among other things, soliciting, receiving, offering or providing remuneration intended to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as Medicare or Medicaid. A person or entity does not have to have actual knowledge of this statute or specific intent to violate it to have committed a violation;

- the federal False Claims Act (and similar state laws) prohibiting, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government or knowingly concealing, or knowingly and improperly avoiding or decreasing, an obligation to pay or transmit money to the federal government. The government may assert that claim includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statute;

- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;

- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

- correction, removal and recall 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;

- complying with the new federal law and regulations requiring Unique Device Identifiers (UDI) on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database (GUDID);

- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and

- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We may be subject to similar foreign laws that may include applicable post-marketing requirements such as safety surveillance. Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, we are subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

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

Regulation of Medical Devices in the EEA

There is currently no premarket government review of medical devices in the EEA (which is comprised of the 28 Member States of the EU plus Norway, Liechtenstein and Iceland). However, all medical devices placed on the market in the EEA must meet the relevant essential requirements laid down in Annex I of Directive 93/42/EEC concerning medical devices, or the Medical Devices Directive. There is also a directive specifically addressing Active Implantable Medical Devices (Directive 90/385/EEC). The most fundamental essential requirement is that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment, and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter. Compliance with a standard developed to implement an essential requirement also creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Conformity assessment procedures require an assessment of available clinical evidence, literature data for the product and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a Notified Body. Notified bodies are often separate entities and are authorized or licensed to perform such assessments by government authorities. The notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE Mark to the device, which allows the device to be placed on the market throughout the EEA. Once the product has been placed on the market in the EEA, the manufacturer must comply with requirements for reporting incidents and field safety corrective actions associated with the medical device.

In order to demonstrate safety and efficacy for their medical devices, manufacturers must conduct clinical investigations in accordance with the requirements of Annex X to the Medical Devices Directive and applicable European and International Organization for Standardization standards, as implemented or adopted in the EEA member states. Clinical trials for medical devices usually require the approval of an ethics review board and approval by or notification to the national regulatory authorities. Both regulators and ethics committees also require the submission of serious adverse event reports during a study and may request a copy of the final study report.

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposal would replace the Medical Devices Directive and the Active Implantable Medical Devices Directive with a new regulation (the Medical Devices Regulation). Unlike the Directives that must be implemented into national laws, the Regulation would be directly applicable in all EEA Member States and so is intended to eliminate current national differences in regulation of medical devices.

In October 2013, the European Parliament approved a package of reforms to the European Commission's proposals. Under the revised proposals, only designated "special notified bodies" would be entitled to conduct conformity assessments of high-risk devices, such as active implantable devices. These special notified bodies will need to notify the European Commission when they receive an application for a conformity assessment for a new high-risk device. The European Commission will then forward the notification and the accompanying documents on the device to the Medical Devices Coordination Group (MDCG), (a new, yet to be created, body chaired by the European Commission, and representatives of Member States) for an opinion. These new procedures may result in the re-assessment of our existing medical devices, or a longer or more burdensome assessment of our new products.

The Medical Devices Regulation, or MDR, entered into force in May 2017 and becomes applicable three years thereafter. The MDR would, among other things, also impose additional reporting requirements on manufacturers of high risk medical devices, impose an obligation on manufacturers to appoint a "qualified person" responsible for regulatory compliance, and provide for more strict clinical evidence requirements.

We are subject to regulations and product registration requirements in many foreign countries in which we may sell our products, including in the areas of:

- design, development, manufacturing and testing;
- product standards;
- product safety;
- product safety reporting;
- marketing, sales and distribution;
- packaging and storage requirements;
- labeling requirements;
- content and language of instructions for use;
- clinical trials;
- record keeping procedures;
- advertising and promotion;
- recalls and field corrective actions;
- post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- import and export restrictions;
- tariff regulations, duties and tax requirements;
- registration for reimbursement; and
- necessity of testing performed in country by distributors for licensees.

The time required to obtain clearance required by foreign countries may be longer or shorter than that required for FDA clearance, and requirements for licensing a product in a foreign country may differ significantly from FDA requirements.

The MDR includes further controls and requirements on the following activities:

- high level of request for premarket clinical evidence for high risk devices;
- increased scrutiny of technical files for implantable devices;
- monitoring of notified bodies, by independent auditors;
- increased requirements regarding vigilance and product traceability (specifically related to labeling requirements); and
- increased regulation for non-traditional roles such as importer and distributor.

Federal, State and Foreign Fraud and Abuse and Physician Payment Transparency Laws

In addition to FDA restrictions on marketing and promotion of drugs and devices, other federal and state laws restrict our business practices. These laws include, without limitation, foreign, federal, and state anti-kickback and false claims laws, as well as transparency laws regarding payments or other items of value provided to healthcare providers.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including stock, stock options, and the compensation derived through ownership interests.

Recognizing that the federal Anti-Kickback Statute is broad and may prohibit many innocuous or beneficial arrangements within the healthcare industry, the DHHS issued regulations in July 1991, which the Department has referred to as “safe harbors.” These safe harbor regulations set forth certain provisions which, if met in form and substance, will assure medical device manufacturers, healthcare providers and other parties that they will not be prosecuted under the federal Anti-Kickback Statute. Additional safe harbor provisions providing similar protections have been published intermittently since 1991. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the federal Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the federal Anti-Kickback Statute has been violated. In addition, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (described below).

Violations of the federal Anti-Kickback Statute can result in imprisonment, exclusion from Medicare, Medicaid or other governmental programs, as well as civil and criminal penalties, including criminal fines. Civil penalties for such conduct can further be assessed under the federal False Claims Act, including penalties of up to three times the amounts paid for such claims. Conduct and business arrangements that do not fully satisfy one of these safe harbor provisions may result in increased scrutiny by government enforcement authorities. The majority of states also have anti-kickback laws which establish similar prohibitions and in

some cases may apply more broadly to items or services covered by any third-party payor, including commercial insurers and self-pay patients.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. The federal civil False Claims Act also applies to false submissions that cause the government to be paid less than the amount to which it is entitled, such as a rebate. Intent to deceive is not required to establish liability under the civil federal civil False Claims Act.

In addition, private parties may initiate "qui tam" whistleblower lawsuits against any person or entity under the federal civil False Claims Act in the name of the government and share in the proceeds of the lawsuit. Penalties for federal civil False Claim Act violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government and, most critically, may provide the basis for exclusion from the federally funded healthcare program. On May 20, 2009, the Fraud Enforcement Recovery Act of 2009, or FERA, was enacted, which modifies and clarifies certain provisions of the federal civil False Claims Act. In part, the FERA amends the federal civil False Claims Act such that penalties may now apply to any person, including an organization that does not contract directly with the government, who knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim paid in part by the federal government. The government may further prosecute conduct constituting a false claim under the federal criminal False Claims Act. The criminal False Claims Act prohibits the making or presenting of a claim to the government knowing such claim to be false, fictitious or fraudulent and, unlike the federal civil False Claims Act, requires proof of intent to submit a false claim.

The Civil Monetary Penalty Act of 1981 imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

HIPAA also created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and 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. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many foreign countries have similar laws relating to healthcare fraud and abuse. Foreign laws and regulations may vary greatly from country to country. For example, the advertising and promotion of our products is subject to EU Directives concerning misleading and comparative advertising and unfair commercial practices, as well as other EEA Member State legislation governing the advertising and promotion of medical devices. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Also, many U.S. states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs.

Additionally, there has been a recent trend of increased foreign, federal, and state regulation of payments and transfers of value provided to healthcare professionals or entities. The federal Physician Payments Sunshine Act imposes annual reporting requirements on certain drug, biologics, medical supplies and device manufacturers for which payment is available under Medicare, Medicaid or CHIP for payments and other transfers of value provided by them, directly or indirectly, to physicians (including physician family members) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties. Manufacturers must submit reports by the 90th day of each calendar year. Certain foreign countries and U.S. states also mandate implementation of

commercial compliance programs, impose restrictions on device manufacturer marketing practices and require tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities.

Data Privacy and Security Laws

We may also become subject to various federal, state and foreign laws that protect the confidentiality of certain patient health information, including patient medical records, and restrict the use and disclosure of patient health information by healthcare providers, such as HIPAA, as amended by HITECH, in the United States.

Under HIPAA, the DHHS has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers and their business associates. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA violations carry civil and criminal penalties, and, in certain circumstances, criminal penalties. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state.

In the European Union, we may be subject to laws relating to our collection, control, processing and other use of personal data (i.e. data relating to an identifiable living individual). We process personal data in relation to our operations. We process data of both our employees and our customers, including health and medical information. The data privacy regime in the EU includes the EU Data Protection Directive (95/46/EC) regarding the processing of personal data and the free movement of such data, the E-Privacy Directive 2002/58/EC and national laws implementing each of them. Each EU Member State has transposed the requirements laid down by the Data Protection Directive and E-Privacy Directive into its own national data privacy regime and therefore the laws may differ significantly by jurisdiction. We need to ensure compliance with the rules in each jurisdiction where we are established or are otherwise subject to local privacy laws.

The requirements include that personal data may only be collected for specified, explicit and legitimate purposes based on a legal grounds set out in the local laws, and may only be processed in a manner consistent with those purposes. Personal data must also be adequate, relevant, not excessive in relation to the purposes for which it is collected, be secure, not be transferred outside of the EEA unless certain steps are taken to ensure an adequate level of protection and must not be kept for longer than necessary for the purposes of collection. To the extent that we process, control or otherwise use sensitive data relating to living individuals (for example, patients' health or medical information), more stringent rules apply, limiting the circumstances and the manner in which we are legally permitted to process that data and transfer that data outside of the EEA. In particular, in order to process such data, explicit consent to the processing (including any transfer) is usually required from the data subject (being the person to whom the personal data relates).

We are subject to the supervision of local data protection authorities in those jurisdictions where we are established or otherwise subject to applicable law.

Local laws are amended from time to time, and guidance is issued frequently by regulators. Any changes in law and new guidance may impact, and require changes to, our current operations. Additionally, on January 25, 2012, the European Commission published its draft EU General Data Protection Regulation ("GDPR"). On March 12, 2014, the European Parliament formally passed a revised proposal of the Regulation, and the Council of the European Union published its general approach on June 15, 2015. Trilogue discussion between the European Commission, European Parliament and Council of the European Union have concluded and the GDPR came into force May 25, 2018. The Regulation implements significant changes to the EU data protection regime. Unlike the E-Privacy and Data Protection Directives, the Regulation has direct effect in each EU Member State, without the need for further enactment. The Regulation strengthened individuals' rights and imposed stricter requirements on companies processing personal data, and increases financial penalties for non-compliance.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products.

The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The Affordable Care Act imposed, among other things, a new federal excise tax on the sale of certain medical devices (which is suspended until December 31, 2019 and absent further legislative action will be reinstated starting January 1, 2020), provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the Affordable Care Act has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. We do not yet know the full impact that the Affordable Care Act will have on our business. Moreover, the Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but not limited to, repeal or replacement. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments scheduled to begin in 2019 that are based on various performance measures and physicians' participation in alternative payment models, such as accountable care organizations.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Anti-Bribery and Corruption Laws

Our U.S. operations are subject to the FCPA. We are required to comply with the FCPA, which generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments to foreign officials for the purpose of obtaining or retaining business or other benefits. In addition, the FCPA imposes accounting standards and requirements on publicly traded U.S. corporations and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. We also are subject to similar anticorruption legislation implemented in Europe under the Organization for Economic Co-operation and Development's Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

Coverage and Reimbursement

In the United States, our currently approved products are commonly treated as general supplies utilized in orthopedic surgery and if covered by third-party payors, are paid for as part of the surgical procedure. Outside of the United States, there are many reimbursement programs through private payors as well as government programs. In some countries, government reimbursement is the predominant program available to patients and hospitals. Our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures during which our products are used. Failure by physicians, hospitals, ambulatory surgery centers and other users of our products to obtain sufficient coverage and reimbursement from third-party payors for procedures in which our products are used, or adverse changes in government and private third-party payors' coverage and reimbursement policies.

Based on our experience to date, third-party payors generally reimburse for the surgical procedures in which our products are used only if the patient meets the established medical necessity criteria for surgery. Some payors are moving toward a managed care system and control their healthcare costs by limiting authorizations for surgical procedures, including elective procedures using our devices. Although no uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor, reimbursement decisions by particular third-party payors may depend upon a number of factors, including the payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational.

Third-party payors are increasingly auditing and challenging the prices charged for medical products and services with concern for upcoding, miscoding, using inappropriate modifiers, or billing for inappropriate care settings. Some third-party payors must approve coverage for new or innovative devices or procedures before they will reimburse healthcare providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution by the FDA, we may find limited demand for the product unless and until reimbursement approval has been obtained from governmental and private third-party payors.

The Centers for Medicare and Medicaid Services ("CMS") is responsible for administering the Medicare program and sets coverage and reimbursement policies for the Medicare program in the United States. The CMS, in partnership with state governments, also administers the Medicaid program and CHIP. CMS policies may alter coverage and payment related to our product portfolio in the future. These changes may occur as the result of national coverage determinations issued by CMS or as the result of local coverage determinations by contractors under contract with CMS to review and make coverage and payment decisions. Medicaid programs are funded by both federal and state governments, and may vary from state to state and from year to year and will likely play an even larger role in healthcare funding pursuant to the Affordable Care Act.

A key component in ensuring whether the appropriate payment amount is received for physician and other services, including those procedures using our products, is the existence of a Current Procedural Terminology, or CPT, code, to describe the procedure in which the product is used. To receive payment, healthcare practitioners must submit claims to insurers using these codes for payment for medical services. CPT codes are assigned, maintained and annually updated by the American Medical Association and its CPT Editorial Board. If the CPT codes that apply to the procedures performed using our products are changed or deleted, reimbursement for performances of these procedures may be adversely affected.

In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita (patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industry to reduce the costs of products and services. All third-party reimbursement programs are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, requiring second opinions prior to major surgery, careful review of bills, encouragement of healthier lifestyles and other preventative services and exploration of more cost-effective methods of delivering healthcare.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific product lines and procedures. There can be no assurance that procedures using our products will be covered for a specific indication, that our products will be considered cost-effective by third party payors, that an adequate level of reimbursement will be available or that

the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably. More and more, local, product specific reimbursement law is applied as an overlay to medical device regulation, which has provided an additional layer of clearance requirement. Specifically, Australia now requires clinical data for clearance and reimbursement be in the form of prospective, multi-center studies, a high bar not previously applied. In addition, in France, certain innovative devices have been identified as needing to provide clinical evidence to support a "mark-specific" reimbursement.

It is our intent to complete the requisite clinical studies and obtain coverage and reimbursement approval in countries where it makes economic sense to do so.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement levels. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. These updates could directly impact the demand for our products.

ITEM 1A. RISK FACTORS

Our business is subject to many risks. This section includes a discussion of important factors that could affect our business, operating results, financial condition and the trading price of our common stock. You should carefully consider these risk factors, together with all of the other information included in this Annual Report on Form 10-K as well as our other publicly available filings with the SEC.

Risks Related to Our Financial Condition and Capital Requirements

We have incurred losses in the past and may be unable to achieve or sustain profitability in the future.

We incurred net losses in all fiscal years since inception. We incurred net losses of $12.0 million, $8.9 million and $6.6 million for the years ended December 31, 2018, 2017 and 2016, respectively. Our net loss for the year ended December 31, 2016 included a one-time charge of $2.0 million for costs related to our initial public offering. As a result of ongoing losses, as of December 31, 2018, we had an accumulated deficit of $115.1 million. We expect to continue to incur significant product development, clinical and regulatory, sales and marketing and other expenses. In addition, our general and administrative expenses have increased following our initial public offering due to the additional costs associated with being a public company. The net losses we incur may fluctuate significantly from quarter to quarter. We will need to generate significant additional revenue to achieve and sustain profitability, and even if we achieve profitability, we cannot be sure that we will remain profitable for any substantial period of time. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

We may be unable to generate sufficient revenue from the commercialization of our products to achieve and sustain profitability.

At present, we rely solely on the commercialization of our products to generate revenue, and we expect to generate substantially all of our revenue in the foreseeable future from sales of these products. In order to successfully commercialize our products, we will need to continue to expand our marketing efforts to develop new relationships and expand existing relationships with customers, to obtain regulatory clearances or approvals for our products in additional countries, to achieve and maintain compliance with all applicable regulatory requirements and to develop and commercialize our products with new features or for additional indications. If we fail to successfully commercialize our products, we may never receive a return on the substantial investments in product development, sales and marketing, regulatory compliance, manufacturing and quality assurance we have made, as well as further investments we intend to make, which may cause us to fail to generate revenue and gain economies of scale from such investments.

In addition, potential customers may decide not to purchase our products, or our customers may decide to cancel orders due to changes in treatment offerings, research and development plans, adverse clinical outcomes, difficulties in obtaining coverage or reimbursement for procedures using our products, difficulties obtaining approval from a hospital, complications with manufacturing or the utilization of technology developed by other parties, all of which are circumstances outside of our control.

In addition, demand for our products may not increase as quickly as we predict, and we may be unable to increase our revenue levels as we expect. Even if we succeed in increasing adoption of these systems by physicians, hospitals and other healthcare providers, maintaining and creating relationships with our existing and new customers and developing and commercializing new features or indications for these systems, we may be unable to generate sufficient revenue to achieve or sustain profitability.

We may need to raise additional capital to fund our existing commercial operations, develop and commercialize new products and expand our operations.

Based on our current business plan, we believe our current cash, borrowing capacity under our loan agreements, cash receipts from sales of our products and net proceeds from our December 2018 secondary offering of common stock will be sufficient to meet our anticipated cash requirements for at least the next 12 months. If our available cash balances, borrowing capacity, net proceeds from our initial public offering and anticipated cash flow from operations are insufficient to satisfy our liquidity requirements, including because of lower demand for our products as a result of the risks described in this Annual Report on Form 10-K, we may seek to sell common or preferred equity or convertible debt securities, enter into an additional credit facility or another form of third-party funding or seek other debt financing.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts to increase market adoption of our products and address competitive developments;
- provide for supply and inventory costs associated with plans to accommodate potential increases in demand for our products;
- fund development and marketing efforts of any future products or additional features to then-current products;
- acquire, license or invest in new technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth and improve gross margins;
- our rate of progress in establishing coverage and reimbursement arrangements with domestic and international commercial third-party payors and government payors;
- the cost of expanding our operations and offerings, including our sales and marketing efforts;
- our rate of progress in, and cost of the sales and marketing activities associated with, establishing adoption of our products;
- the cost of research and development activities;
- the effect of competing technological and market developments;
- costs related to international expansion; and
- the potential cost of and delays in product development as a result of any regulatory oversight applicable to our products.

Additional capital may not be available at such times or in amounts as needed by us. Even if capital is available, it might be available only on unfavorable terms. Any additional equity or convertible debt financing into which we enter could be dilutive to our existing stockholders. Any future debt financing into which we enter may impose

covenants upon us that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. If access to sufficient capital is not available as and when needed, our business will be materially impaired and we may be required to cease operations, curtail one or more product development or commercialization programs, or we may be required to significantly reduce expenses, sell assets, seek a merger or joint venture partner, file for protection from creditors or liquidate all our assets.

Our sales volumes and our results of operations may fluctuate over the course of the year.

We have experienced and continue to experience meaningful variability in our sales and gross profit among quarters, as well as within each quarter, as a result of a number of factors, which may include, among other things:

- the number of products sold in the quarter;
- the unpredictability of sales of full sets of implants and instruments to our international distributors;
- the demand for, and pricing of, our products and the products of our competitors;
- the timing of or failure to obtain regulatory clearances or approvals for our products;
- the costs, benefits and timing of new product introductions;
- increased competition;
- the availability and cost of components and materials;
- the number of selling days in the quarter;
- fluctuation and foreign currency exchange rates; or
- impairment and other special charges.

Our loan and security agreement with Squadron Capital LLC contains covenants that may restrict our business and financing activities.

Effective December 31 2017, we entered into a Fourth Amended and Restated Loan and Security agreement (the "Loan Agreement") with Squadron Capital LLC ("Squadron"). Pursuant to the Loan Agreement, we consolidated a majority of the term loan amounts into a $20.0 million term note and reestablished a $15.0 million revolving credit facility.

As of December 31, 2018, we had approximately $19.9 million in outstanding indebtedness under the Loan Agreement. The Loan Agreement restricts our ability to, among other things:

- dispose of or sell our assets;
- modify our organizational documents;
- merge with or acquire other entities or assets;
- incur additional indebtedness;
- create liens on our assets;

- pay dividends; and
- make investments.

The covenants in the Loan Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the Loan Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the Loan Agreement to become immediately due and payable and terminate all commitments to extend further credit. See "Management's Discussion and Analysis of Financial Condition and Results of Operations — Indebtedness — Loan Agreement."

If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, we may be unable to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts.

We are subject to taxation in numerous U.S. states and territories, as well as certain countries outside the U.S. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of the newly enacted U.S. federal income tax law, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements.

Our ability to use net operating losses to offset future taxable income may be subject to limitations.

As of December 31, 2018, we had federal and state net operating loss carryforwards of $87.3 million. The federal and state net operating loss carryforwards will begin to expire, if not utilized, beginning in 2028. The deferred tax assets were fully offset by a valuation allowance as of December 31, 2018 and 2017, and no income tax benefit has been recognized in our consolidated statements of operations. Under the newly enacted federal income tax law, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the newly enacted federal tax law. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. We determined that an ownership change occurred on May 30, 2014, resulting in a limitation of approximately $1.1 million per year being imposed on the use of our pre-change NOLs of approximately $49.0 million. This limitation will be increased in the first five years after the ownership change by the amounts of recognized built-in gains as determined under the tax rules, which increase should be approximately $2.3 million in each such year. A second ownership change occurred on December 11, 2018. The estimated annual limitation is $9.7 million, which is increased by $22.4 million over the first five years as a result of an unrealized built in gain. It is possible that we have experienced other ownership changes. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our net operating loss carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Risks Related to Our Business and Strategy

Our long-term growth depends on our ability to commercialize our products in development and to develop and commercialize additional products through our research and development efforts, and if we fail to do so we may be unable to compete effectively.

In order to increase our market share in the pediatric orthopedic markets, we must successfully commercialize our current products in development, enhance our existing product offerings and introduce new products in response to changing customer demands and competitive pressures and technologies. Our industry is characterized by intense competition, rapid technological changes, new product introductions and enhancements and evolving industry standards. Our business prospects depend in part on our ability to develop and commercialize new products and applications for our technology, including in new markets that develop as a result of technological and scientific advances, while improving the performance and cost-effectiveness of our products. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our products. It is important that we anticipate changes in technology and market demand, as well as physician, hospital and healthcare provider practices to successfully develop, obtain clearance or approval, if required, and successfully introduce new, enhanced and competitive technologies to meet our prospective customers' needs on a timely and cost-effective basis.

We might be unable to successfully commercialize our current products with domestic or international regulatory clearances or approvals or develop or obtain regulatory clearances or approvals to market new products. Additionally, these products and any future products might not be accepted by the orthopedic surgeons or the third-party payors who reimburse for the procedures performed with our products or may not be successfully commercialized due to other factors. The success of any new product offering or enhancement to an existing product will depend on numerous factors, including our ability to:

- properly identify and anticipate clinician and patient needs;
- develop and introduce new products or product enhancements in a timely manner;
- adequately protect our intellectual property and avoid infringing upon the intellectual property rights of third parties;
- demonstrate the safety and efficacy of new products; and
- obtain the necessary regulatory clearances or approvals for new products or product enhancements.

If we do not develop and obtain regulatory clearances or approvals for new products or product enhancements in time to meet market demand, or if there is insufficient demand for these products or enhancements, our results of operations will suffer. Our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. In addition, even if we are able to develop enhancements or new generations of our products successfully, these enhancements or new generations of products may not produce sales in excess of the costs of development and they may be quickly rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

Nevertheless, we must carefully manage our introduction of new products. If potential customers believe such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory as we transition to new products, and we have no experience in managing product transitions.

If the quality of our products does not meet the expectations of physicians or patients, then our brand and reputation could suffer and our business could be adversely impacted.

In the course of conducting our business, we must adequately address quality issues that may arise with our products, as well as defects in third-party components included in our products. Furthermore, a malfunction by one of our products may not be detected for an extended period of time, which may result in delay or failure to remedy the condition for which the product was prescribed. Although we have established internal procedures

to minimize risks that may arise from quality issues, we may be unable to eliminate or mitigate occurrences of these issues and associated liabilities.

We operate in a very competitive business environment and if we are unable to compete successfully against our existing or potential competitors, our sales and operating results may be negatively affected and we may not grow.

Our currently marketed products are, and any future products we develop and commercialize will be, subject to intense competition. The industry in which we operate is intensely competitive, subject to rapid change and highly sensitive to the introduction of new products or other market activities of industry participants. Our ability to compete successfully will depend on our ability to develop products that reach the market in a timely manner, receive adequate coverage and reimbursement from third-party payors, and are safer, less invasive and more effective than competing products and treatments. Because of the size of the potential market, we anticipate that companies will dedicate significant resources to developing competing products.

We have competitors in each of our three product categories, including the DePuy Synthes Companies (a subsidiary of Johnson and Johnson), Medtronic plc and Smith & Nephew plc. At any time, these and other potential market entrants may develop new devices or treatment alternatives that may render our products obsolete or uncompetitive. In addition, they may gain a market advantage by developing and patenting competitive products or processes earlier than we can or by obtaining regulatory clearances or market registrations more rapidly than we can. Many of our current and potential competitors have substantially greater sales and financial resources than we do. In addition, these companies may have more established distribution networks, entrenched relationships with orthopedic surgeons and greater experience in launching, marketing, distributing and selling products.

In addition, new market participants continue to enter the orthopedic industry. Many of these new competitors specialize in a specific product or focus on a particular market sector, making it more difficult for us to increase our overall market position. The frequent introduction by competitors of products that are or claim to be superior to our products or that are alternatives to our existing or planned products may also create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the orthopedic surgery market generally.

We also face a particular challenge of overcoming the long-standing practices by some orthopedic surgeons of using the products of our larger, more established competitors. Orthopedic surgeons who have completed many successful, complex surgeries using the products made by these competitors may be disinclined to adopt new products with which they are less familiar. Further, orthopedic surgeons may choose to use the products of our larger, more established competitors because of their broad and comprehensive adult orthopedic offerings. If these orthopedic surgeons do not adopt our products, then our revenue growth may slow or decline and our stock price may decline.

Our competitors may also develop and patent processes or products earlier than we can or obtain domestic or international regulatory clearances or approvals for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products. We also compete with our competitors in acquiring technologies and technology licenses complementary to our products or advantageous to our business. In addition, we compete with our competitors to engage the services of independent sales agencies and distributors, both those presently working with us and those with whom we hope to work as we expand.

We provide implant and instrument sets for nearly all surgeries performed using our products, and maintaining sufficient levels of inventory could consume a significant amount of our resources, reduce our cash flows and lead to inventory impairment charges.

We are required to maintain significant levels of implant and instrument sets for consignment to our customers. The amount of this investment is driven by the number of orthopedic surgeons or hospitals using our products, and as the number of different orthopedic surgeons and hospitals that use our products increases, the number of implant and instrument sets required to meet this demand will increase. Because we do not have the sales volume of some larger companies, we may be unable to utilize our instrument sets as often and our return on

assets may be lower when compared to such companies. In addition, because fewer than all of the components of each set are used in a typical surgery, certain portions of the set may become obsolete before they can be used. In the event that a substantial portion of our inventory becomes obsolete, the resulting costs associated with the inventory impairment charges and costs required to replace such inventory could have a material adverse effect on our earnings and cash flows. In addition, as we introduce new products, new implant and instrument sets may be required, with a significant initial investment required to accommodate the launch of the product.

The provision of loaned instrument sets to our customers may implicate certain federal and state fraud and abuse laws.

In the United States, we typically loan instrument sets for each surgery performed using our products at no additional charge to the customer. The provision of these instruments at no charge to our customers may implicate certain federal and state fraud and abuse laws. Because the provision of loaned instrument sets may result in a benefit to our customers, the government could view this practice as a prohibited transfer of value intended to induce customers to purchase our products that are used in procedures reimbursed by a federal healthcare program. For further discussion of these laws, see “Risks Related to Regulatory Matters."

We are subject to certain federal, state and foreign fraud and abuse laws and health information privacy and security laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

We may seek to grow our business through acquisitions or investments in new or complementary businesses, products or technologies, through the licensing of products or technologies from third parties or other strategic alliances, and the failure to manage acquisitions, investments, licenses or other strategic alliances, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results, dilute our stockholders’ ownership, increase our debt or cause us to incur significant expense.

Our success depends on our ability to continually enhance and broaden our product offerings in response to changing customer demands, competitive pressures, technologies and market pressures. Accordingly, from time to time we may consider opportunities to acquire, make investments in or license other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. Potential and completed acquisitions, strategic investments, licenses and other alliances involve numerous risks, including:

- difficulty assimilating or integrating acquired or licensed technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions or strategic alliances, including the assumption of unknown or contingent liabilities and the incurrence of debt or future write-offs of intangible assets or goodwill;
- diversion of management’s attention from our core business and disruption of ongoing operations;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential losses related to investments in other companies;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms or at all 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 strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures, languages and legal and regulatory environments, currency risks and the particular economic, political and regulatory risks associated with specific countries.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. Additional funds may not be available on terms that are favorable to us, or at all. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our stock as consideration.

We may be unable to gain the support of leading hospitals and key opinion leaders, which may make it difficult to establish our products as a standard of care and achieve market acceptance.

Our strategy includes educating leading hospitals and key opinion leaders in the industry. If these hospitals and key opinion leaders determine that alternative technologies are more effective or that the benefits offered by our products are not sufficient to justify their higher cost, or if we encounter difficulty promoting adoption or establishing these systems as a standard of care, our ability to achieve market acceptance of the products we introduce could be significantly limited.

We may be unable to successfully demonstrate to orthopedic surgeons the merits of our products compared to those of our competitors.

Orthopedic surgeons play a significant role in determining the course of treatment and, ultimately, the type of products that will be used to treat a patient. As a result, our success depends, in large part, on our ability to effectively market to them and demonstrate to orthopedic surgeons the merits of our products compared to those of our competitors for use in treating patients. Acceptance of our products depends on educating orthopedic surgeons as to the distinctive characteristics, perceived clinical benefits, safety and cost-effectiveness of our products as compared to our competitors' products, and on training orthopedic surgeons in the proper use of our products. If we are not successful in convincing orthopedic surgeons of the merits of our products or educating them on the use of our products, they may not use our products or use them effectively and we may be unable to increase our sales, sustain our growth or achieve and sustain profitability.

Furthermore, we believe many orthopedic surgeons may be hesitant to adopt our products unless they determine, based on experience, clinical data and published peer-reviewed journal articles, that our products provide benefits or are attractive alternatives to our competitors' products. Orthopedic surgeons may be hesitant to change their surgical treatment practices for the following reasons, among others:

- lack of experience with our products;
- existing relationships with competitors and sales distributors that sell competitive products;
- lack or perceived lack of evidence supporting additional patient benefits;
- perceived liability risks generally associated with the use of new products and procedures;
- less attractive availability of coverage and reimbursement within healthcare payment systems compared to procedures using other products and techniques;
- costs associated with the purchase of new products and equipment; and
- the time commitment that may be required for training.

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

If orthopedic surgeons fail to safely and appropriately use our products, or if we are unable to train orthopedic surgeons on the safe and appropriate use of our products, we may be unable to achieve our expected growth.

An important part of our sales process includes the ability to screen for and identify orthopedic surgeons who have the requisite training and experience to safely and appropriately use our products. If orthopedic 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. If we are unable to successfully identify orthopedic surgeon customers who will be able to successfully deploy our products, we may be unable to achieve our expected growth.

There is a learning process involved for orthopedic surgeons to become proficient in the use of our products. It is critical to the success of our commercialization efforts with respect to future products to train a sufficient number of orthopedic surgeons and to provide them with adequate instruction in the use of our products. This training process may take longer than expected and may therefore affect our ability to increase sales. Convincing orthopedic surgeons to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in these efforts.

Although we believe our interactions with orthopedic surgeons are conducted in compliance with FDA, federal and state fraud and abuse and other applicable laws and regulations developed both nationally and in foreign countries, if the FDA or other competent authority determines that any of our activities constitute promotion of an unapproved use or promotion of an intended purpose not covered by FDA approved labeling or the current European Union product certification, or CE Mark, affixed to our product, they could request that we modify our activities, issue corrective advertising or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine and criminal penalty. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

We have a limited operating history and may face difficulties encountered by early stage companies in new and evolving markets.

We began operations in 2007. Accordingly, we have a limited operating history upon which to base an evaluation of our business and prospects. In assessing our prospects, you must consider the risks and difficulties frequently encountered by early stage companies in new and evolving markets. These risks include our ability to:

- manage rapidly changing and expanding operations;
- establish and increase awareness of our brand and strengthen customer loyalty;
- increase the number of our independent sales agencies and international distributors to expand sales of our products in the United States and in targeted international markets;
- implement and successfully execute our business and marketing strategy;
- respond effectively to competitive pressures and developments;
- continue to develop and enhance our products and products in development;
- obtain regulatory clearance or approval to commercialize new products and enhance our existing products;

- expand our presence in existing and commence operations in new international markets; and
- attract, retain and motivate qualified personnel.

Our business is subject to seasonal fluctuations.

Our business is subject to seasonal fluctuations in that our revenue is typically higher in the summer months and holiday periods, driven by higher sales of our scoliosis and trauma and deformity products, which is influenced by the higher incidence of pediatric surgeries during these periods due to recovery time provided by breaks in the school year. Additionally, our scoliosis patients tend to have additional health challenges that make scheduling their procedures variable in nature. As a result of these factors, our financial results for any single quarter or for periods of less than a year are not necessarily indicative of the results that may be achieved for a full fiscal year.

If we are unable to convince hospital facilities to approve the use of our products, our sales may decrease.

In the United States, in order for orthopedic surgeons to use our devices, the hospital facilities where these orthopedic surgeons treat patients will typically require us to obtain approval from the facility's value analysis committee, or VAC. VACs typically review the comparative effectiveness and cost of medical devices used in the facility. The makeup and evaluation processes for VACs vary considerably, and it can be a lengthy, costly and time-consuming effort to obtain approval by the relevant VAC. For example, even if we have an agreement with a hospital system for the purchase of our products, in most cases, we must obtain VAC approval by each hospital within the system to sell at that particular hospital. Additionally, hospitals typically require separate VAC approval for each specialty in which our products are used, which may result in multiple VAC approval processes within the same hospital even if such product has already been approved for use by a different specialty group. We may need VAC approval for each different device to be used by the orthopedic surgeons in that specialty. In addition, hospital facilities and group purchasing organizations, or GPOs, which manage purchasing for multiple facilities, may also require us to enter into a purchase agreement and satisfy numerous elements of their administrative procurement process, which can also be a lengthy, costly, and time-consuming effort. If we do not obtain access to hospital facilities in a timely manner, or at all, via these VAC and purchase contract processes, or otherwise, or if we are unable to secure contracts in a timely manner, or at all, our operating costs will increase, our sales may decrease, and our operating results may be harmed. Furthermore, we may expend significant effort in these costly and time-consuming processes and still may not obtain VAC approval or a purchase contract from such hospitals or GPOs.

We have limited experience in marketing and selling our products, and if we are unable to successfully expand our sales infrastructure and adequately address our customers' needs, it could negatively impact sales and market acceptance of our products and we may never generate sufficient revenue to achieve or sustain profitability.

We have limited experience in marketing and selling our products. We began selling our products in the United States in 2008 and internationally in 2011. As of December 31, 2018, our sales organization consisted of 35 independent stocking distributors and five independent sales agencies in 39 countries. In 2017, we began to supplement our use of independent distributors with direct sales programs in the United Kingdom, Ireland, Australia and New Zealand. In 2018, we began to sell direct in Canada. In these markets, we work through sales agencies that are paid a commission. Our operating results are directly dependent upon the sales and marketing efforts of our independent sales agencies and distributors. If our independent sales agencies or distributors fail to adequately promote, market and sell our products, our sales could significantly decrease.

In addition, our future sales will largely depend on our ability to increase our marketing efforts and adequately address our customers' needs. We believe it is necessary to utilize a sales force that includes sales agencies with specific technical backgrounds that can support our customers' needs. We will also need to attract independent sales personnel and attract and develop marketing personnel with industry expertise. Competition for such independent sales agencies, distributors and marketing employees is intense and we may be unable to attract and retain sufficient personnel to maintain an effective sales and marketing force. If we are unable to adequately address our customers' needs, it could negatively impact sales and market acceptance of our products, and we may not generate sufficient revenue to sustain profitability.

As we launch new products and increase our marketing efforts with respect to existing products, we will need to expand the reach of our marketing and sales networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled independent sales agencies and distributors with significant technical knowledge in various areas. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, new hires may not become as productive as may be necessary to maintain or increase our sales. If we are unable to expand our sales and marketing capabilities domestically and internationally, we may be unable to effectively commercialize our products.

We lack published long-term data supporting superior clinical outcomes enabled by our products, which could limit sales.

We lack published long-term data supporting superior clinical outcomes enabled by our products. For this reason, orthopedic surgeons and other clinicians may be slow to adopt our products, we may not have comparative data that our competitors have or are generating, and we may be subject to greater regulatory and product liability risks. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes. Such results would slow the adoption of our products by orthopedic surgeons, would significantly reduce our ability to achieve expected sales and could prevent us from achieving and maintaining profitability.

In addition, because certain of our products have only been on the market for a few years, we have limited data with respect to treatment using these products. If future patient studies or clinical testing do not support our belief that our products offer a more advantageous treatment for a broad spectrum of pediatric orthopedic conditions, market acceptance of our products could fail to increase or could decrease.

If coverage and reimbursement from third-party payors for procedures using our products significantly decline, orthopedic surgeons, hospitals and other healthcare providers may be reluctant to use our products and our sales may decline.

In the United States, healthcare providers who purchase our products generally rely on third-party payors, including Medicare, Medicaid and private health insurance plans, to pay for all or a portion of the cost of our products in the procedures in which they are employed. Because there is often no separate reimbursement for products used in surgical procedures, the additional cost associated with the use of our products can impact the profit margin of the hospital or surgery center where the surgery is performed. Some of our target customers may be unwilling to adopt our products in light of the additional associated cost. Further, any decline in the amount payors are willing to reimburse our customers for the procedures using our products may make it difficult for existing customers to continue using, or to adopt, our products and could create additional pricing pressure for us. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of reimbursement.

To contain costs of new technologies, governmental healthcare programs and third-party payors are increasingly scrutinizing new and existing treatments by requiring extensive evidence of favorable clinical outcomes. Orthopedic surgeons, hospitals and other healthcare providers may not purchase our products if they do not receive satisfactory reimbursement from these third-party payors for the cost of the procedures using our products. Payors 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. If third-party payors issue non-coverage policies or if our customers are not reimbursed at adequate levels, this could adversely affect sales of our products.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement rates and policies. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. These updates could directly impact the demand for our products. For example, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, provided for a 0.5% annual increase in payment rates under the Medicare Physician Fee Schedule, or PFS, through 2019, but no annual update from 2020 through 2025. MACRA also introduced a Quality Payment Program, or QPP, for Medicare physicians, nurses and other “eligible clinicians” beginning in 2019. At this time, it is unclear how the introduction of the QPP will impact overall reimbursement under the PFS. While MACRA applies only to Medicare reimbursement, Medicaid and

private payors often follow Medicare payment limitations in setting their own reimbursement rates, and any reduction in Medicare reimbursement may result in a similar reduction in payments from private payors, which may result in reduced demand for our products. However, there is no uniform policy of coverage and reimbursement among payors in the United States. Therefore, coverage and reimbursement for procedures can differ significantly from payor to payor.

Moreover, some healthcare providers in the United States 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 attempt to control costs by authorizing fewer surgical procedures or by requiring the use of the least expensive clinically appropriate products available. Additionally, as a result of reform of the U.S. healthcare system, changes in reimbursement policies or healthcare cost containment initiatives may limit or restrict coverage and reimbursement for our products and cause our revenue to decline.

Outside of the United States, reimbursement systems vary significantly by country. Many foreign markets have government-managed healthcare systems that govern reimbursement for orthopedic implants and procedures. Additionally, some foreign reimbursement systems provide for limited payments in a given period and therefore result in extended payment periods. If adequate levels of reimbursement from third-party payors outside of the United States are not obtained, international sales of our products may decline.

The marketability of our products may suffer if government and commercial third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our employees, consultants, independent sales agencies and distributors and other commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, consultants, independent sales agencies and distributors and other commercial partners may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or other unauthorized activities that violate the regulations of the FDA and other U.S. healthcare regulators, as well as non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to such regulators, manufacturing standards, healthcare fraud and abuse laws and regulations in the United States and abroad or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry, including the sale of medical devices, are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. It is not always possible to identify and deter misconduct by our employees, sales agencies, distributors and other third parties, and the precautions we take to detect and prevent this activity 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. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations.

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, foreign liability, employee benefits liability, property, umbrella, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if these policies will provide us with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

We bear the risk of warranty claims on our products.

While we have no history of warranty claims, have no warranty reserves and had no warranty expense for the years ended December 31, 2018, 2017 or 2016, we bear the risk of warranty claims on the products we supply. We may not be successful in claiming recovery under any warranty or indemnity provided to us by our suppliers or vendors in the event of a successful warranty claim against us by a customer or that any recovery from such vendor or supplier would be adequate. In addition, warranty claims brought by our customers related to third-party components may arise after our ability to bring corresponding warranty claims against such suppliers expires, which could result in costs to us.

The proliferation of physician-owned distributorships could result in increased pricing pressure on our products or harm our ability to sell our products to physicians who own or are affiliated with those distributorships.

Physician-owned distributorships, or PODs, are product distributors that are owned, directly or indirectly, by physicians. PODs derive a portion, or substantially all, of their revenue from selling, or arranging for the sale of, products ordered by the physician-owners for use in procedures the physician-owners perform on their own patients at hospitals and other facilities that purchase from or through the POD, or otherwise generate revenue based directly or indirectly on product orders arranged for by physician-owners.

On March 26, 2013, the Office of Inspector General of the U.S. Department of Health and Human Services, or the DHHS, issued a special fraud alert on PODs and stated that it views PODs as inherently suspect under the federal Anti-Kickback Statute and is concerned about the proliferation of PODs. Notwithstanding the DHHS's concern about PODs, the number of PODs in the spinal surgery industry may continue to grow as economic pressures increase throughout the industry, hospitals, insurers and physicians search for ways to reduce costs and, in the case of the physicians, search for ways to increase their incomes. PODs and the physicians who own, or partially own, them have significant market knowledge and access to the orthopedic surgeons who use our products and the hospitals that purchase our products and thus the growth of PODs may reduce our ability to compete effectively for business from orthopedic surgeons who own such distributorships.

Risks Related to Administrative, Organizational and Commercial Operations and Growth

We may be unable to manage our anticipated growth effectively, which could make it difficult to execute our business strategy.

We have been growing rapidly and have a relatively short history of operating as a commercial company. For example, our revenue grew from $37.3 million for the year ended December 31, 2016 to $57.6 million for the year ended December 31, 2018. We intend to continue to grow our business operations and may experience periods of rapid growth and expansion. This anticipated growth could create a strain on our organizational, administrative and operational infrastructure, including our supply chain operations, quality control, technical support and customer service, sales force management and general and financial administration. We may be unable to maintain the quality of or delivery timelines of our products or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. We may implement new enterprise software systems in a number of areas affecting a broad range of business processes and functional areas. The time and resources required to implement these new systems is uncertain and failure to complete this in a timely and efficient manner could harm our business.

As our commercial operations and sales volume grow, we will need to continue to increase our workflow capacity for our supply chain, customer service, billing and general process improvements and expand our internal quality assurance program, among other things. These increases in scale or expansion of personnel may not be successfully implemented.

The loss of our senior management or our inability to attract and retain highly skilled salespeople and engineers could negatively impact our business.

Our success depends on the skills, experience and performance of the members of our executive management team. The individual and collective efforts of these employees will be important as we continue to develop our products and as we expand our commercial activities. We believe there are only a limited number of individuals

with the requisite skills to serve in many of our key positions, and the loss or incapacity of existing members of our executive management team could negatively impact our operations if we experience difficulties in hiring qualified successors. We do not maintain key man life insurance with any of our employees. We have employment agreements with each of the members of our senior management; however, the existence of these employment agreement does not guarantee our retention of these employees for any period of time.

Our commercial, supply chain and research and development programs and operations depend on our ability to attract and retain highly skilled salespeople and engineers. We may be unable to attract or retain qualified managers, salespeople or engineers in the future due to the competition for qualified personnel among medical device businesses. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. Recruiting and retention difficulties can limit our ability to support our commercial, supply chain and research and development programs. All of our employees are at-will, which means that either we or the employee may terminate his or her employment at any time. The loss of key employees, the failure of any key employee to perform or our inability to attract and retain skilled employees, as needed, or an inability to effectively plan for and implement a succession plan for key employees could harm our business.

We face risks associated with our international business.

We market and sell our products in 39 countries outside of the United States. For the years ended December 31, 2018, 2017 and 2016, approximately 24%, 23% and 23% of our revenue was attributable to our international customers, respectively. These customers are generally allowed to return products, and some are thinly capitalized. The sale and shipment of our products across international borders, as well as the purchase of components and products from international sources, subjects us to extensive U.S. and other foreign governmental trade, import and export and customs regulations and laws. Compliance with these regulations and laws is costly and exposes us to penalties for non-compliance. We expect our international activities will be dynamic over the foreseeable future as we continue to pursue opportunities in international markets. Our international business operations are subject to a variety of risks, including:

- difficulties in staffing and managing foreign and geographically dispersed operations;
- having to comply with various U.S. and international laws, including export control laws and the U.S. Foreign Corrupt Practices Act of 1977, or the FCPA, and anti-money laundering laws;
- differing regulatory requirements for obtaining clearances or approvals to market our products;
- changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the United States;
- tariffs and trade barriers, export regulations and other regulatory and contractual limitations on our ability to sell our products in certain foreign markets;
- fluctuations in foreign currency exchange rates;
- imposition of limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;
- differing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- imposition of differing labor laws and standards;
- economic, political or social instability in foreign countries and regions;
- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action; and
- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us.

We expect we will continue expanding into other international markets; however, our expansion plans may not be realized, or if realized, may not be successful. We expect each market to have particular regulatory and funding hurdles to overcome and future developments in these markets, including the uncertainty relating to governmental policies and regulations, could harm our business.

We could be negatively impacted by violations of applicable anti-corruption laws or violations of our internal policies designed to ensure ethical business practices.

We operate in a number of countries throughout the world, including in countries that do not have as strong a commitment to anti-corruption and ethical behavior that is required by U.S. laws or by corporate policies. We are subject to the risk that we, our U.S. employees or our employees located in other jurisdictions or any third parties such as our sales agencies and distributors that we engage to do work on our behalf in foreign countries may take action determined to be in violation of anti-corruption laws in any jurisdiction in which we conduct business, including the FCPA and the Bribery Act of 2010, or the U.K. Anti-Bribery Act. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made.

As a substantial portion of our revenue is, and we expect will continue to be, from jurisdictions outside of the United States, we face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. Although we have implemented a company policy requiring our employees and consultants to comply with the FCPA and similar laws, such policy may not be effective at preventing all potential FCPA or other violations. Although our agreements with our international distributors clearly state our expectations for our distributors' compliance with U.S. laws, including the FCPA, and provide us with various remedies upon any non-compliance, including the ability to terminate the agreement, our distributors may not comply with U.S. laws, including the FCPA.

In addition, we operate in certain countries in which the government may take an ownership stake in an enterprise and such government ownership may not be readily apparent, thereby increasing potential anti-corruption law violations. Any violation of the FCPA and U.K. Anti-Bribery Act or any similar anti-corruption law or regulation could result in substantial fines, sanctions, civil and/or criminal penalties and curtailment of operations in certain jurisdictions and might harm our business, financial condition or results of operations. In addition, we have internal ethics policies with which we require our employees to comply in order to ensure that our business is conducted in a manner that our management deems appropriate. If these anti-corruption laws or internal policies were to be violated, our reputation and operations could also be substantially harmed. Further, detecting, investigating and resolving actual or alleged violations is expensive and can consume significant time and attention of our senior management. As a result of our focus on managing our growth, our development of infrastructure designed to identify FCPA matters and monitor compliance is at an early stage.

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

We have international operations and, as a result, an increase in the value of the U.S. dollar relative to foreign currencies could require us to reduce our selling price or risk making our products less competitive in international markets or our costs could increase. Also, if our international sales increase, we may enter into a greater number of transactions denominated in non-U.S. dollars, which could expose us to foreign currency risks, including changes in currency exchange rates. We do not currently engage in any hedging transactions. If we are unable to address these risks and challenges effectively, our international operations may not be successful and our business could be harmed.

We incur significant costs as a result of operating as a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act, as well as rules implemented by the Securities and Exchange Commission, or the SEC, and The NASDAQ Global Market, or NASDAQ. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel will devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and as a result of the new corporate governance and executive compensation related rules, regulations and guidelines prompted by the Dodd-Frank Wall Street Reform and Consumer Protection Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

As a public company, we are obligated to maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

As a public company, the Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. Our disclosure controls and other procedures have been designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Securities Exchange Act of 1934, or the Exchange Act, is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to maintain effective controls could negatively impact the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we may be required to include in our periodic reports we will file with the SEC under Section 404 of the Sarbanes-Oxley Act, harm our operating results, cause us to fail to meet our reporting obligations or result in a restatement of our prior period financial statements. In the event that we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results and the price of our common stock could decline. In addition, if we are unable to continue to meet these requirements, we may be unable to remain listed on NASDAQ.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting until the first annual report required to be filed with the SEC following the date we are no longer an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act (the "JOBS Act").

If we experience significant disruptions in our information technology systems, our business may be adversely affected.

We depend on our information technology systems for the efficient functioning of our business, including accounting, data storage, compliance, purchasing and inventory management. We do not have redundant systems at this time. While we will attempt to mitigate interruptions, we may experience difficulties in implementing some upgrades, which would impact our business operations, or experience difficulties in operating our business during the upgrade, either of which could disrupt our operations, including our ability to timely ship and track product orders, project inventory requirements, manage our supply chain and otherwise adequately service our customers. In the event we experience significant disruptions as a result of the current implementation of our information technology systems, we may be unable to repair our systems in an efficient and timely manner. Accordingly, such events may disrupt or reduce the efficiency of our entire operation and have a material adverse effect on our results of operations and cash flows.

We are increasingly dependent on sophisticated information technology for our infrastructure. Our information systems require an ongoing commitment of significant resources to maintain, protect and enhance existing systems. Failure to maintain or protect our information systems and data integrity effectively could have a materially adverse effect on our business. For example, third parties may attempt to hack into our systems and obtain proprietary information.

The Company's information technology systems, some of which are dependent on services provided by third parties, serve an important role in the operation of the business. These systems could be damaged or cease to function properly due to any number of causes, such as catastrophic events, power outages, security breaches, computer viruses or cyber-based attacks. The Company has contingency plans in place to prevent or mitigate the impact of these events, however, if they are not effective on a timely basis, business interruptions could occur which may adversely impact results of operations.

Increased cyber-security threats also pose a potential risk to the security of the Company's information technology systems, as well as the confidentiality, integrity and availability of data stored on these systems. Any breach could result in disclosure or misuse of confidential or proprietary information, including sensitive customer, vendor, employee or financial information. Such events could cause damage to the Company's reputation and result in significant recovery or remediation costs, which may adversely impact results of operations.

We may be subject to various litigation claims and legal proceedings.

We, as well as certain of our officers and distributors, may be subject to other claims or lawsuits. Regardless of the outcome, these lawsuits may result in significant legal fees and expenses and could divert management's time and other resources. If the claims contained in these lawsuits are successfully asserted against us, we could be liable for damages and be required to alter or cease certain of our business practices or product lines.

If product liability lawsuits are brought against us, our business may be harmed, and 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, manufacture and sale of medical devices for orthopedic surgery procedures. These surgeries involve significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. Furthermore, if orthopedic surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients.

We have had, and continue to have, a small number of product liability claims relating to our products, and in the future, we may be subject to additional product liability claims.

Regardless of the merit or eventual outcome, product liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- significant litigation costs;
- substantial monetary awards to or costly settlements with patients;
- product recalls;
- material defense costs;
- loss of revenue;
- the inability to commercialize new products or product candidates; and

- diversion of management attention from pursuing our business strategy.

Our existing product liability insurance coverage may be inadequate to protect us from any liabilities we might incur. If a product liability claim or series of claims is brought against us for uninsured liabilities or in excess of our insurance coverage, our business could suffer. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates or the inability to secure coverage in the future. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers. In addition, we may be unable to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. Any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources and adversely affect or eliminate the prospects for commercialization or sales of a product or product candidate that is the subject of any such claim.

Our operations are vulnerable to interruption or loss due to natural or other disasters, power loss, strikes and other events beyond our control.

A major earthquake, fire or other disaster (such as a major flood, tsunami, volcanic eruption or terrorist attack) affecting our facilities, or those of our suppliers, could significantly disrupt our operations, and delay or prevent product shipment or installation during the time required to repair, rebuild or replace our suppliers' damaged manufacturing facilities; these delays could be lengthy and costly. If any of our customers' facilities are negatively impacted by a disaster, shipments of our products could be delayed. Additionally, customers may delay purchases of our products until operations return to normal. Even if we are able to quickly respond to a disaster, the ongoing effects of the disaster could create some uncertainty in the operations of our business. In addition, our facilities may be subject to a shortage of available electrical power and other energy supplies. Any shortages may increase our costs for power and energy supplies or could result in blackouts, which could disrupt the operations of our affected facilities and harm our business. In addition, concerns about terrorism, the effects of a terrorist attack, political turmoil or an outbreak of epidemic diseases could have a negative effect on our operations, those of our suppliers and customers and the ability to travel.

Risks Related to Regulatory Matters

Our products and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

We and our products are subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; marketing, sales and distribution; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces these regulatory requirements through periodic unannounced inspections. We do not know whether we will pass any future FDA inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: warning letters; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of current clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties.

We may not receive the necessary clearances or approvals for our future products, and failure to timely obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

An element of our strategy is to continue to upgrade our products, add new features and expand clearance or approval of our current products to new indications. In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive

either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act, or the FDCA, or approval of a premarket approval application, or PMA, from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. 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 are sometimes required to support substantial equivalence. In the PMA process, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device, which may limit the market for the device.

In the United States, we have obtained 510(k) premarket clearance from the FDA to market each of our products requiring such clearance. Any modifications to these existing products may require new 510(k) clearance; however, future modifications may be subject to the substantially more costly, time-consuming and uncertain PMA process. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could cause our sales to decline.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: we may be unable to demonstrate to the FDA's satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use; the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required; and the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510(k) clearance process, the FDA initiated an evaluation, and in January 2011, announced several proposed actions intended to reform the 510(k) clearance process. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. In addition, as part of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, 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. Some of these proposals and reforms could impose additional regulatory requirements upon us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances.

In order to sell our products in member countries of the EEA our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the CE Mark to our products, without which they cannot be sold

or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue an EC Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a Member State of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE Mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE Mark to our surgical systems, which would prevent us from selling them within the EEA.

We or our distributors will also need to obtain regulatory approval in other foreign jurisdictions in which we plan to market and sell our products.

Modifications to our products may require new 510(k) clearances or PMA approvals, and may require us to cease marketing or recall the modified products until clearances are obtained.

Any modification to a 510(k)-cleared product 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, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have made modifications to our products in the past and have determined based on our review of the applicable FDA regulations and guidance that in certain instances new 510(k) clearances were not required. We may make similar modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMAs for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. In addition, the FDA may not approve or clear our products for the indications that are necessary or desirable for successful commercialization or could require clinical trials to support any modifications. Any delay or failure in obtaining required clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Furthermore, the FDA's ongoing review of the 510(k) clearance process may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a new 510(k) notification for a modification to a previously cleared product must be submitted, or applying more onerous review criteria to such submissions. For example, the FDA is currently reviewing its guidance describing when it believes a manufacturer is obligated to submit a new 510(k) for modifications or changes to a previously cleared device. The FDA is expected to issue revised guidance, originally issued in 1997, to assist device manufacturers in making this determination. It is unclear whether the FDA's approach in this new guidance will result in substantive changes to existing policy and practice regarding the assessment of whether a new 510(k) is required for changes or modifications to existing devices. The FDA continues to review its 510(k) clearance process, which could result in additional changes to regulatory requirements or guidance documents, which could increase the costs of compliance or restrict our ability to maintain current clearances.

Our products must be manufactured in accordance with federal and state regulations, and we could be forced to recall our installed systems or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our products must comply with the FDA's Quality System Regulation, or QSR, which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals or clearances; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us or our employees.

Any of these actions could significantly and negatively impact supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and suffer reduced revenue and increased costs.

If treatment guidelines for the orthopedic conditions we are targeting change or the standard of care evolves, we may need to redesign and seek new marketing authorization from the FDA for one or more of our products.

If treatment guidelines for the orthopedic conditions we are targeting or the standard of care for such conditions evolves, we may need to redesign the applicable product and seek new clearances or approvals from the FDA. Our 510(k) clearances from the FDA are based on current treatment guidelines. If treatment guidelines change so that different treatments become desirable, the clinical utility of one or more of our products could be diminished and our business could suffer.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Our products have been cleared by the FDA for specific indications. We train our marketing personnel and independent sales agencies and distributors to not promote our products for uses outside of the FDA-cleared indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those cleared by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

Our products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance, seizure of our products or delay in clearance of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. We have in the past conducted several voluntary recalls of devices with lot-specific quality issues. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new approvals or clearances for the device before we may market or distribute the corrected device. Seeking such approvals or clearances may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales.

If we or our distributors do not obtain and maintain international regulatory registrations or approvals for our products, we will be unable to market and sell our products outside of the United States.

Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we or our distributors obtain the approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or approvals, can be expensive and time-consuming, and we or our distributors may not receive regulatory approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or approvals, if required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we or our distributors may need to apply for additional regulatory approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we or our distributors have received. If we or our distributors are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory clearance or approval by the FDA does not ensure clearance or approval by regulatory authorities in other countries, and clearance or approval by one or more foreign regulatory authorities does not ensure clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

In September 2012, the European Commission published proposals for the revision of the EU regulatory framework for medical devices. The proposal would replace the EU Medical Devices Directive and the Active Implantable Medical Devices Directive with a new regulation, the Medical Devices Regulation. Unlike the Directives that must be implemented into national laws, the Regulation would be directly applicable in all EEA Member States and so is intended to eliminate current national differences in regulation of medical devices.

In October 2013, the European Parliament approved a package of reforms to the European Commission's proposals. Under the revised proposals, only designated "special notified bodies" would be entitled to conduct conformity assessments of high-risk devices. These special notified bodies will need to notify the European Commission when they receive an application for a conformity assessment for a new high-risk device. The European Commission will then forward the notification and the accompanying documents on the device to the Medical Devices Coordination Group, or MDCG (a new, yet to be created body chaired by the European Commission and representatives of certain European states), for an opinion. These new procedures may result in a longer or more burdensome assessment of our new products.

The Medical Devices Regulation, or MDR, entered into force in May 2017 and will become applicable in 2020. The MDR imposes additional reporting requirements on manufacturers of high-risk medical devices, imposes an obligation on manufacturers to appoint a "qualified person" responsible for regulatory compliance and provides for more strict clinical evidence requirements.

We are subject to certain federal, state and foreign fraud and abuse laws, health information privacy and security laws and transparency laws, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

There are numerous U.S. federal and state, as well as foreign, laws pertaining to healthcare fraud and abuse, including anti-kickback, false claims and physician transparency laws. Our business practices and relationships with providers and hospitals are subject to scrutiny under these laws. We may also be subject to patient information privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either the referral of an individual or furnishing or arranging for a good or service, for which payment may be made, in whole or in part, under federal healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from a

violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Violations of the federal Anti-Kickback Statute may result in substantial civil or criminal penalties, civil penalties under the Civil Monetary Penalties Law, civil penalties under the federal False Claims Act and exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal civil and criminal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal healthcare programs that are false or fraudulent. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil penalties, including treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other things, executing a scheme to defraud any healthcare benefit program and making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- the federal Physician Sunshine Act under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, or CHIP, to report annually to the DHHS Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians, which is defined broadly to include other healthcare providers and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by physicians and their immediate family members. Manufacturers are required to submit annual reports to CMS and failure to do so may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws or regulations;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements. Failure to comply with the HIPAA privacy and security standards can result in civil monetary penalties, and, in certain circumstances, criminal penalties. State attorneys general can also bring a civil action to enjoin a HIPAA violation or to obtain statutory damages on behalf of residents of his or her state; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians

and other healthcare providers or marketing expenditures; state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. We have a variety of arrangements with our customers that could implicate these laws, including, among others, our consignment arrangements and our practice of loaning instrument sets to customers at no additional cost. We have also entered into consulting agreements and royalty agreements with physicians, including some who have ownership interests in us and/or influence the ordering of or use our products in procedures they perform. Compensation under some of these arrangements includes the provision of stock or stock options. We could be adversely affected if regulatory agencies determine our financial relationships with such physicians to be in violation of applicable laws. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to.

If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, could harm our cash flows, financial condition and results of operations.

In March 2010, the Affordable Care Act was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Among other ways in which it may impact our business, the Affordable Care Act:

- imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, with limited exceptions (described in more detail below), although the effective rate paid may be lower. Under the Consolidated Appropriations Act, 2016, the excise tax has been suspended from January 1, 2016 to December 31, 2019, and, absent further legislative action, will be reinstated starting January 1, 2020;

- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;

- implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and

- expanded the eligibility criteria for Medicaid programs.

We do not yet know the full impact that the Affordable Care Act will have on our business. The Trump Administration and the U.S. Congress may take further action regarding the Affordable Care Act, including, but

not limited to, repeal or replacement. Additionally, all or a portion of the Affordable Care Act and related subsequent legislation may be modified, repealed or otherwise invalidated through judicial challenge, which could result in lower numbers of insured individuals, reduced coverage for insured individuals and adversely affect our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit reimbursement for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Our business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which may be expensive and restrict how we do business.

Our third-party manufacturers' activities may involve the controlled storage, use and disposal of hazardous materials. Our manufacturers are subject to federal, state, local and foreign laws and regulations governing the use, generation, manufacture, storage, handling and disposal of these hazardous materials. We currently carry no insurance specifically covering environmental claims relating to the use of hazardous materials, but we do reserve funds to address these claims at both the federal and state levels. Although we believe the safety procedures of our manufacturers for handling and disposing of these materials and waste products comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental injury or contamination from the use, storage, handling or disposal of hazardous materials. In the event of an accident, state or federal or other applicable authorities may curtail our use of these materials and interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages and fines, which could be substantial.

Risks Related to Our Reliance on Third Parties

We rely on a network of third-party independent sales agencies and distributors to market and distribute our products, and if we are unable to maintain and expand this network, we may be unable to generate anticipated sales.

We rely on our network of independent sales agencies and distributors to market and distribute our products in both the United States and international markets.

In the United States, our products are primarily sold by a network of 33 independent sales agencies. We may not be successful in maintaining strong relationships with our independent sales agencies. In addition, our independent sales agencies are not required to sell our products on an exclusive basis and also are not required to purchase any minimum quantity of our products. The failure of our network of independent sales agencies to generate U.S. sales of our products and promote our brand effectively would impair our business and results of operations.

We also sell our products in international markets, primarily through a network of 35 independent distributors and five independent sales agencies. We sell our products in 39 countries outside of the United States, and we expect a significant amount of our revenue to come from international sales for the foreseeable future. In the past, we have experienced issues collecting payments from certain of our independent distributors and we may again experience such issues in the future.

We face significant challenges and risks in managing our geographically dispersed distribution network and retaining the individuals who make up that network. We cannot control the efforts and resources our third-party sales agencies and distributors will devote to marketing our products. Our sales agencies and distributors may be

unable to successfully market and sell our products and may not devote sufficient time and resources to support the marketing and selling efforts that enable the products to develop, achieve or sustain market acceptance in their respective jurisdictions. Additionally, in some international jurisdictions, we rely on our distributors to manage the regulatory process, while complying with all applicable rules and regulations, and we are dependent on their ability to do so effectively. If we are unable to attract additional international distributors, our international revenue may not grow.

If any of our independent sales agencies or distributors were to cease to do business with us, our sales could be adversely affected. Some of our independent sales agencies and distributors have historically accounted for a material portion of our sales volume. Sales to two of our independent sales agencies accounted for 12.1% and 11.2%, respectively, of our revenue in 2018. Sales to two of our independent sales agencies accounted for 10.1% and 10.1%, respectively, of our revenue in 2017. Sales to two of our independent sales agencies accounted for 10.7% and 10.1%, respectively, of our revenue in 2016. If any such agency or distributor were to cease to sell and market our products, our sales could be adversely affected. In addition, if a dispute arises with a sales agency or distributor or if a sales agency or distributor is terminated by us or goes out of business, it may take time to locate an alternative sales agency or distributor, to seek appropriate regulatory approvals and to train new personnel to market our products, and our ability to sell those systems in the region formerly serviced by such terminated agent or distributor could be harmed. Any of our sales agencies or distributors could become insolvent or otherwise become unable to pay amounts owed to us when due. Any of these factors could reduce our revenue from affected markets, increase our costs in those markets or damage our reputation. If an independent sales agency or distributor were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales.

In any such situation in which we lose the services of an independent sales agency or distributor, we may need to seek alternative sales agencies or distributors, and our sales may be adversely affected. Because of the intense competition for their services, we may be unable to recruit or retain additional qualified independent sales agencies or distributors to work with us. We may be unable to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified independent sales agencies or distributors would prevent us from expanding our business and generating sales.

As a result of our reliance on third-party sales agencies and distributors, we may be subject to disruptions and increased costs due to factors beyond our control, including labor strikes, third-party error and other issues. If the services of any of these third-party sales agencies or distributors become unsatisfactory, including the failure of such sales agencies or distributors to properly train orthopedic surgeons in the utilization of our products, we may experience delays in meeting our customers' product demands and we may be unable to find a suitable replacement on a timely basis or on commercially reasonable terms. Any failure to deliver products in a timely manner may damage our reputation and could cause us to lose current or potential customers.

We rely on third-party contract manufacturers to assemble our products, and a loss or degradation in performance of these contract manufacturers could have a material adverse effect on our business and financial condition.

We rely on a small number of third-party contract manufacturers in the United States to assemble our products. If any of these contract manufacturers fails to adequately perform, our revenue and profitability could be adversely affected. Inadequate performance could include, among other things, the production of products that do not meet our quality standards, which could cause us to seek additional sources of manufacturing. Additionally, our contract manufacturers may decide in the future to discontinue or reduce the level of business they conduct with us. If we are required to change contract manufacturers due to any termination of our relationships with our contract manufacturers, we may lose revenue, experience manufacturing delays, incur increased costs or otherwise suffer impairment to our customer relationships. We cannot guarantee that we will be able to establish alternative manufacturing relationships on similar terms or without delay. Furthermore, our contract manufacturers could require us to move to another one of their production facilities. This could disrupt our ability to fulfill orders during a transition and impact our ability to utilize our current supply chain. In addition, we currently use Structure Medical, LLC, a Squadron-affiliated entity, as a supplier for components of our products.

Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our products to our customers and for tracking of these shipments. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our products and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery services we use would adversely affect our ability to process orders for our products on a timely basis.

We rely on a limited number of third-party suppliers for the majority of our products and may be unable to find replacements or immediately transition to alternative suppliers.

We rely on several suppliers for the majority of our products, with whom we do not have long-term supply contracts. These suppliers may be unwilling or unable to supply these products to us reliably and at the prices and levels we anticipate or are required by the market. For us to be successful, our suppliers must be able to provide us with products in substantial quantities, in compliance with regulatory requirements, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. An interruption in our commercial operations could occur if we encounter delays or difficulties in securing these products, and if we cannot obtain an acceptable substitute. If we are required to transition to new third-party suppliers for certain products, the use of products furnished by these alternative suppliers could require us to alter our operations.

Furthermore, if we are required to change the manufacturer of our products, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of those products. If the change in manufacturer results in a significant change to any product, a new 510(k) clearance from the FDA or similar international regulatory authorization may be necessary before we implement the change, which could cause substantial delays. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely or cost-effective manner.

Risks Related to Intellectual Property

If we are unable to adequately protect our intellectual property rights, or if we are accused of infringing on the intellectual property rights of others, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

Our commercial success will depend in part on our success in obtaining and maintaining issued patents and other intellectual property rights in the United States and elsewhere and protecting our proprietary technology. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We own numerous issued patents and pending patent applications that relate to our platform technology. As of December 31, 2018, we owned 12 issued U.S. patents and 14 issued foreign patents and we had 19 pending U.S. patent applications and 16 pending foreign patent applications. Assuming all required fees continue to be paid, issued U.S. patents owned by us will expire between 2024 and 2035.

We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our products, any additional features we develop for our products or any new products. Other parties may have developed technologies that may be related or competitive to our platform, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications, either by claiming the same methods or devices or by claiming subject matter that could dominate our patent position. The patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with

certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated or circumvented. Proceedings challenging our patents could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such proceedings may be costly. Thus, any patents that we may own may not provide any protection against competitors. Furthermore, an adverse decision in a derivation proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to commercialize our products.

Furthermore, though an issued patent is presumed valid and enforceable, its issuance is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods. We may be unable to prevent the unauthorized disclosure or use of our technical knowledge or trade secrets by consultants, suppliers, vendors, former employees and current employees. The laws of some foreign countries do not protect our proprietary rights to the same extent as the laws of the United States, and we may encounter significant problems in protecting our proprietary rights in these countries.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components that are used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

In addition, proceedings to enforce or defend our patents could put our patents at risk of being invalidated, held unenforceable or interpreted narrowly. Such proceedings could also provoke third parties to assert claims against us, including that some or all of the claims in one or more of our patents are invalid or otherwise unenforceable. If any of our patents covering our products are invalidated or found unenforceable, or if a court found that valid, enforceable patents held by third parties covered one or more of our products, our competitive position could be harmed or we could be required to incur significant expenses to enforce or defend our rights.

The degree of future protection for our proprietary rights is uncertain, and we cannot ensure that:

- any of our patents, or any of our pending patent applications, if issued, will include claims having a scope sufficient to protect our products;
- any of our pending patent applications may issue as patents;
- we will be able to successfully commercialize our products on a substantial scale, if approved, before our relevant patents we may have expire;
- we were the first to make the inventions covered by each of our patents and pending patent applications;
- we were the first to file patent applications for these inventions;
- others will not develop similar or alternative technologies that do not infringe our patents;
- any of our patents will be found to ultimately be valid and enforceable;
- any patents issued to us will provide a basis for an exclusive market for our commercially viable products, will provide us with any competitive advantages or will not be challenged by third parties;
- we will develop additional proprietary technologies or products that are separately patentable; or
- our commercial activities or products will not infringe upon the patents of others.

We rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants. We also have agreements with our employees and selected consultants that obligate them to assign their inventions to us and have non-compete agreements with some, but

not all, of our consultants. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants who are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products or impact our stock price.

Our commercial success will depend in part on not infringing the patents or violating the other proprietary rights of others. Significant litigation and administrative proceedings regarding patent rights occur in our industry. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of patents issued to third parties. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived, so there may be applications of others now pending or recently revived patents of which we are unaware. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products. Third parties may, in the future, assert claims that we are employing their proprietary technology without authorization, including claims from competitors or from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may have no deterrent effect. As we continue to commercialize our products in their current or updated forms, launch new products and enter new markets, we expect competitors may claim that one or more of our products infringe their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. The large number of patents, the rapid filing rate of new patent applications and issuances, the complexities of the technology involved, and the uncertainty of litigation and administrative proceedings may increase the risk of business resources and management's attention being diverted to patent administration and litigation. We have, and we may in the future, receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents. See "Item 3. — Legal Proceedings."

Moreover, we may become party to future adversarial proceedings regarding our patent portfolio or the patents of third parties. Such proceedings could include supplemental examination or contested post-grant proceedings such as review, reexamination, interference or derivation proceedings before the U.S. Patent and Trademark Office and challenges in U.S. District Court or before the U.S. International Trade Commission. Patents may be subjected to opposition, post-grant review or comparable proceedings lodged in various foreign, both national and regional, patent offices. The legal threshold for initiating litigation or contested proceedings may be low, so that even lawsuits or proceedings with a low probability of success might be initiated. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can.

Any lawsuits resulting from such allegations could subject us to significant liability for damages and invalidate our proprietary rights. Any potential intellectual property litigation also could force us to do one or more of the following:

- stop making, selling, importing or using products or technologies that allegedly infringe the asserted intellectual property;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property rights against others; incur significant legal expenses;
- pay substantial damages or royalties to the party whose intellectual property rights we may be found to be infringing;
- pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be infringing;

- redesign those products that contain the allegedly infringing intellectual property, which could be costly, disruptive or infeasible; and

- attempt to obtain a license to the relevant intellectual property from third parties, which may not be available on reasonable terms or at all, or from third parties who may attempt to license rights that they do not have.

Any litigation or 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 we are found to infringe the intellectual property rights of third parties, we could be required to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties and could be prevented from selling our products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. We could encounter delays in product introductions while we attempt to develop alternative methods or products. 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.

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

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position could be harmed.

In addition to patent protection, we also rely upon copyright and trade secret protection, as well as non-disclosure agreements and invention assignment agreements with our employees, consultants and third parties, to protect our confidential and proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive and time-consuming, and the outcome is unpredictable. Even though we use commonly accepted security measures, trade secret violations are often a matter of state law, and the criteria for protection of trade secrets can vary among different jurisdictions. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our business and competitive position could be harmed.

We may be unable to enforce our intellectual property rights throughout the world.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. This could make it difficult for us to stop infringement of our foreign patents, if obtained, or the misappropriation of our other intellectual property rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming

process with uncertain outcomes. Patent protection available in one country may not be available in other countries. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of our intellectual property.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. In addition, we may face claims by third parties that our agreements with employees, contractors or consultants obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, in addition to paying monetary damages or a settlement payment, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Recent changes in U.S. patent laws may limit our ability to obtain, defend and/or enforce our patents.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith America Invents Act, or the Leahy-Smith Act, includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and also affect patent litigation. The U.S. Patent and Trademark Office recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, which became effective on March 16, 2013. The first to file provisions limit the rights of an inventor to patent an invention if not the first to file an application for patenting that invention, even if such invention was the first invention. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business.

However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the enforcement and defense of our issued patents. For example, the Leahy-Smith Act provides that an administrative tribunal known as the Patent Trial and Appeals Board, or PTAB, provides a venue for challenging the validity of patents at a cost that may be lower than district court litigation and on timelines that are much faster. Although it is not clear what, if any, long-term impact the PTAB proceedings will have on the operation of our business, the initial results of patent challenge proceedings before the PTAB since its inception in 2013 have resulted in the invalidation of many U.S. patent claims. The availability of the PTAB as a lower-cost, faster and potentially more potent tribunal for challenging patents could increase the likelihood that our own patents will be challenged, thereby increasing the uncertainties and costs of maintaining and enforcing them.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile.

Our stock price has been and is likely to continue to be volatile. The stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their shares of our common stock at or above the price at which they purchased their shares. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- commercial success and market acceptance of our products;
- success of our competitors in developing or commercializing products;
- ability to commercialize or obtain regulatory approvals for our products, or delays in commercializing or obtaining regulatory approvals;
- strategic transactions undertaken by us;
- additions or departures of key personnel;
- product liability claims;
- prevailing economic conditions;
- disputes concerning our intellectual property or other proprietary rights;
- FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry;
- healthcare reform measures in the United States;
- sales of our common stock by our officers, directors or significant stockholders;
- future sales or issuances of equity or debt securities by us;
- business disruptions caused by earthquakes, fires or other natural disasters; and
- issuance of new or changed securities analysts' reports or recommendations regarding us.

In addition, the stock markets in general, and the markets for companies like ours in particular, have from time to time experienced extreme volatility that have has been often unrelated to the operating performance of the issuer. A certain degree of stock price volatility can be attributed to being a newly public company. These broad market and industry fluctuations may negatively impact the price or liquidity of our common stock, regardless of our operating performance.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

The market price of our securities may be volatile, and in the past companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns.

We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to us could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. We may remain an emerging growth company until as late as December 31, 2022, though we may cease to be an emerging growth company earlier under certain circumstances, including (i) if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30, in which case we would cease to be an emerging growth company as of the following December 31, or (ii) if our gross revenue exceeds $1.07 billion in any fiscal year. "Emerging growth companies" may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. Investors could find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, Section 102 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, or the Securities Act, for complying with new or revised accounting standards. An emerging growth company can therefore delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen to "opt out" of such extended transition period, and as a result, we comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

We are also a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended. As a result, many of the same exemptions from reporting requirements available to us as an emerging growth company are also available to us as a smaller reporting company, including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation. To the extent that we continue to qualify as a smaller reporting company, after we cease to qualify as an emerging growth company, those exemptions may continue to be available to us. Some investors may find our common stock less attractive because we rely on these exemptions, there may be a less active trading market for our common stock and our stock price may be more volatile.

Future sales of our common stock may cause our stock price to decline.

Sales of a substantial number of shares of our common stock in the public market could occur at any time, subject to certain restrictions described below. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have a total of 14,538,202 outstanding shares of common stock, all of which may be resold in the public market immediately without restriction, other than shares owned by our affiliates, which may be sold pursuant to Rule 144 under the Securities Act, subject to the conditions of Rule 144 including volume limitations. However, the resale of an aggregate of 5,986,054 shares have been restricted until March 8, 2019, as a result of lock-up agreements executed by our directors, certain of our executive officers and certain other shareholders in conjunction with our December 2018 secondary offering. The underwriters who are party to the lock-up agreements may, however, in their sole discretion, permit the stockholders who are subject to the lock-up agreements to sell shares prior to the expiration of the lock-up period. In addition, holders of an aggregate of approximately 5,382,619 shares of our common stock will have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have registered all shares of common stock that we may issue under our equity compensation plans on a Registration Statement on Form S-8. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above.

If there is no viable public market for our common stock, you may be unable to sell your shares.

Although our common stock is listed on NASDAQ, an active trading market for our shares may not be sustained. You may be unable to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common

stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

Our operating results for a particular period may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to fluctuations. Our operating results will be affected by numerous factors, including: variations in the level of expenses related to our products or future development programs; level of underlying demand for our products; addition or termination of clinical trials; our execution of any collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved; and regulatory developments affecting our products or our competitors.

If our operating results for a particular period fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe comparisons of our financial results from various reporting periods are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert control over matters subject to stockholder approval.

Based on the beneficial ownership of our common stock as of December 31, 2018, our officers and directors, together with holders of 5% or more of our outstanding common stock and their respective affiliates, beneficially own approximately 45.3% of our outstanding common stock. Accordingly, these stockholders will continue to have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could attempt to delay or prevent a change in control of the company, even if such a change in control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of the company or our assets and might affect the prevailing price of our common stock. The significant concentration of stock ownership may negatively impact the price of our common stock due to investors' perception that conflicts of interest may exist or arise. In addition, Squadron currently has the right to designate four members of our board of directors.

Provisions of our charter documents or Delaware law could delay or prevent an acquisition of the company, even if the acquisition would be beneficial to our stockholders, which could make it more difficult for you to change management.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. In addition, these provisions may frustrate or prevent any attempt by our stockholders to replace or remove our current management by making it more difficult to replace or remove our board of directors. These provisions include:

- a classified board of directors so that not all directors are elected at one time;
- a prohibition on stockholder action through written consent;
- no cumulative voting in the election of directors;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director;

- a requirement that special meetings of stockholders be called only by the board of directors, the chairman of the board of directors, the chief executive officer or, in the absence of a chief executive officer, the president;

- an advance notice requirement for stockholder proposals and nominations;

- the authority of our board of directors to issue preferred stock with such terms as our board of directors may determine; and

- a requirement of approval of not less than 66 2⁄3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our amended and restated certificate of incorporation.

In addition, Delaware law prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person who, together with its affiliates, owns, or within the last three years has owned, 15% or more of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Accordingly, Delaware law may discourage, delay or prevent a change in control of our company.

Provisions in our charter documents and other provisions of Delaware law could limit the price that investors are willing to pay in the future for shares of our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

We do not anticipate paying any cash dividends on our common stock in the foreseeable future; therefore, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We have never declared or paid any cash dividends on our common stock and do not intend to do so in the foreseeable future. We currently intend to retain all available funds and any future earnings to finance the growth and development of our business. In addition, the Loan Agreement contains, and the terms of any future credit agreements we enter into may contain, terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If no securities or industry analysts maintain coverage of the company, the price for our common stock could be negatively impacted. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our stock price could decline. In addition, if our operating results fail to meet the forecast of analysts, our stock price could decline. If one or more of these analysts cease coverage of the company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our stock price and trading volume to decline.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We own and occupy approximately 22,000 square feet of office space in Warsaw, Indiana, following an expansion of our existing warehouse facilities in 2018. We believe our current facilities are suitable and adequate to meet our current needs. We may add new facilities or expand existing facilities as we add employees, and we believe suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we are involved in various legal proceedings arising in the ordinary course of our business. On January 20, 2017, K2M, Inc. filed suit against us in the United States District Court for the District of Delaware (*K2M, Inc. v. OrthoPediatrics Corp. et al.*, Case No. 1:17-cv-0061) seeking unspecified damages for alleged infringement of U.S. Patent No. 9,532,816. The complaint was amended on August 21, 2017 to add, among other things, a claim of patent infringement regarding U.S. Patent No. 9,655,664. These patents relate to certain instruments used in our RESPONSE™ spine systems, which represent a portion of our total scoliosis portfolio. We have denied these claims and responded with counterclaims seeking declaratory relief that the patents in question are both invalid and not infringed. The parties attended a court-ordered mediation on October 24, 2017, which did not resolve the dispute, but as we move forward with this matter we welcome constructive discussions on a negotiated settlement. Nevertheless, we view our case as particularly strong and will continue to vigorously defend this matter. On January 8 and 22, 2018, we filed our first and second petitions for *inter partes review* ("IPR") with the United States Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") to challenge the patentability of U.S. Patent No. 9,532,816 (OrthoPediatrics Corp., v. K2M, Inc., *Inter Partes* Case No. IPR2018-00429 and IPR2018-00521). On June 28, 2018, the PTAB instituted the subject IPRs and set a trial date of February 20, 2019 for both IPRs. Due to inclement weather, the subject February 20 hearing was postponed and took place on February 21, 2019. To date, PTAB has not rendered a decision concerning the subject IPRs. Additionally, the parties have agreed to stay the above-referenced district court proceedings pending the outcome of the subject IPR proceedings. The Court ordered the stay on July 10, 2018. Moreover, on August 21, 2018, we filed three petitions with PTAB to challenge the patentability of the above-referenced U.S. Patent No. 9,655,664 (OrthoPediatrics Corp., v. K2M, Inc., Inter Partes Case Nos. IPR2018-01546, IPR2018-01547, and IPR2018-01548). On February 14 and 22, 2019, PTAB declined to initiate IPR Case Nos. IPR2018-01546 and IPR2018-01547, respectively. Although we believe that the K2M lawsuit is without merit and will vigorously defend the claims asserted against us, intellectual property litigation can involve complex factual and legal questions, and an adverse resolution of this proceeding could have a material adverse effect on our business, operating results and financial condition. See “Risk Factors — Risks Related to Intellectual Property — Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend significant time and money and could prevent us from selling our products or impact our stock price.”

We are not presently a party to any other legal proceedings the outcome of which, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, operating results or financial condition.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

SUPPLEMENTAL INFORMATION - EXECUTIVE OFFICERS OF THE REGISTRANT

The names, ages, and positions with the Company of all executive officers of the Company and all persons chosen to become executive officers are listed below. The officers are elected by the Board of Directors of the Company for a term of one year or until the election of their successors. There are no arrangements between any officer and any other person pursuant to which he or she was selected as an officer.

Name	Age	Position
Executive Officers		
Mark C. Throdahl	67	President, Chief Executive Officer and Director
Fred L. Hite	51	Chief Financial Officer and Director
David R. Bailey	39	Executive Vice President
Gregory A. Odle	49	Executive Vice President
Daniel J. Gerritzen	49	General Counsel and Secretary

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

MARKET INFORMATION

Our common stock has been listed on the NASDAQ Global Market under the symbol "KIDS" since October 12, 2017. Prior to that date, there was no established public trading market for our common stock.

DIVIDEND POLICY

We have not declared or paid any cash dividends on our common stock. We have no present intention to pay dividends in the foreseeable future, but rather intend to retain all of our consolidated earnings to finance future growth. Any future determination to pay dividends will be made at the discretion of our Board of Directors. See the "CAPITAL" section of "Management's Discussion & Analysis of Financial Condition and Results of Operations" included as Item 7 of this Annual Report on Form 10-K and Note 9 of the Notes to Consolidated Financial Statements included as Item 8 of this Annual Report on Form 10-K for a discussion regarding dividend restrictions.

HOLDERS OF RECORD

At the close of business on March 6, 2019, the number of shares outstanding was 14,677,200. There were 216 stockholders of record on that date.

PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

There were no equity securities purchased by the issuer or any affiliated purchaser for the three months ended December 31, 2018.

RECENT SALES OF UNREGISTERED SECURITIES

We have not sold any unregistered securities since our October 12, 2017 initial public offering.

USE OF PROCEEDS

On October 11, 2017, our Registration Statement on Form S-1 (File No. 333-212076) relating to our initial public offering of our common stock, or our IPO, was declared effective by the SEC. Pursuant to our IPO, we issued and sold 4.6 million shares of common stock at a public offering price of $13.00 per share for aggregate gross proceeds of $59.8 million. We received approximately $46.9 million in net proceeds after deducting $4.2 million of underwriting discounts and commissions, paying approximately $2.7 million of offering costs and paying approximately $6.0 million of Series B dividends.

As of December 31, 2018, the majority of the net proceeds have been used primarily to purchase implant and instrument sets for consignment to our customers, to fund research and development activities, to expand our sales and marketing programs and for working capital and other general corporate purposes. There has been no material change in the planned use of the remaining net proceeds from our IPO as described in our final prospectus filed with the SEC, on October 12, 2017, pursuant to Rule 424(b)(4) under the Securities Act.

EQUITY COMPENSATION PLAN INFORMATION

The following table provides information about the Company's common stock that may be issued under equity compensation plans as of December 31, 2018.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercised price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensations plans (excluding securities reflected in first column)
Equity compensation plans approved by stockholders	296,177	$24.85	1,108,999
			1,108,999
Total	296,177	$24.85	

ITEM 6. SELECTED FINANCIAL DATA

The following selected financial data has been derived from our audited consolidated financial statements.

(In Thousands, Except Share Data)	2018	2017	2016	2015
Operations				
Net revenue	$ 57,559	$ 45,620	$ 37,298	$ 31,004
Cost of revenue	14,879	11,170	10,931	9,367
Gross profit	42,680	34,450	26,367	21,637
Operating loss [1] [3]	(9,553)	(6,472)	(6,127)	(6,592)
Total other expenses	2,472	2,460	445	1,261
Net loss from continuing operations [1] [3]	(12,025)	(8,932)	(6,572)	(7,853)
Loss (gain) from discontinued operations	—	—	—	38
Net loss [1] [3]	(12,025)	(8,932)	(6,572)	(7,891)
Adjusted EBITDA [4]	$ 518	$ (58)	$ (995)	$ (3,547)
Per Share Data				
Net loss per share attributable to common stockholders - basic and diluted (2)	$ (0.96)	$ (5.86)	$ (7.14)	$ (7.27)
Balance Sheet Data				
Total assets	$ 112,105	$ 82,301	$ 30,676	$ 30,691
Total liabilities	30,373	34,806	24,682	19,376
Redeemable convertible preferred stock	—	—	71,303	65,427
Total stockholders' equity (deficit)	81,732	47,495	(65,309)	(54,112)

(1) The 2018 and 2017 results include $1,986 and $2,049 noncash accelerated restricted stock expense related to our October 2017 IPO.

(2) The 2017 Net Loss per share attributable to common stockholders - basic and diluted includes the impact of the $16,000 Series A preference payment paid in common stock partially offset by the impact of the $5,965 forfeiture of 50% of the Series B accumulated dividends related to our October 2017 IPO.

(3) The 2016 results includes $1,969 of expenses related to our aborted IPO.

(4) EBITDA is a non-GAAP financial measure which consists of net loss attributable to OrthoPediatrics Corp. before interest, other expense (income) and depreciation and amortization. Adjusted EBITDA, also a non-GAAP financial measure, is EBITDA adjusted to add back stock-based compensation expense, accelerated vesting of restricted stock upon our IPO, public company costs and initial public offering costs. Adjusted EBITDA is presented because we believe it is a useful indicator of our operating performance. Management uses the measure as a measure of the Company's operating performance and for planning purposes, including financial projections. We believe this measure is useful to investors as supplemental information because it is frequently used by analysts, investors and other interested parties to evaluate companies in our industry. We believe Adjusted EBITDA is useful to its management and investors as a measure of comparative operating performance from period to period. Adjusted EBITDA is a non-GAAP financial measure and should not be considered as an alternative to, or superior to, net income or loss as a measure of financial performance or cash flows from operations as a measure of liquidity, or any other performance measure derived in accordance with GAAP, and it should not be construed to imply that the Company's future results will be unaffected by unusual or non-recurring items. In addition, the measure is not intended to be a measure of free cash flow for management's discretionary use, as it does not reflect certain cash requirements such as debt service requirements, capital expenditures and other cash costs that may recur in the future. Adjusted EBITDA contains certain other limitations, including the failure to reflect our cash expenditures, cash requirements for working capital needs and other potential cash requirements. In evaluating Adjusted EBITDA, you should be aware that in the future the Company may incur expenses that are the same or similar to some of the adjustments in this presentation. Our presentation of Adjusted EBITDA should not be construed to imply that its future results will be unaffected by any such adjustments. Management compensates for these limitations by primarily relying on the Company's GAAP results in addition to using Adjusted EBITDA on a supplemental basis. Our definition of this measure is not necessarily comparable to other similarly titled captions of other companies due to different methods of calculation.

The schedule below contains a reconciliation of Adjusted EBITDA to Net Loss.

(In Thousands, Except Share Data)	2018	2017	2016	2015
Net Loss	$ (12,025)	$ (8,932)	$ (6,572)	$ (7,891)
Interest expense (income), net	2,255	2,490	1,476	1,230
Other expense (income)	217	(30)	(1,031)	31
Depreciation and amortization	2,892	2,405	1,902	1,854
Stock-based compensation	1,199	1,429	1,251	1,229
Accelerated vesting of restricted stock upon our IPO	1,986	2,049	—	—
Public company costs	1,365	531	—	—
Initial public offering costs	—	—	1,979	—
Non-recurring professional services fees	2,629	531	—	—
Adjusted EBITDA	$ 518	$ (58)	$ (995)	$ (3,547)

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes thereto and other financial information included 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 Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the ''Risk Factors'' section of this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are the only global medical device company focused exclusively on providing a comprehensive trauma and deformity correction, scoliosis and sports medicine product offering to the pediatric orthopedic market in order to improve the lives of children with orthopedic conditions. We design, develop and commercialize innovative orthopedic implants and instruments to meet the specialized needs of pediatric surgeons and their patients, who we believe have been largely neglected by the orthopedic industry. We currently serve three of the largest categories in this market. We estimate that the portion of this market that we currently serve represents a $2.5 billion opportunity globally, including over $1.1 billion in the United States.

We sell implants and instruments to our customers for use by pediatric orthopedic surgeons to treat orthopedic conditions in children. We provide our implants in sets that consist of a range of implant sizes and include the instruments necessary to perform the surgical procedure. In the United States and a few selected international markets, our customers typically expect us to have full sets of implants and instruments on site at each hospital but do not purchase the implants until they are used in surgery. Accordingly, we must make an up-front investment in inventory of consigned implants and instruments before we can generate revenue from a particular hospital and we maintain substantial levels of inventory at any given time.

We currently market 26 surgical systems that serve three of the largest categories within the pediatric orthopedic market: (i) trauma and deformity, (ii) scoliosis and (iii) sports medicine. We rely on a broad network of third parties to manufacture the components of our products, which we then inspect and package. We believe our innovative products promote improved surgical accuracy, increase consistency of outcomes and enhance surgeon confidence in achieving high standards of care. In the future, we expect to expand our product offering within these categories, as well as to address additional categories of the pediatric orthopedic market.

The majority of our revenue has been generated in the United States, where we sell our products through a network of 33 independent sales agencies employing more than 130 sales representatives specifically focused on pediatrics. These independent sales agents are trained by us, distribute our products and are compensated through sales-based commissions and performance bonuses. We do not sell our products through or participate in physician-owned distributorships, or PODs.

We market and sell our products internationally in 39 countries through independent stocking distributors. Our independent distributors manage the billing relationship with each hospital in their respective territories and are responsible for servicing the product needs of their surgeon customers. In 2017, we began to supplement our use of independent distributors with direct sales programs in the United Kingdom, Ireland, Australia and New Zealand. In 2018, we further expanded to sell direct in Canada. In these markets, we work through sales agencies that are paid a commission, similar to our U.S. sales model. These arrangements have generated an increase in revenue and gross margin. For the years ended December 31, 2018, 2017 and 2016, international sales accounted for approximately 24%, 23% and 23% of our revenue, respectively.

We believe there are significant opportunities for us to strengthen our position in U.S. and international markets by increasing investments in consigned implant and instrument sets, strengthening our global sales and distribution infrastructure and expanding our product offering.

We have grown our revenue from approximately $10.2 million for the year ended December 31, 2011 to $57.6 million for the year ended December 31, 2018, reflecting a growth rate each year of at least 20%. For the years

ended December 31, 2018, 2017 and 2016, our revenue was $57.6 million, $45.6 million and $37.3 million, respectively, and our net loss was $12.0 million, $8.9 million and $6.6 million, respectively. Our net loss for the year ended December 31, 2018 and 2017, included $2.0 million and $2.0 million, respectively, of non-cash accelerated vesting of restricted stock compensation expense related to our October 2017 IPO. Our net loss for the year ended December 31, 2016 included a one-time charge of $2.0 million for costs related to our planned initial public offering.

Components of our Results of Operations

Revenue

In the United States, we generate revenue primarily from the sale of our implants, and to a much lesser extent, from the sale of our instruments. We primarily consign our implants and instrument sets to independent sales agencies, who in turn deliver them to hospitals for use in procedures. We then supply these independent sales agencies with products to replace the consigned inventory as it is used in surgeries. We primarily recognize revenue when the products are used by the hospital for surgeries on a case by case basis. On rare occasions, hospitals purchase products for their own inventory, and revenue is recognized when the products are shipped and the title and risk of loss passes to the hospital customer.

Outside of the United States, we sell the majority of our products through independent stocking distributors and, more recently, through independent sales agencies. Our distributors are generally allowed to return products, and some are thinly capitalized. Based on our history of collections and returns from international distributors, we have concluded that collectability is not reasonably assured at the time of delivery. Accordingly, for sales made through distributors, we do not recognize revenue and associated cost of revenue at the time title transfers, but rather when cash has been received from the distributor in payment. Until such payment, the cost of revenue is recorded as inventory held by international distributors, net of estimated unreturnable inventory on the balance sheet.

In the case of our international sales made directly through sales agencies in the United Kingdom, Ireland, Australia, New Zealand and Canada, our sales model is similar to that for United States sales. We consign sets to hospitals, ship replacement products, bill and collect receivables. Our revenue recognition is also similar, with revenue being recognized when our products are used by the hospital for surgeries on a case by case basis.

We expect that our United States and international sales will grow in the near term across all three of our product categories as we continue to introduce new product line extensions, consign more implant and instrument sets, open new international markets and expand the number of our clinical training programs. We also expect to increase our revenue by expanding our customer base both in the United States and internationally by strengthening our global sales and distribution infrastructure.

Cost of Revenue and Gross Margin

Our cost of revenue consists primarily of products purchased from third-party suppliers, inbound freight, excess and obsolete inventory adjustments and royalties. Our implants and instruments are manufactured to our specifications by third-party suppliers. The majority of our implants and instruments are produced in the United States. We recognize cost of revenue for consigned implants at the time the implant is used in surgery and the related revenue is recognized. Prior to their use in surgery, the cost of consigned implants is recorded as inventory in our balance sheet. The costs of instruments are typically capitalized and not included in cost of revenue. We expect our cost of revenue to increase in absolute dollars due primarily to increased sales volume and changes in the geographic mix of our sales as our international operations tend to have a higher cost of revenue as a percentage of sales.

Our gross profit is calculated by subtracting our cost of revenue from revenue and is expected to increase in absolute dollars due primarily to increased sales volume and sales mix to customers based in the United States. Our gross profit as a percentage of total revenue, or gross margin, was similar across all periods presented. Our gross margin is impacted by the mix of revenue between the United States, where we earn a higher gross margin that is required to pay sales commissions, and international, where we earn a lower gross margin because the distributor is responsible for paying sales commissions.

Sales and Marketing Expenses

Our sales and marketing expenses primarily consist of commissions to our domestic and international independent sales agencies, as well as compensation, commissions, benefits and other related personnel costs. Commissions and bonuses are generally based on a percentage of sales. Our international independent distributors purchase implant and instrument sets and replenishment stock for resale, and we do not pay commissions or any other sales-related costs for international sales. We expect our sales and marketing expenses to continue to increase in absolute dollars with the commercialization of our current and pipeline products and continued investment in our global sales organization to reach new customers.

General and Administrative Expenses

Our general and administrative expenses primarily consist of compensation, benefits and other related costs for personnel employed in our executive management, administration, finance, legal, quality and regulatory, product management, warehousing, information technology and human resources departments, including stock-based compensation for all personnel, as well as facility costs. We include insurance expenses in general and administrative expenses, as well as costs related to the maintenance and protection of our intellectual property portfolio. Our general and administrative expenses also include the depreciation of our capitalized instrument sets, which represented $2.8 million, $1.9 million and $1.5 million for the years ended December 31, 2018, 2017 and 2016, respectively. We expect our general and administrative expenses to continue to increase in absolute dollars as we hire additional personnel to support the growth of our business. In addition, we expect to incur increased expenses as a result of being a public company. We expect the growth rate of our general and administrative expenses will be lower than the growth rate of our revenue.

Initial Public Offering Costs

During the year ended December 31, 2016, we incurred approximately $2.0 million of expenses associated with our initially filed registration statement on Form S-1. Our planned initial public offering was postponed for a period in excess of 90 days and, as a result, it was deemed an abandoned offering. During the year ended December 31, 2017, we incurred $1.8 million of additional costs, primarily consisting of legal, accounting and other direct fees and costs related to our initial public offering, or our IPO. These costs were initially deferred and capitalized and then reclassified to stockholders’ equity at the conclusion of our IPO on October 12, 2017. In October 2017, we also recorded $2.0 million non-cash restricted stock expense related to the accelerated vesting associated with our IPO.

In December 2018, we completed a secondary offering and incurred $0.4 million of costs primarily consisting of legal, accounting and other direct fees and costs. These costs were initially deferred and capitalized and then reclassified to stockholders' equity at the conclusion of our secondary offering on December 11, 2018. During the first four months of 2018, we also recorded an additional $2.0 million non-cash restricted stock expense related to the accelerated vesting associated with our IPO.

Research and Development Expenses

Our research and development expenses primarily consist of costs associated with engineering, product development, consulting services, outside prototyping services, outside research activities, materials and development of our intellectual property portfolio. We also include related personnel and consultants’ compensation expense. We expect research and development expenses to continue to increase both in absolute dollars and as a percentage of revenue as we continue to develop new products to expand our product offering, broaden our intellectual property portfolio and add research and development personnel.

Other Expenses

Our other expenses primarily consist of borrowing costs and expenses related to long-term debt.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

The following table sets forth our results of operations for the years ended December 31, 2018 and 2017:

(in thousands, except percentages)	2018	2017	Increase (Decrease)	% Increase (Decrease)
Net revenue	$ 57,559	$ 45,620	$ 11,939	26 %
Cost of revenue	14,879	11,170	3,709	33 %
Sales and marketing expenses	26,563	20,527	6,036	29 %
General and administrative expenses	20,938	16,972	3,966	23 %
Research and development expenses	4,732	3,423	1,309	38 %
Other expenses	2,472	2,460	12	— %
Net loss from continuing operations	$ (12,025)	$ (8,932)	$ (3,093)	35 %

Revenue

The following tables set forth our revenue by geography and product category for the years ended December 31, 2018 and 2017:

	Revenue by Geography Year Ended December 31,			
(in thousands, except percentages)	2018	% of revenue	2017	% of revenue
U.S.	$ 43,461	76%	$ 34,909	77%
International	14,098	24%	10,711	23%
Total	$ 57,559	100%	$ 45,620	100%

	Revenue by Product Category Year Ended December 31,			
(in thousands, except percentages)	2018	% of revenue	2017	% of revenue
Trauma and deformity	$ 39,695	69%	$ 32,801	72%
Scoliosis	16,662	29%	11,585	25%
Sports medicine/other	1,202	2%	1,234	3%
Total	$ 57,559	100%	$ 45,620	100%

Revenue increased $11.9 million, or 26%, from $45.6 million for the year ended December 31, 2017 to $57.6 million for the year ended December 31, 2018. The increase was due primarily to trauma and deformity sales growth of $6.9 million, or 21%, primarily driven by sales of our PediNail and PediFrag products, and scoliosis sales growth of $5.1 million, or 44%, primarily driven by sales of our RESPONSE™ and other licensed products. Nearly all of the increase in each of the trauma and deformity and scoliosis categories was due to an increase in the unit volume sold and not a result of price changes.

Cost of Revenue and Gross Margin

Cost of revenue was $14.9 million and $11.2 million for the years ended December 31, 2018 and 2017, respectively. Gross margin was 74% for the year ended December 31, 2018 and 76% for the year ended December 31, 2017. The decrease in gross margin was due primarily to an increase in cost of goods sold related to an increase in international and distributed product sales.

Sales and Marketing Expenses

Sales and marketing expenses increased $6.0 million, or 29.4%, from $20.5 million for the year ended December 31, 2017 to $26.6 million for the year ended December 31, 2018. The increase was due primarily to increased sales commission expenses, driven by the increase in unit volume sold, and marketing expenses.

General and Administrative Expenses

General and administrative expenses increased $4.0 million, or 23%, from $17.0 million for the year ended December 31, 2017 to $20.9 million for the year ended December 31, 2018. The increase was due primarily to the addition of personnel and resources to support the growth of our business, additional public company costs, and additional non-recurring legal fees. Depreciation and amortization expenses increased $0.5 million, or 20%, from $2.4 million for the year ended December 31, 2017 to $2.9 million for the year ended December 31, 2018. The increase was primarily due to increased investments in consigned surgical instrument sets and amortization on intangible licenses.

Research and Development Expenses

Research and development expenses increased $1.3 million, or 38%, from $3.4 million for the year ended December 31, 2017 to $4.7 million for the year ended December 31, 2018. The increase was due to the addition of personnel to support our product pipeline and the growth of our business.

Other Expenses

Other expenses were $2.5 million for each of the years ended December 31, 2018 and 2017. The expense in both of these periods consisted primarily of interest expense on long-term debt.

Comparison of the Years Ended December 31, 2017 and 2016

The following table sets for the our results of operations for the years ended December 31, 2017 and 2016:

(in thousands, except percentages)	2017	2016	Increase (Decrease)	% Increase (Decrease)
Net revenue	$ 45,620	$ 37,298	$ 8,322	22 %
Cost of revenue	11,170	10,931	239	2 %
Sales and marketing expenses	20,527	16,661	3,866	23 %
General and administrative expenses	16,972	11,631	5,341	46 %
Initial public offering costs	—	1,979	(1,979)	(100) %
Research and development expenses	3,423	2,223	1,200	54 %
Other expenses	2,460	445	2,015	453 %
Net loss from continuing operations	$ (8,932)	$ (6,572)	$ (2,360)	36 %

Revenue

The following tables set forth our revenue by geography and product category for the years ended December 31, 2017 and 2016:

	Revenue by Geography Year Ended December 31,			
(in thousands, except percentages)	2017	% of revenue	2016	% of revenue
U.S.	$ 34,909	77%	$ 28,839	77%
International	10,711	23%	8,459	23%
Total	$ 45,620	100%	$ 37,298	100%

	Revenue by Product Category Year Ended December 31,			
(in thousands, except percentages)	2017	% of revenue	2016	% of revenue
Trauma and deformity	$ 32,801	72%	$ 26,844	73%
Scoliosis	11,585	25%	9,349	25%
Sports medicine/other	1,234	3%	1,105	3%
Total	$ 45,620	100%	$ 37,298	100%

Revenue increased $8.3 million, or 22%, from $37.3 million for the year ended December 31, 2016 to $45.6 million for the year ended December 31, 2017. The increase was due primarily to trauma and deformity sales growth of $6.0 million, or 22%, primarily driven by sales of our PediPlate product, scoliosis sales growth of $2.2 million, or 24%, primarily driven by sales of our RESPONSE™ and Bandloc products, and sports medicine/other sales growth of $0.1 million, or 12%. Nearly all of the increase was due to the increase in unit volume sold and not a result of price changes.

Cost of Revenue and Gross Margin

Cost of revenue was $11.2 million and $10.9 million for the years ended December 31, 2017 and 2016, respectively. Gross margin was 76% for the year ended December 31, 2017 and 71% for the year ended December 31, 2016. The increase in gross margin was due primarily to increased sales and greater cost controls.

Sales and Marketing Expenses

Sales and marketing expenses increased $3.9 million, or 23%, from $16.7 million for the year ended December 31, 2016 to $20.5 million for the year ended December 31, 2017. The increase was due primarily to increased sales commission expenses, driven by the increase in unit volume sold, and marketing expenses.

General and Administrative Expenses

General and administrative expenses increased $5.3 million, or 46%, from $11.6 million for the year ended December 31, 2016 to $17.0 million for the year ended December 31, 2017. The increase was due primarily to the addition of personnel and resources to support the growth of our business, additional public company costs incurred after our IPO and $2.0 million of additional stock compensation expense related to the accelerated vesting of restricted stock upon our IPO. Depreciation and amortization expenses increased $0.5 million, or 26%, from $1.9 million for the year ended December 31, 2016 to $2.4 million for the year ended December 31, 2017. The increase was primarily due to prior increased investments in consigned surgical instrument sets and amortization on intangible licenses.

Research and Development Expenses

Research and development expenses increased $1.2 million, or 54%, from $2.2 million for the year ended December 31, 2016 to $3.4 million for the year ended December 31, 2017. The increase was due to the addition of personnel to support our product pipeline and the growth of our business.

Other Expenses

Other expenses were $2.5 million and $0.4 million for the years ended December 31, 2017 and 2016, respectively. In June 2016, we recognized $0.9 million of income related to the expiration of a research and development fee obligation for our first generation RESPONSE™ spine system. The remaining expense in both of these periods consisted primarily of interest expense on long-term debt.

Liquidity and Capital Resources

We have incurred operating losses since inception and negative cash flows from operating activities of $15.6 million, $7.2 million and $1.1 million for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, we had an accumulated deficit of $115.1 million. We anticipate that our losses will continue in the near term as we continue to expand our product portfolio and invest in additional consigned implant and instrument sets to support our expansion into existing and new markets. Since inception, we have funded our operations primarily with proceeds from the sales of our common and preferred stock, convertible securities and debt, as well as through sales of our products. As of December 31, 2018 we had cash and cash equivalents of $60.7 million.

We believe our existing cash and cash equivalents, amounts available under the Loan Agreement, cash receipts from sales of our products and net proceeds from our December 2018 secondary offering will be sufficient to meet our anticipated cash requirements for at least the next 12 months. Nonetheless, from time to time, we may seek additional financing sources to meet our working capital requirements, make continued research and development investments and make capital expenditures needed for us to maintain and grow our business. We may not be able to obtain additional financing on terms favorable to us, if at all. It is also possible that we may

allocate significant amounts of capital toward products or technologies for which market demand is lower than anticipated and, as a result, abandon such efforts. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, or if we expend capital on products or technologies that are unsuccessful, our ability to continue to support our business growth and to respond to business challenges could be significantly limited, or we may have to scale back our operations. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock.

Cash Flows

The following table sets forth our cash flows from operating, investing and financing activities for the periods indicated:

	Year Ended December 31,		
(in thousands)	2018	2017	2016
Net cash used in operating activities	$ (15,583)	$ (7,217)	$ (1,119)
Net cash used in investing activities	(5,965)	(6,544)	(4,754)
Net cash provided by financing activities	39,657	54,734	3,604
Net increase (decrease) in cash and cash equivalents	$ 18,109	$ 40,973	$ (2,269)

Cash Used in Operating Activities

Net cash used in operating activities was $15.6 million, $7.2 million and $1.1 million for the years ended December 31, 2018, 2017 and 2016, respectively. The primary use of this cash was to fund our operations related to the development and commercialization of our products in each of these years. Net cash provided by (used for) working capital was $(9.6) million, $(4.2) million and $3.2 million for the years ended December 31, 2018, 2017 and 2016, respectively. During 2018, we increased warehouse inventory by $5.7 million as we deployed additional inventory following our IPO and accounts receivable increased by $3.8 million as our sales increased. During 2017, the primary driver of working capital cash use was a $4.3 million increase in warehouse inventory. During 2016, we increased warehouse inventory by $1.0 million and decreased other working capital by $4.2 million as we refocused on cash preservation. We had a net loss of $12.0 million, $8.9 million and $6.6 million for the years ended December 31, 2018, 2017 and 2016, respectively, which drove a difference in the use of operating cash between the periods. Our net loss for the year ended December 31, 2016 included a one-time charge of $2.0 million for costs related to the delay of our initial public offering. Our net loss for the years ended December 31, 2018 and 2017 each included a $2.0 million non-cash expense associated with the accelerated vesting of our restricted stock related to our IPO.

Cash Used in Investing Activities

Net cash used in investing activities was $6.0 million, $6.5 million and $4.8 million for the years ended December 31, 2018, 2017 and 2016, respectively. Net cash used in investing activities consisted primarily of purchases of instrument sets, which were consigned in the United States and select international markets, of $5.2 million, $5.2 million and $4.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. In 2018 and 2017, we purchased an additional $0.2 million and $1.3 million in new product licenses, respectively.

Cash Provided By Financing Activities

Net cash provided by financing activities was $39.7 million, $54.7 million and $3.6 million for the years ended December 31, 2018, 2017 and 2016, respectively. Net cash provided by financing activities in 2018 consisted primarily of proceeds from the issuance of common stock, net of issuance costs, of $43.4 million offset by a $4.0 million payment on our revolving credit facility. Net cash provided by financing activities during 2017 consisted primarily of proceeds from the issuance of common stock, net of issuance costs, of $53.8 million and proceeds from the issuance of debt of $8.0 million, which was partially offset by payments of preferred stock dividends of $6.0 million and shares surrendered by employees to pay taxes on restricted stock of $1.0 million. Net cash provided by financing activities during 2016 consisted primarily of proceeds of $4.5 million from the issuance of debt to an affiliate, offset by the payment of $0.8 million of deferred costs related to the delay of our initial public offering and $0.1 million in mortgage payments.

Indebtedness

Loan Agreement

Effective December 31, 2017, we entered into a Fourth Amended and Restated Loan and Security Agreement (the "Loan Agreement") with Squadron Capital LLC (the "Lender"). Under the terms of the Loan Agreement, the Lender has provided to us a term loan in the principal amount of $20.0 million and a revolving loan in an aggregate principal amount that will not exceed $15.0 million. Interest on the term loan and revolving loan accrues at the lesser of (a) three month LIBOR plus 8.61%, and (b) 10.0% (the "Applicable Rate") and is payable monthly by us. The Loan Agreement expires in January 2023.

The Loan Agreement amended and restated the Third Amended and Restated Loan and Security Agreement between the Lender and us, dated April 26, 2017, the Amended and Restated Term Note A, dated April 26, 2017 and the Term Note B, dated as of April 26, 2017, by (a) consolidating the prior term note amounts into the $20.0 million term note and establishing the $15.0 million revolving loan, (b) changing the term loan interest rate to the Applicable Rate (compared to the previous rates of 10.0% and 11.0% for the Term Note A and Term Note B, respectively) and establishing the Applicable Rate as the interest rate for the revolving loan, and (c) extending the loan period through January 31, 2023, except as accelerated pursuant to the Loan Agreement (compared to the previous maturity of May 31, 2019).

The largest principal amount outstanding under the Loan Agreement (or its predecessor agreement) at any time since December 2017 was $25.3 million. As of December 31, 2018, we had approximately $20 million in outstanding indebtedness under the Loan Agreement. Borrowings under the Loan Agreement are secured by substantially all of our assets and are unconditionally guaranteed by each of our subsidiaries.

There are no traditional financial covenants associated with the Loan Agreement. However, there are negative covenants that prohibit us from, among other things, transferring any of our material assets, merging with or acquiring another entity, entering into a transaction that would result in a change of control, incurring additional indebtedness, creating any lien on our property, making investments in third parties and redeeming stock or paying dividends, in each case subject to certain exceptions as further detailed in the Loan Agreement.

The Loan Agreement includes events of default, the occurrence and continuation of any of which provides Squadron with the right to exercise remedies against us and the collateral securing the loans, including cash. These events of default include, among other things, the failure to pay amounts due under the credit facilities, insolvency, the occurrence of a material adverse event, which includes a material adverse change in our business, operations or properties (financial or otherwise) or a material impairment of the prospect of repayment of any portion of the obligations, the occurrence of any default under certain other indebtedness and a final judgment against us in an amount greater than $250,000. The occurrence of a material adverse change could result in the acceleration of payment of the debt.

We are obligated to make monthly interest-only payments on the term loan facilities until the earlier of: (i) a transaction pursuant to which any person acquires (a) shares of our capital stock possessing the voting power to elect a majority of our board of directors or (b) all or substantially all of our assets on a consolidated basis; or (ii) January 31, 2023, at which point the term loan credit facilities, plus all accrued, unpaid interest thereon, will become due.

We may prepay the term loan facility in whole or in part without premium or penalty upon ten days' prior written notice to Squadron.

Mortgage Note

In August 2013, pursuant to the purchase of our office and warehouse space, we entered into a mortgage note payable to Tawani Enterprises Inc., the owner of which is a member of Squadron's Managing Committee. Pursuant to the terms of the mortgage note, we pay Tawani Enterprises Inc. monthly principal and interest installments of $15,543, with interest compounded at 5% until maturity in August 2028, at which time a final payment of remaining principal and interest will become due. The mortgage is secured by the related real estate and building. The mortgage balance was $1.4 million and $1.5 million as of December 31, 2018 and 2017, respectively.

Pediatric Orthopedic Business Seasonality

Our revenue is typically higher in the summer months and holiday periods, driven by higher sales of our trauma and deformity and scoliosis products, which is influenced by the higher incidence of pediatric surgeries during these periods due to recovery time provided by breaks in the school year. Additionally, our scoliosis patients tend to have additional health challenges that make scheduling their procedures variable in nature.

Critical Accounting Policies and Significant Judgments and Estimates

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenue and expenses during the reporting periods. We monitor and analyze these items for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in the notes to our consolidated financial statements appearing elsewhere in this annual report, we believe the following accounting policies are most critical to understanding and evaluating our reported financial results.

Revenue Recognition

In the United States and in five international markets, we primarily sell our implants, and to a much lesser extent our instruments, through third-party independent sales agencies to medical facilities and hospitals. For such sales, revenue and associated cost of revenue is recognized when a product is used in a procedure. In a few cases, hospitals purchase our products for their own inventory, and such revenue and associated cost of revenue is recognized when a product is shipped or delivered and the title and risk of loss passes to the customer.

International sales are primarily through independent stocking distributors. Generally, these distributors are allowed to return products, can be thinly capitalized and in some cases do not pay for our products until they have been resold. Based on our history of collections and returns from international distributors, we have concluded that collectability is not reasonably assured. Accordingly, we recognize international revenue and associated cost of revenue when cash is received from the distributor. In the case of international sales made directly through sales agencies, we recognize revenue when our products are used by the hospital for surgeries on a case by case basis.

We have invoiced international sales to distributors that have not been recognized as revenue totaling $0.3 million and $1.7 million as of December 31, 2018 and 2017, respectively. Associated cost of revenue, which is reported as inventory held by distributors on the consolidated balance sheets until the related revenue is recognized, was $0.2 million and $1.0 million as of December 31, 2018 and 2017, respectively.

Inventory Valuation

Inventory is stated at the lower of cost or net realizable value, with cost determined using the first-in-first-out method. Inventory, which consists of implants and instruments included in deployed sets in the field or held in our warehouse, is considered finished goods and is purchased from third parties.

We evaluate the carrying value of our inventory in relation to the estimated forecast of product demand, which takes into consideration the life cycle of the products. A significant decrease in demand could result in an increase in the amount of excess inventory on hand, which could lead to additional charges for excess and obsolete inventory.

The need to maintain substantial levels of inventory impacts our estimates for excess and obsolete inventory. Each of our systems are designed to include implantable products that come in different sizes and shapes to

accommodate the surgeon's needs. Typically, a small number of the set components are used in each surgical procedure. Certain components within each set may become obsolete before other components based on the usage patterns. We adjust inventory values to reflect these usage patterns and life cycle.

In addition, we continue to introduce new products, which we believe will increase our revenue. As a result, we may be required to take additional charges for excess and obsolete inventory in the future.

Stock-based Compensation

We recognize compensation costs related to restricted stock granted to employees based on the estimated fair value of the awards on the date of the grant amortized over the restriction period. Forfeitures are recorded upon forfeiture date.

Historically, for all periods prior to our IPO, the fair values of the shares of common stock underlying our restricted stock and stock option awards were estimated on each grant date by management and approved by the board of directors. In order to determine the fair value of our common stock underlying such grants, we consider multiple inputs to value our common stock, including the value of equity, enterprise value and key price points in our capital structure. Given the absence of a public trading market for our common stock at that time, we exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including the preferences and dividends of our redeemable convertible preferred stock relative to those of our common stock; our operating results and financial conditions, including our level of available capital resources; equity market conditions affecting comparable public companies; general U.S. market conditions and the lack of marketability of our common stock.

In valuing our common stock, we used the market approach, which is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. In using the market approach, we have considered both the guideline public company method and the precedent transaction method. We allocated the enterprise value across our classes of capital stock to determine the fair value of our common stock at each valuation date. After the equity value was allocated to the share classes, we applied a discount for lack of marketability to our common shares because we were valuing a minority interest in our company as a closely held, non-public company with no liquid market for its shares. We also considered the various rights and privileges of our redeemable convertible preferred stock relative to our common stock, including anti-dilution protection, cumulative dividend rights, protective provisions in our certificate of incorporation and rights to participate in future rounds of financing.

For stock-based awards granted after the completion of our IPO, our Board of Directors intends to determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported on the date of grant.

We recorded total stock-based compensation expenses of $3.2 million, $3.5 million and $1.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. In October 2017, we recorded a $2.0 million non-cash restricted stock compensation expense related to the accelerated vesting of our restricted stock compensation expense in conjunction with our IPO. During the first four months of 2018, we recorded an additional $2.0 million non-cash restricted stock expense related to the accelerated vesting of our restricted stock following our IPO. We expect to continue to grant restricted stock and other equity-based awards in the future, and to the extent that we do, our stock-based compensation expenses in future periods may increase.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2018:

	Payments Due by Period				
(in thousands)	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Total debt	$ 21,418	$ 118	$ 393	$ 20,296	$ 611
Minimum royalty payments	$ 4,000	$ 500	$ 1,500	$ 1,000	$ 1,000

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, as defined by applicable regulations of the SEC, that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Net Operating Losses

As of December 31, 2018, we had federal and state tax net operating loss carryforwards, or NOLs, of approximately $87.3 million, which begin to expire in 2028 unless utilized. The deferred tax assets were fully offset by a valuation allowance as of December 31, 2018 and 2017, and no income tax benefit has been recognized in our consolidated statements of operations.

Pursuant to Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, annual use of our pre-change NOLs may be limited in the post-change period in the event that an ‘‘ownership change’’ occurs, which is generally defined as a cumulative change in equity ownership by ‘‘5% shareholders’’ that exceeds 50 percentage points over a rolling three-year period. We determined that an ownership change occurred on May 30, 2014, resulting in a limitation of approximately $1.1 million per year being imposed on the use of our pre-change NOLs of approximately $49.0 million. This limitation will be increased in the first five years after the ownership change by the amounts of recognized built-in gains as determined under the tax rules, which increase should be approximately $2.3 million in each such year. An additional Section 382 ownership change was deemed to have occurred followiong our secondary offering in December 2018 resulting in a limitation of approximately $9.7 million per year.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

Our cash balances as of December 31, 2018 and 2017 consisted of cash held in an operating account that earns nominal interest income. We are exposed to market risk related to fluctuations in interest rates and bond market prices. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the nature of our cash holdings, a sudden change in market interest rates would not be expected to have a material impact on our financial condition or results of operation.

Foreign Currency

A substantial portion of our operations are located in the United States, and the majority of our sales since inception have been made in United States dollars. Accordingly, we have assessed that we do not have any material net exposure to foreign currency rate fluctuations. However, as our business in markets outside of the United States continues to increase, we will be exposed to foreign currency exchange risk related to our foreign operations. Fluctuations in the rate of exchange between the United States dollar and foreign currencies, primarily the Pound Sterling, the Euro and the Australian Dollar, could adversely affect our financial results, including our revenues, revenue growth rates, gross margins, income and losses as well as assets and liabilities. We do not currently hedge our exposure to foreign currency exchange rate fluctuations, but we may choose to do so in the future. We estimate that an immediate 10% adverse change in foreign exchange rates not currently pegged to the U.S. dollar would have decreased our reported net income by an immaterial amount for the years ended December 31, 2018, 2017 and 2016.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of OrthoPediatrics Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of OrthoPediatrics Corp. and subsidiaries (the “Company”) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, redeemable convertible preferred stock and stockholders’ equity (deficit), and cash flows for each of the three 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 three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with 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 audit to obtain reasonable assurance about whether the financial statements are free from material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

/s/ Deloitte & Touche LLP

Indianapolis, Indiana
March 7, 2019

We have served as the Company's auditor since 2015.

ORTHOPEDIATRICS CORP.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share information)

	As of December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash	$ 60,691	$ 42,582
Accounts receivable - trade, less allowance for doubtful accounts of $134 and $143, respectively	8,999	5,603
Inventories, net	25,541	19,498
Inventories held by international distributors, net	167	1,047
Notes receivable	502	—
Prepaid expenses and other current assets	1,256	831
Total current assets	97,156	69,561
Property and equipment, net	12,768	10,391
Other assets:		
Amortizable intangible assets, net	1,921	2,089
Other intangible assets	260	260
Total other assets	2,181	2,349
Total assets	$ 112,105	$ 82,301
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable - trade	$ 3,971	$ 5,495
Accrued compensation and benefits	3,552	2,905
Current portion of long-term debt with affiliate	118	113
Other current liabilities	1,576	954
Total current liabilities	9,217	9,467
Long-term liabilities:		
Long-term debt with affiliate, net of current portion	21,156	21,418
Revolving credit facility with affiliate	—	3,921
Total long-term liabilities	21,156	25,339
Total liabilities	30,373	34,806
Commitments and contingencies (Note 14)		
Stockholders' equity:		
Common stock, $0.00025 par value; 50,000,000 shares authorized at December 31, 2018 and 2017, respectively; 14,538,202 shares and 12,621,781 shares issued and outstanding as of December 31, 2018 and 2017, respectively	4	2
Additional paid-in capital	197,442	150,424
Accumulated deficit	(115,091)	(103,066)
Accumulated other comprehensive (loss) income	(623)	135
Total stockholders' equity	81,732	47,495
Total liabilities and stockholders' equity	$ 112,105	$ 82,301

See notes to consolidated financial statements.

ORTHOPEDIATRICS CORP.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share information)

	Year Ended December 31,		
	2018	2017	2016
Net revenue	$ 57,559	$ 45,620	$ 37,298
Cost of revenue	14,879	11,170	10,931
Gross profit	42,680	34,450	26,367
Operating expenses:			
Sales and marketing	26,563	20,527	16,661
General and administrative	20,938	16,972	11,631
Initial public offering costs	—	—	1,979
Research and development	4,732	3,423	2,223
Total operating expenses	52,233	40,922	32,494
Operating loss	(9,553)	(6,472)	(6,127)
Other expenses:			
Interest expense	2,255	2,490	1,476
Other expense (income)	217	(30)	(1,031)
Total other expenses	2,472	2,460	445
Net loss from continuing operations	(12,025)	(8,932)	(6,572)
Net loss	$ (12,025)	$ (8,932)	$ (6,572)
Net loss attributable to common stockholders	$ (12,025)	$ (23,530)	$ (12,448)
Weighted average common shares - basic and diluted	12,567,387	4,017,330	1,744,356
Net loss per share attributable to common stockholders - basic and diluted	$ (0.96)	$ (5.86)	$ (7.14)

See notes to consolidated financial statements.

ORTHOPEDIATRICS CORP.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
Net loss	$ (12,025)	$ (8,932)	$ (6,572)
Other comprehensive (loss) income:			
Foreign currency translation adjustment	(758)	135	—
Other comprehensive (loss) income	(758)	135	—
Comprehensive loss	$ (12,783)	$ (8,797)	$ (6,572)

See notes to consolidated financial statements.

ORTHOPEDIATRICS CORP.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share information)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity (Deficit)
	Shares	Value	Shares	Value	Shares	Value				
Balance at January 1, 2016	1,000,000	$ 21,654	4,446,978	$ 43,773	2,338,010	$ 1	$ 17,449	$ (71,562)	$ —	$ (54,112)
Net loss	—	—	—	—	—	—	—	(6,572)	—	(6,572)
Accretion of redeemable preferred stock to redemption value	—	1,785	—	4,091	—	—	(5,876)	—	—	(5,876)
Restricted stock	—	—	—	—	83,589	—	1,251	—	—	1,251
Balance at December 31, 2016	1,000,000	23,439	4,446,978	47,864	2,421,599	1	12,824	(78,134)	—	(65,309)
Net loss	—	—	—	—	—	—	—	(8,932)	—	(8,932)
Accretion of redeemable preferred stock to redemption value	—	1,500	—	3,063	—	—	(4,563)	—	—	(4,563)
Restricted stock	—	—	—	—	108,468	—	3,478	—	—	3,478
Shares surrendered by employees to pay taxes on restricted stock	—	—	—	—	(76,146)	—	(990)	—	—	(990)
Conversion of redeemable preferred shares to common stock upon IPO	(1,000,000)	(16,000)	(4,446,978)	(39,000)	3,649,475	1	54,996	—	—	54,997
Conversion of Series A redeemable preferred stock dividends to common stock upon IPO	—	(8,939)	—	—	687,616	—	8,939	—	—	8,939
Payment of Series B redeemable preferred stock dividends and reversal of 50% accrued dividends upon IPO	—	—	—	(11,927)	—	—	5,965	—	—	5,965
Series A redeemable preferred stock liquidation preference payment	—	—	—	—	1,230,769	—	16,000	(16,000)	—	—
Issuance of common stock, net of issuance cost	—	—	—	—	4,600,000	—	53,775	—	—	53,775
Other comprehensive income	—	—	—	—	—	—	—	—	135	135
Balance at December 31, 2017	—	—	—	—	12,621,781	2	150,424	(103,066)	135	47,495
Net loss	—	—	—	—	—	—	—	(12,025)	—	(12,025)
Issuance of common stock, net of issuance cost	—	—	—	—	1,725,000	1	43,423	—	—	43,424
Restricted stock	—	—	—	—	177,208	1	3,185	—	—	3,186
Stock option exercise	—	—	—	—	14,213	—	410	—	—	410
Other comprehensive loss	—	—	—	—	—	—	—	—	(758)	(758)
Balance at December 31, 2018	—	—	—	—	14,538,202	$ 4	$ 197,442	$ (115,091)	$ (623)	$ 81,732

See notes to consolidated financial statements.

ORTHOPEDIATRICS CORP.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,		
	2018	2017	2016
OPERATING ACTIVITIES			
Net loss	$ (12,025)	$ (8,932)	$ (6,572)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,892	2,405	1,902
Stock-based compensation	3,185	3,478	1,251
Research and development fee obligation	—	—	(889)
Changes in certain current assets and liabilities:			
Accounts receivable - trade	(3,801)	(1,505)	(280)
Inventories	(5,681)	(4,287)	(1,029)
Inventories held by international distributors	880	(123)	1,918
Prepaid expenses and other current assets	(425)	(598)	(11)
Accounts payable - trade	(1,524)	1,952	1,544
Accrued expenses and other liabilities	947	258	1,675
Research and development fee obligation	—	—	(628)
Other	(31)	135	—
Net cash used in operating activities	(15,583)	(7,217)	(1,119)
INVESTING ACTIVITIES			
Purchase of notes receivable	(502)	—	—
Purchases of licenses	(210)	(1,337)	(406)
Purchases of property and equipment	(5,253)	(5,207)	(4,348)
Net cash used in investing activities	(5,965)	(6,544)	(4,754)
FINANCING ACTIVITIES			
Proceeds from issuance of debt with affiliate	—	7,992	4,500
Payment of revolving credit facility with affiliate	(4,065)	—	—
Proceeds from issuance of common stock, net of issuance costs	43,425	53,775	—
Payment of preferred stock dividends	—	(5,965)	—
Proceeds from exercise of stock options	410	—	—
Shares surrendered by employees to pay taxes on restricted shares	—	(990)	—
Payments on mortgage notes	(113)	(78)	(102)
Payments of deferred offering costs	—	—	(794)
Net cash provided by financing activities	39,657	54,734	3,604
NET INCREASE (DECREASE) IN CASH	18,109	40,973	(2,269)
Cash, beginning of year	42,582	1,609	3,878
Cash, end of period	$ 60,691	$ 42,582	$ 1,609
SUPPLEMENTAL DISCLOSURES			
Cash paid for interest	$ 2,255	$ 2,490	$ 1,476
Accretion of redeemable convertible preferred stock	$ —	$ 4,563	$ 5,876
Transfer of instruments from property and equipment to inventory	$ 362	$ 1,249	$ 1,225

See notes to consolidated financial statements.

NOTE 1 – BUSINESS

OrthoPediatrics Corp., a Delaware Corporation, is a medical device company committed to designing, developing and marketing anatomically appropriate implants and devices for children with orthopedic conditions, giving pediatric orthopedic surgeons and caregivers the ability to treat children with technologies specifically designed to meet their needs. We sell our specialized products, including PediLoc®, PediPlates®, Cannulated Screws, PediFlex™ nail, PediNail™, PediLoc® Tibia, ACL Reconstruction System, Locking Cannulated Blade, Locking Proximal Femur, Spica Tables, RESPONSE™ Spine, Bandloc, Pediguard and Pediatric Nailing Platform | Femur, to various hospitals and medical facilities throughout the United States and various international markets. We currently use a contract manufacturing model for the manufacturing of implants and related surgical instrumentation.

In early 2017, we expanded operations and established legal entities in the United Kingdom, Australia and New Zealand permitting us to sell under an agency model direct to local hospitals in these countries. In September 2018, we further expanded operations in Canada selling direct to local hospitals.

Our controlling investor is Squadron Capital (“Squadron”), a family office firm headquartered near Hartford, Connecticut.

NOTE 2 – SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying consolidated financial statements include the accounts of OrthoPediatrics Corp. and its wholly-owned subsidiaries, OrthoPediatrics US Distribution Corp., OrthoPediatrics EU Limited, OrthoPediatrics AUS PTY LTD and OrthoPediatrics NZ Limited (collectively, the “Company,” “we,” “our,” or “us”). All intercompany balances and transactions have been eliminated.

We have prepared the accompanying consolidated financial statements in conformity with accounting principles generally accepted in the United States of America (“GAAP”). The accompanying consolidated financial statements have been prepared assuming our Company will continue as a going concern. We have experienced recurring losses from operations since our inception and had an accumulated deficit of $115,091 and $103,066 as of December 31, 2018 and 2017, respectively. Our note payable and revolving credit facility with Squadron was due to mature and our redeemable convertible preferred stock was due to become redeemable in May 2017. Accordingly, in April 2017, we entered into an amended loan agreement with Squadron providing an additional $16,000 of availability and extending the maturity date of the note payable, revolving credit facility and redeemable convertible preferred stock to May 31, 2019 with an automatic one year extension to May 31, 2020 if we meet certain revenue goals. Effective December 31, 2017, we entered into another amended loan agreement with Squadron to consolidate a majority of our term note into a $20,000 term loan, reestablished a $15,000 revolver, reduced the interest rate and extended the loan period through January 31, 2023. Management continues to monitor cash flows and liquidity on a regular basis. During the year ended December 31, 2017, we borrowed $10,333 under our revolving credit facility, repaid $2,133 and transferred $4,100 to Term Loan A. During 2018, we did not borrow any additional amounts and repaid $4,100 of principal. We believe that our cash balance at December 31, 2018, expected cash flows from operations for the next twelve months subsequent to the issuance of the consolidated financial statements and the availability under the revolving credit facility are sufficient to enable us to maintain current and essential planned operations for the next twelve months subsequent to the issuance of the consolidated financial statements. Our ability to fund planned operations internally beyond that date may be substantially dependent upon our ability to obtain sufficient funding at acceptable terms.

On October 12, 2017, we completed an initial public offering ("IPO") of our common stock, in which we issued and sold 4.6 million shares of common stock at a public offering price of $13.00 per share for aggregate gross proceeds of $59,800. We received approximately $46,900 in net proceeds after deducting $4,200 of underwriting discounts and commissions, paying approximately $2,700 of offering costs and paying approximately $6,000 of Series B dividends. Upon the closing of the IPO, all of the outstanding shares of Series A and B redeemable convertible preferred stock and the Series A accrued dividends and the $16,000 cash preference payment automatically converted into shares of common stock at a 1:1 conversion ratio.

On December 11, 2018, we completed a secondary offering of our common stock, in which we issued and sold 1.725 million shares of common stock at a public offering price of $27.00 per share for aggregate gross proceeds of $46,575. We received approximately $43,423 in net proceeds after deducting $2,800 of underwriting discounts and commissions and paying approximately $360 in offering costs.

Use of Estimates

Preparation of our consolidated financial statements requires the use of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses, as of the date of the consolidated financial statements. By their nature, these judgments are subject to an inherent degree of uncertainty. We use historical experience and other assumptions as the basis for our judgments and estimates. Because future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Any changes in these estimates will be reflected in our consolidated financial statements.

Foreign Currency Transactions

We currently bill our international distributors in U.S. dollars, resulting in minimal foreign exchange transaction expense.

Beginning in the second quarter of 2017, we began selling direct within the United Kingdom, Ireland, Australia and New Zealand and billing using the local currency for each country. In September 2018, we began selling direct in Canada. The financial statements of our foreign subsidiaries are accounted for and have been translated into U.S. dollars using end-of-period exchange rates for assets and liabilities and average exchange rates during each reporting period for results of operations. Foreign currency translation adjustments have been recorded as a separate component of the consolidated statements of comprehensive loss.

Fair Value of Financial Instruments

The accounting standards related to fair value measurements define fair value and provide a consistent framework for measuring fair value under the authoritative literature. Valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect market assumptions. This guidance only applies when other standards require or permit the fair value measurement of assets and liabilities. The guidance does not expand the use of fair value measurements. A fair value hierarchy was established, which prioritizes the inputs used in measuring fair value into three broad levels.

Level 1 – Quoted prices in active markets for identical assets or liabilities;

Level 2 – Observable market-based inputs or unobservable inputs that are corroborated by market data; and

Level 3 – Significant unobservable inputs that are not corroborated by market data. Generally, these fair value measures are model-based valuation techniques such as discounted cash flows, and are based on the best information available, including our own data.

We do not have any assets or liabilities that are measured on a recurring basis under the presented fair value hierarchy.

Revenue from Contracts with Customers

The Company adopted ASC 606, "*Revenue From Contracts with Customers* (ASC 606)", on January 1, 2018 using the modified retrospective method for all contracts not completed as of the date of adoption. The adoption of

ASC 606 did not have any impact on the Company's consolidated historical financial statements. The reported results for 2018 reflect the application of ASC 606 guidance while the reported results for 2017 were prepared under the guidance of "ASC 605, *Revenue Recognition* (ASC 605)." In accordance with ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods or services, and excludes any sales incentives or taxes collected from a customer which are subsequently remitted to government authorities.

Revenue Recognition – United States

Revenue in the United States is generated primarily from the sale of our implants and, to a much lesser extent, from the sale of our instruments. Sales in the United States are primarily to hospital accounts through independent sales agencies. We recognize revenue when our performance obligations under the terms of a contract with our customer are satisfied. This typically occurs when we transfer control of our products to the customers, generally upon implantation or when title passes upon shipment. The products are generally consigned to our independent sales agencies, and revenue is recognized when the products are used by or shipped to the hospital for surgeries on a case by case basis. On rare occasions, hospitals purchase product for their own inventory, and revenue is recognized when the products are shipped and the title and risk of loss passes to the customer. Pricing for each customer is dictated by a unique pricing agreement, which does not generally include rebates or discounts. Sales to two of our independent sales agencies accounted for 12.1% and 11.2% of our revenue in 2018. Sales to two of our independent sales agencies accounted for 12.1% and 11.2% of our revenue in 2017, respectively. Sales to two of our independent sales agencies accounted for 10.1% and 10.1% of our revenue in 2016, respectively.

Revenue Recognition – International

Outside of the United States, we primarily sell our products through independent stocking distributors. Generally, the distributors are allowed to return products, and some are thinly capitalized. Based on our history of collections and returns from international customers, we have concluded that collectability is not reasonably assured at the time of delivery for certain customers who have not evidenced a consistent pattern of timely payment. Accordingly, we do not recognize international revenue and associated cost of revenue at the time title transfers for these customers for whom collectibility has not been deemed probable based on the customer's history and ability to pay, but rather when cash has been received. Until such payment, cost of revenue is recorded as inventories held by international distributors, net of adjustment for estimated unreturnable inventory, on our consolidated balance sheets.

For international independent stocking distributors for whom we have determined collectibility is probable, based on a history of reliable collections, we have concluded that a contract exists and revenue should be recognized when we transfer control of our products to the customer, generally upon implantation or when title passes upon shipment.

In early 2017, we expanded operations and established legal entities in the United Kingdom, Australia and New Zealand and in Canada in September 2018, permitting us to sell under an agency model direct to local hospitals in these countries. The products are generally consigned to our independent sales agencies, and revenue is recognized when the products are used by or shipped to the hospital for surgeries on a case by case basis. On rare occasions, hospitals purchase products for their own inventory, and revenue is recognized when the products are shipped and the title and risk of loss passes to the customer. Pricing for each customer is dictated by a unique pricing agreement, which does not generally include rebates or discounts.

At December 31, 2018 and 2017, we have invoiced international sales to distributors that have not been recognized as revenue totaling $280 and $1,654, respectively. Associated cost of revenue, which is reported as inventory held by international distributors on our consolidated balance sheets, was $167 and $1,047 at December 31, 2018 and 2017, respectively.

Cash and Cash Equivalents

We maintain cash in bank deposit accounts which, at times, may exceed federally insured limits. To date, we have not experienced any loss in such accounts. We consider all highly liquid investments with original maturity

of three months or less at inception to be cash equivalents. The carrying amounts reported in the balance sheets for cash are valued at cost, which approximates fair value.

Accounts Receivable

Accounts receivable are uncollateralized customer obligations due under normal trade terms, generally requiring payment within 30 days from the invoice date. Account balances with invoices over 30 days past due are considered delinquent. No interest is charged on past due accounts. Payments of accounts receivable are applied to the specific invoices identified on the customer's remittance advice or, if unspecified, to the customer's account as an unapplied credit.

The carrying amount of accounts receivable is reduced by an allowance that reflects management's best estimate of the amounts that will not be collected, determined principally on the basis of historical experience, management's assessment of the collectability of specific customer accounts and the aging of the accounts receivable. All accounts or portions thereof deemed to be uncollectible or to require an excessive collection cost are written off to the allowance for doubtful accounts.

Inventories, net

Inventories are stated at the lower of cost or net realizable value, with cost determined using the first-in-first-out method. Inventories, which consist of implants and instruments held in our warehouse or with third-party independent sales agencies or distributors, are considered finished goods and are purchased from third parties.

We evaluate the carrying value of our inventories in relation to the estimated forecast of product demand, which takes into consideration the life cycle of the product. A significant decrease in demand could result in an increase in the amount of excess inventory on hand, which could lead to additional charges for excess and obsolete inventory.

The need to maintain substantial levels of inventory impacts our estimates for excess and obsolete inventory. Each of our implant systems are designed to include implantable products that come in different sizes and shapes to accommodate the surgeon’s needs. Typically, a small number of the set components are used in each surgical procedure. Certain components within each set may become obsolete before other components based on the usage patterns. We adjust inventory values, as needed, to reflect these usage patterns and life cycle.

In addition, we continue to introduce new products, which may require us to take additional charges for excess and obsolete inventory in the future.

Charges for excess and obsolete inventory are included in cost of revenue and were $504, $344 and $219 for the years ended December 31, 2018, 2017 and 2016, respectively.

Costs Related to the Initial Public Offering

We expensed $1,979 of costs associated with our registration statement on Form S-1 filed during the year ended December 31, 2016. Our planned initial public offering was postponed for a period in excess of 90 days and, as a result, it was deemed an aborted offering in accordance with Staff Accounting Bulletin Topic 5A. These costs are included in operating expenses in the statements of operations for the year ended December 31, 2016.

At the time of the IPO, $1,840 of additional costs, primarily consisting of legal, accounting and other direct fees and costs related to the IPO incurred during 2017 and were initially deferred and capitalized and then reclassified to stockholders’ equity at the conclusion of our IPO on October 12, 2017. Additionally, $1,986 and $2,049 of additional non-cash expense related to the accelerated vesting of restricted stock was included in general and administrative expenses in 2018 and 2017, respectively.

Costs Related to the Secondary Offering

On December 11, 2018, we completed a secondary offering of our common stock. Offering expenses in the amount of $357, primarily consisting of legal, accounting and other direct fees and costs related to the offering, were initially deferred and capitalized and then reclassified to stockholders' equity at the conclusion of our secondary offering on December 11, 2018.

Property and Equipment, net

Property and equipment are carried at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful life of the assets. When assets are retired or otherwise disposed of, costs and related accumulated depreciation are removed from the accounts, and any resulting gain or loss is recognized in operations for the period. Maintenance and repairs that prolong or extend the useful life are capitalized, whereas standard maintenance, replacements, and repair costs are expensed as incurred.

Instruments are hand-held devices, specifically designed for use with our implants and are used by surgeons during surgery. Instruments deployed within the United States, United Kingdom, Australia, New Zealand and Canada are carried at cost less accumulated depreciation and are recorded in property and equipment, net on the consolidated balance sheets.

Sample inventory consists of our implants and instruments, and is maintained to market and promote our products. Sample inventory is carried at cost less accumulated depreciation.

Depreciable lives are generally as follows:

Building and building improvements	25 to 30 years
Furniture and fixtures	5 to 7 years
Computer equipment	3 to 5 years
Business software	3 years
Office and other equipment	5 to 7 years
Instruments	5 years
Sample inventory	2 years

Amortizable Intangible Assets, net

Amortizable intangible assets include fees necessary to secure various patents and licenses. Amortization is calculated on a straight-line basis over the estimated useful life of the patents and licenses. Amortization for patents and licenses commences at the time of patent approval, and for licenses upon market launch, respectively. Intangible assets are amortized over a 3 to 20 year period.

Amortizable intangible assets are assessed for impairment annually or whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount to future net undiscounted cash flows expected to be generated by the associated asset. If such assets are determined to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair market value of the assets. No impairment charges were recorded in any of the periods presented.

Other Intangible Assets

We have indefinite lived tradename assets that are reviewed for impairment by performing a quantitative analysis, which occurs annually in the fourth quarter or whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability is measured by a comparison of the carrying amount to future net undiscounted cash flows expected to be generated by the associated asset. If such assets are determined to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount exceeds the fair market value of the assets. No impairment charges were recorded in any of the periods presented.

Shipping and Handling Costs

Shipping and handling costs that are billed to the customer are included in net revenue and were $513, $336 and $320, for the years ended December 31, 2018, 2017 and 2016, respectively. Shipping and handling costs that are not billed to the customer are included in sales and marketing expenses and were $2,148, $1,783 and $1,502, for the years ended December 31, 2018, 2017 and 2016, respectively.

Cost of Revenue

Cost of revenue consists primarily of products purchased from third-party suppliers, excess and obsolete inventory adjustments, inbound freight, and royalties. Our implants and instruments are manufactured to our specifications by third-party suppliers who meet our manufacturer qualifications standards. Our third-party manufacturers are required to meet Food and Drug Administration (the "FDA"), International Organization for Standardization and other country-specific quality standards. The majority of our implants and instruments are produced in the United States.

Sales and Marketing Expenses

Sales and marketing expenses primarily consist of commissions to our domestic and select international independent sales agencies and consignment distributors, as well as compensation, commissions, benefits and other related costs for personnel we employ. Commissions and bonuses are generally based on a percentage of sales. Our international independent stocking distributors purchase instrument sets and replenishment stock for resale, and we do not pay commissions or any other sales related costs for international sales to distributors.

Advertising Costs

Advertising costs consist primarily of print advertising, trade shows, and other related expenses. Advertising costs are expensed as incurred and are recorded as a component of sales and marketing expense. Advertising costs were $978, $1,128 and $920 for the years ended December 31, 2018, 2017 and 2016, respectively.

Research and Development Costs

Research and development costs are expensed as incurred. Our research and development expenses primarily consist of costs associated with engineering, product development, consulting services, outside prototyping services, outside research activities, materials, development and protection of our intellectual property portfolio, as well as other costs associated with development of our products. Research and development costs also include related personnel and consultants' compensation expense.

Research and development costs were $4,732, $3,423 and $2,223 for the years ended December 31, 2018, 2017 and 2016, respectively.

In 2016, we also had a research and development fee obligation to a third-party for its assistance in the development of our first generation spine system and our locking cannulated blade and locking proximal femur hip systems. The research and development fee expired during the year ended December 31, 2016. At the conclusion of the contract, we paid $341 and the remaining balance of $889 was recognized in other income in the statement of operations.

Stock-Based Compensation

Prior to our IPO, we maintained an Amended and Restated 2007 Equity Incentive Plan (the "2007 Plan") that provides for grants of options and restricted stock to employees, directors and associated third-party representatives of our company as determined by the Board of Directors. The 2007 Plan had authorized 1,585,000 shares for award.

Immediately prior to our IPO, we adopted our 2017 Incentive Award Plan (the "2017 Plan") which replaced the 2007 Plan. The 2017 Plan provides for grants of options and restricted stock to officers, employees, consultants or directors of our Company. The 2017 Plan has authorized 1,789,647 shares for award.

Options holders, upon vesting, may purchase common stock at the exercise price, which is the estimated fair value of our common stock on the date of grant. Option grants generally vest immediately or over a three years period. No stock options were granted in any of the periods presented.

Restricted stock may not be transferred prior to the expiration of the restricted period. The restricted stock that has been granted under the 2007 Plan has restriction periods that generally last until the earlier of six years from the date of grant, or an initial public offering or change in control, as defined in the 2007 Plan. All restricted stock granted prior to May 2014 vested upon our IPO and the remaining grants under the 2007 Plan vested six months

after the IPO. We have elected to recognize the reversal of stock compensation expense when a restricted stock forfeiture occurs as opposed to estimating future forfeitures.

We record the fair value of restricted stock at the grant date. Stock-based compensation is recognized ratably over the requisite service period, which is generally the restriction period for restricted stock.

In determining the fair value of our common stock at the grant date for awards issued prior to our IPO, which is the basis for the fair value of stock based awards, we use the market approach, which is based on the assumption that the value of an asset is equal to the value of a substitute asset with the same characteristics. In using the market approach, we consider both the guideline public company method and the precedent transaction method. Given the absence of a public trading market for our common stock at that time, we exercise reasonable judgment and consider a number of objective and subjective factors to determine the best estimate of the fair value of our common stock, including: the preferences and dividends of our redeemable convertible preferred stock relative to those of our common stock; our operating results and financial conditions, including our level of available capital resources; equity market conditions affecting comparable public companies; general U.S. market conditions; and the lack of marketability of our common stock. Prior to our IPO, for restricted stock awards we applied a discount for lack of marketability to the fair value of common shares due to estimate the impact of valuing a minority interest in our Company as a closely held, non-public company with no liquid market for its shares.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) includes foreign currency translation adjustments.

Income Taxes

We account for income taxes under the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, we determine deferred tax assets and liabilities on the basis of the differences between the financial statement and tax bases of assets and liabilities by using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date.

We recognize deferred tax assets to the extent that we believe that these assets are more likely than not to be realized. In making such a determination, we consider all available positive and negative evidence. If we determine that we would be able to realize our deferred tax assets in the future in excess of their net recorded amount, we would make an adjustment to the valuation allowance.

We record uncertain tax positions on the bases of a two-step process in which (1) we determine whether it is more likely than not that the tax positions will be sustained on the basis of the technical merits of the positions and (2) for those tax positions that meet the more-likely-than-not recognition threshold, we recognize the largest amount of tax benefit that is more than 50% likely to be realized upon ultimate settlement with the related tax authority.

"Emerging Growth Company" Reporting Requirements

We qualify as an "emerging growth company" as defined in the JOBS Act. For as long as a company is deemed to be an emerging growth company, it may take advantage of specified reduced reporting and other regulatory requirements that are generally unavailable to other public companies. Among other things, we are not required to provide an auditor attestation report on the assessment of the internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002.

Section 107 of the JOBS Act also provides that an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

In April 2017, the SEC adopted new rules that included an inflation-adjusted threshold in the definition of an emerging growth company. Under the new inflation-adjusted threshold, we would cease to be an emerging growth company on the last day of the fiscal year in which our annual gross revenues exceed $1.07 billion. This is an increase of $70 million from the previous $1 billion threshold.

Recent Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09 "*Revenue from Contracts with Customers*," on the recognition of revenue for all contracts with customers designed to improve comparability and enhance financial statement disclosures. The underlying principle of this comprehensive model is that revenue is recognized to depict the transfer of promised goods or services to customers in an amount that reflects the payment to which the company expects to be entitled in exchange for those goods or services. It also requires enhanced disclosures about revenue, provides guidance for transactions that were not previously addressed comprehensively, and improves guidance for multiple-element arrangements. The FASB subsequently issued amendments to ASU No. 2014-09 that have the same effective date and transition date. These new standards became effective for us on January 1, 2018. We elected to apply the modified retrospective approach, and we have not identified any accounting changes that would materially impact the amount of reported revenues and did not record any adjustments on January 1, 2018, related to this new guidance.

In February 2016, the FASB issued ASU 2016-02 "*Leases,*" which increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. The Company adopted the standard on January 1, 2019.

The new standard requires lessees to recognize both the right-of-use assets and lease liabilities in the balance sheet for most leases, whereas under previous GAAP only finance lease liabilities (previously referred to as capital leases) were recognized in the balance sheet. In addition, the definition of a lease has been revised which may result in changes to the classification of an arrangement as a lease. Under the new standard, an arrangement that conveys the right to control the use of an identified asset by obtaining substantially all of its economic benefits and directing how it is used is a lease, whereas the previous definition focuses on the ability to control the use of the asset or to obtain its output. Quantitative and qualitative disclosures related to the amount, timing and judgments of an entity's accounting for leases and the related cash flows are expanded. Disclosure requirements apply to both lessees and lessors, whereas previous disclosures related only to lessees. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from previous GAAP. Lessor accounting is also largely unchanged.

The new standard provides a number of transition practical expedients, which the Company has elected, including:

- a "package of three" expedients that must be taken together and allow entities to (1) not reassess whether existing contracts contain leases, (2) carryforward the existing lease classification, and (3) not reassess initial direct costs associated with existing leases, and
- an implementation expedient which allows the requirements of the standard in the period of adoption with no restatement of prior periods.

The Company has assessed the lease standard and executed a detailed implementation plan in preparation for adoption, which included the following key activities:

- Developed a complete lease inventory and abstracted the required data attributes as applicable in a manner that supports the Company's lease portfolio.
- Evaluated the transition practical expedients available under the standard.
- Identified, assessed and documented technical accounting issues, policy considerations and financial reporting implications.
- Identified and implemented changes to processes and controls to ensure all impacts of the new standard are effectively addressed.

The adoption of the new standard is not expected to result in material right of use asset or lease obligation for operating leases recorded in the Company's consolidated balance sheets on January 1, 2019, primarily due to the

lack of existing lease contracts, or other contracts that meet the standard for consideration as a lease under the definitions discussed above. The Company has limited operating leases for office equipment maintained at its headquarters, but does lease any real estate or office space.

The impact of adopting the new standard on retained earnings as of January 1, 2019 is expected to be immaterial.

In August 2016, the FASB issued ASU No. 2016-15 *"Statement of Cash Flows (Topic 230) – a Consensus of the FASB's Emerging Issues Task Force"* which provides guidance intended to reduce diversity in practice in how certain transactions are classified in the statement of cash flows. ASU 2016-15 is effective for fiscal years beginning after December 15, 2017 and interim periods within those fiscal years. This new guidance was effective for us on January 1, 2018 and did not have a material effect on our consolidated financial position, results of operations and cash flows.

NOTE 3 - PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following:

	December 31,	
	2018	2017
Land	$ 1,435	$ 1,435
Building and building improvements	1,053	1,053
Computer equipment and software	1,558	970
Office and other equipment	614	614
Instruments	14,266	10,666
Sample inventory	1,859	1,619
Construction in progress	1,850	1,977
	22,635	18,334
Less: accumulated depreciation	(9,867)	(7,943)
Total property and equipment, net	$ 12,768	$ 10,391

Depreciation expense is included in general and administrative expenses and was $2,514, $2,159 and $1,867 for the years ended December 31, 2018, 2017 and 2016, respectively.

NOTE 4 - INTANGIBLE ASSETS

As of December 31, 2018, the balances of amortizable intangible assets were as follows:

	Weighted-Average Amortization Period	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
Patents	10.7 years	$ 127	$ (60)	$ 67
License agreements	5.3 years	2,495	(641)	1,854
Total amortizable assets		$ 2,622	$ (701)	$ 1,921

As of December 31, 2017, the balances of amortizable intangible assets were as follows:

	Weighted-Average Amortization Period	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
Patents	11.7 years	$ 127	$ (54)	$ 73
License agreements	6.0 years	2,285	(269)	2,016
Total amortizable assets		$ 2,412	$ (323)	2,089

Amortization expense was $378, $246 and $35 for the years ended December 31, 2018, 2017 and 2016, respectively. Future amortization expenses are expected as follows:

Year Ending December 31:	
2019	$ 383
2020	359
2021	302
2022	219
2023	102
Thereafter	556
	$ 1,921

Licenses are tied to product launches and do not begin amortizing until the product is launched to the market. Anticipated market launch is in 2019 and 2020 for products for which we obtained licensing in 2018.

Trademarks are non-amortizing intangible assets which had a value of $260 for all periods presented.

NOTE 5 – ACCRUED COMPENSATION AND BENEFITS

Accrued compensation and benefits consisted of the following:

	December 31,	
	2018	2017
Accrued compensation and related costs	$ 1,323	$ 1,304
Accrued commissions	2,229	1,601
Total accrued compensation and benefits	$ 3,552	$ 2,905

NOTE 6 - DEBT AND CREDIT ARRANGEMENTS

Long-term debt consisted of the following:

	December 31,	
	2018	2017
Note payable to Squadron	$ 19,856	$ 20,000
Revolving credit facility with Squadron	—	3,921
Mortgage payable to affiliate	1,418	1,531
Total debt	21,274	25,452
Less: current maturities	118	113
Long-term debt, net of current maturities	$ 21,156	$ 25,339

In May 2014, we entered into a Second Amended and Restated Loan and Security Agreement with Squadron Capital LLC, or Squadron, in connection with a restructuring of our debt and equity. The terms of this agreement required monthly interest only payments computed at 10% per annum with all principal and unpaid interest due at maturity in May 2017. The note payable was secured by substantially all of our assets. In November 2015, this agreement was amended to provide a revolving loan commitment of an additional $7,000. The revolving loan commitment was structured under the same terms and conditions with interest payable monthly computed at 10% per annum and principal due at maturity in May 2017.

In April 2017, we entered into a Third Amended and Restated Loan and Security Agreement with Squadron providing us with two term loan credit facilities (an $18,400 facility made available to a Term Note A and a $16,000 facility made available pursuant to a Term Note B, each maturing on March 31, 2019). Interest under Term Note A and the Term Note B was payable monthly and computed at a per annum rate of 10% and 11%, respectively. In additional, the agreement provided for a $1,000 extension fee payable in three annual installments. The extension fee was recorded in full upon closing as a deferred financing cost within long-term debt with affiliate, net of current portion, on the December 31, 2017 consolidated balance sheet and was to be recognized ratably over the term of the agreement as deferred financing charges within interest expense on the consolidated statements of operations assuming an IPO did not happen.

Effective December 31, 2017, we entered into a Fourth Amended and Restated Loan and Security Agreement, or the Loan Agreement, with Squadron. Pursuant to the Loan Agreement, a majority of the term loan amounts under the previous agreement with Squadron were consolidated into a $20,000 term note and a $15,000 revolving credit facility was established. Also, $667 of the previously discussed extension fee was cancelled as of the completion of our IPO in October 2017. Both facilities include interest only payments and provide for an interest rate equal to the greater of (a) three month LIBOR plus 8.61% and (b) 10%. The Loan Agreement also extended the maturity date to January 31, 2023. Borrowings under the Loan Agreement are secured by substantially all of our assets and are unconditionally guaranteed by each of our subsidiaries.

There are no traditional financial covenants associated with the Loan Agreement. However, there are negative covenants that prohibit us from, among other things, transferring any of our material assets, merging with or acquiring another entity, entering into a transaction that would result in a change of control, incurring additional indebtedness, creating any lien on our property, making investments in third parties and redeeming stock or paying dividends.

The fair value of our note payable to Squadron was estimated based on prices for the same or similar issues and the current interest rates offered for the debt of the same remaining maturities, which are considered level 2 inputs in accordance with ASC Topic 820, "*Fair Value Measurements and Disclosures*." At December 31, 2018 and 2017, the fair value approximated the carrying value.

In connection with the purchase of our office and warehouse space in Warsaw, Indiana in August 2013, we entered into a mortgage note payable to Tawani Enterprises Inc., an affiliate of Squadron. Pursuant to the terms of the mortgage note, we pay Tawani Enterprises Inc. monthly principal and interest installments of $16 with interest compounded at 5% until maturity in 2028, at which time a final payment of remaining principal and interest is due. The mortgage is secured by the related real estate and building. As of December 31, 2018 and 2017, the mortgage balance was $1,418 and $1,531, respectively, of which current principal due of $118 and $113, respectively, was included in current portion of long-term debt.

At December 31, 2018, the aggregate future principal payments on our debt arrangements are as follows:

2019	$ 118
2020	124
2021	131
2022	137
2023	20,000
Thereafter	764
	$ 21,274

Interest expense relating to notes payable to Squadron and mortgage note payable with Tawani was $2,255, $2,490 and $1,476 for the years ended December 31, 2018, 2017 and 2016, respectively.

NOTE 7 - STRATEGIC ARRANGEMENTS

Effective December 1, 2007, we entered into a 10 year agreement with Case Western Reserve University ("CASE") to assist in certain aspects of our research and development. Effective August 2, 2017, we entered into an Amended and Restated License Agreement to account for additional licensed product extend the agreement for another ten years. The main focus of this research and development involves leveraging our exclusive rights to the Hamann-Todd Collection of the Cleveland National History Museum, the world's largest pediatric osteological collection, to assist in the design of implants which match pediatric bone curvature and structure.

In exchange for services, CASE receives certain royalties and up-front fees. The royalties and certain fees are contingent upon our obtaining FDA approval and the launch of our products into the marketplace. CASE receives a minimum annual royalty of $10 or a royalty of 3% of net sales on products, whichever is greater. Additionally, for each new product developed, CASE will receive milestone payments of $5 for FDA approval to sell our products within the United States and a milestone payment of $10 for general product launch. Additionally, CASE receives a royalty of 3% of net sales on products fully developed and being sold in the marketplace.

The royalty expense recognized related to the CASE agreement is recorded as a component of cost of revenue and amounted to $145, $148 and $119 for the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018 and 2017, $36 and $37, respectively, was due to CASE.

NOTE 8 - INCOME TAXES

On December 22, 2017, the Tax Cuts and Jobs Act (the Tax Act) was signed into United States tax law. The Tax Act made broad and complex changes to the U.S. tax code, including, but not limited to, (1) reduction of the U.S. federal corporate tax rate from 35 percent to 21 percent; (2) elimination of the corporate alternative minimum tax (AMT); (3) a general elimination of U.S. federal income taxes on dividends from foreign subsidiaries; (4) current inclusion in U.S. federal taxable income of certain earnings of controlled foreign corporations; (5) a new limitation on deductible interest expense; (6) limitations on the deductibility of certain executive compensation; (7) limitations on the use of FTCs to reduce the U.S. income tax liability; and (8) limitations on net operating losses (NOLs) generated after December 31, 2017, to 80 percent of taxable income.

The SEC staff issued SEC Staff Accounting Bulletin No. 118, Income Tax Accounting Implications of the Tax Cuts and Jobs Act (SAB 118), which provides guidance on accounting for the tax effects of the Tax Act. SAB 118 provides a measurement period that should not extend beyond one year from the Tax Act enactment date for companies to complete the accounting under ASC 740, "Income Taxes." In accordance with SAB 118, a company must reflect the income tax effects of those aspects of the Tax Act for which the accounting under ASC 740 is complete. To the extent that a company's accounting for certain income tax effects of the Tax Act is incomplete but it is able to determine a reasonable estimate, it must record a provisional estimate in the financial statements. If a company cannot determine a provisional estimate to be included in the financial statements, it should continue to apply ASC 740 on the basis of the provisions of the laws that were in effect immediately before the enactment of the Tax Act.

The Tax Act reduced the US federal corporate tax rate from a graduated rate up to 35% to a flat rate of 21%, effective January 1, 2018. The Company adjusted its deferred tax assets and liabilities at December 31, 2017 to reflect the Tax Act's reduction of corporate income tax rates which are expected to be in effect in future years as the deferred tax assets and liabilities are realized. The effect of this provisional adjustment in the deferred provision for income taxes is a discrete net expense of $11,095, however this is offset with a reduction in the valuation allowance as of December 31, 2018.

As of December 31, 2018, the Company has completed the accounting for this provision and determined that the amount recognized in 2017 related to the re-measurement of the deferred tax assets and liabilities as a result of the reduced US tax rate was materially correct and no current period adjustments have been recorded.

The components of income tax expense (benefit) for the years ended December 31, 2018, 2017 and 2016 are as follows:

	2018	2017	2016
Deferred:			
Federal	$ (3,663)	$ 8,494	$ (3,184)
State	564	(131)	(477)
	(3,099)	8,363	(3,661)
(Decrease) Increase in valuation allowance	3,099	(8,363)	3,661
Total tax expense	$ —	$ —	$ —

The reconciliation between the effective tax rate and the statutory tax rate is as follows:

	December 31,		
	2018	2017	2016
Federal statutory rate	21.0 %	34.0 %	34.0 %
State statutory rate, net of federal benefit	0.9 %	0.8 %	4.1 %
Effect of foreign rates different from statutory	0.2 %	(0.2)%	— %
Change in state rate	(1.2)%	3.8 %	— %
Change in federal rate (34% to 21%)	— %	(9.8)%	— %
Nondeductible/nontaxable items	4.9 %	(122.2)%	(12.2)%
Change in valuation allowance	(25.8)%	93.6 %	(25.9)%
Income tax expense (benefit)	— %	—%	— %

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The primary temporary differences that give rise to the deferred tax assets and liabilities are certain inventory adjustments, amortization, research and development fees, and net operating loss carryforwards.

The deferred tax assets and liabilities consisted of the following at December 31, 2018 and 2017:

	2018	2017
Deferred tax assets:		
Inventories, net	$ 1,183	$ 1,168
Stock based compensation	443	1,035
Loss carryforwards	22,093	18,523
Credit carryforwards	416	336
Interest carryforward	495	—
Intangibles	134	117
Other	121	105
Total deferred tax assets	24,885	21,284
Valuation allowance	(24,321)	(21,222)
Net deferred tax assets	564	62
Deferred tax liabilities:		
Property, plant and equipment	(564)	(62)
Total deferred tax liabilities	(564)	(62)
Deferred tax assets, net	$ —	$ —

The deferred tax assets were fully offset by a valuation allowance at December 31, 2018 and 2017, and no income tax benefit has been recognized in our consolidated statements of operations for each of the three years in the period ended December 31, 2018. As of December 31, 2018, we had available federal and state tax loss carryforwards of $87,345 and tax credits for federal and state tax purposes of $335. Net operating losses generated prior to December 31, 2017 will begin to expire in 2028. Federal net operating losses generated after January 1, 2018 will have an indefinite carryforward period. An ownership change under Section 382 of the Internal Revenue Code was deemed to occur on May 30, 2014. Given the limitation calculation, we anticipate approximately $16,200 in losses generated prior to the ownership change date will be subject to potential limitation. The estimated annual limitation is $1,062, which is increased by $2,302 over the first five years as a result of an unrealized built in gain. A second ownership change under Section 382 was deemed to occur on December 11, 2018. The estimated annual limitation is $9,736, which is increased by $22,430 over the first five years as a result of an unrealized built in gain. NOLs sustained prior to May 30, 2014 will still be constricted by the lower limitation.

Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. A significant piece of objective negative evidence evaluated was the cumulative loss incurred over the three-year period ended December 31, 2018. Such objective evidence limits the ability to consider other subjective evidence, such as our projections for future growth.

We are subject to taxation in the United States, Indiana and various other state and international jurisdictions. As of December 31, 2018, all tax years from 2010 remain open to examination by the major taxing jurisdictions to

which we are subject due to our net operating loss and credit carryforwards from those years. We believe that the income tax filing positions will be sustained on audit and do not anticipate any adjustments that will result in a material change. Therefore, no reserve for uncertain income tax positions has been recorded. Interest and penalties, if any, associated with income tax examinations will be to record such items as a component of income taxes.

At December 31, 2018, our foreign operations held cash totaling $0.6 million. Except for the nontaxable repayment of intercompany loans, our intent is to permanently reinvest these funds to our U.S. operations. Under the worldwide taxation system in effect prior to the enactment of the Tax Act, US corporate income tax applied to all of a company's income, regardless of whether it was earned in the US or overseas. However, foreign income earned by a foreign subsidiary of a U.S. corporation was generally not taxed until the foreign earnings were repatriated to the US. Enactment of The Tax Act created a territorial tax system under which future dividends of earnings of foreign subsidiaries already subjected to the transition tax under the Act will not be subject to federal income tax, with the exception of foreign exchange rate gains or losses on distributions, capital gains on sale of investment, foreign withholding taxes, and certain state taxes. Based upon the Company's facts and circumstances, no previously accumulated untaxed earnings and profits existed in the foreign jurisdictions, and therefore, the company did not recognize a transition tax liability. The Tax Act also creates a new requirement that Global Intangible Low Taxed Income ("GILTI") earned by controlled foreign corporations ("CFCs") must be included currently in the gross income of the CFCs' U.S. shareholder. GILTI is the excess of the shareholder's "net CFC tested income" over the net deemed tangible income return, which is currently defined as the excess of 1) 10 percent of the aggregate of the U.S. shareholder's pro rata share of the qualified business asset investment of each CFC with respect to which it was a U.S. shareholder over 2) the amount of certain interest expense taken into account in the determination of net CFC-tested income. The company did not have any current foreign earnings and therefore GILTI did not apply for the year ended December 31, 2018. Under US GAAP, we are allowed to make an accounting policy choice of either 1) treating taxes due on future U.S. inclusions in taxable income related to GILTI as a current-period expense when incurred (the "period cost method") or 2) factoring such amounts into a company's measurement of its deferred taxes (the "deferred method"). We have selected the period cost method. As a result, we have not provided deferred taxes related to the temporary differences that upon reversal will affect the amount of income subject to GILTI in the period.

NOTE 9 - STOCKHOLDERS' EQUITY

Stock Options

The fair value for options granted at the time of issuance were estimated at the date of grant using a Black-Scholes options pricing model. Significant assumptions included in the option value model include the fair value of our common stock at the grant date, weighted average volatility, risk-free interest rate, dividend yield and the forfeiture rate. There were no stock options granted in any of the periods presented.

Our stock option activity and related information are summarized as follows:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Terms (in Years)
Outstanding at January 1, 2016	248,871	$ 23.82	3.4
Forfeited or expired	(670)	$ 30.97	
Outstanding at Outstanding at December 31, 2016	248,201	$ 23.81	2.4
Forfeited or expired	(71,242)	$ 9.85	
Outstanding at December 31, 2017	176,959	$ 29.42	2.0
Forfeited or expired	(50,652)	$ 27.61	
Outstanding at Exercised	(14,213)	$ 29.85	
Outstanding at December 31, 2018	112,094	$ 30.32	1.8

Options generally include a time-based vesting schedule permitting the options to vest ratably over three years. At December 31, 2018 and 2017, all options were fully vested.

There was no stock-based compensation expense on stock options for all periods presented.

Restricted Stock

Our restricted stock activity and related information are summarized as follows:

	Restricted Stock	Weighted-Average Remaining Contractual Terms (in Years)
Outstanding at January 1, 2016	593,653	4.3
Granted	89,384	
Forfeited	(5,796)	
Outstanding at December 31, 2016	677,241	3.5
Granted	122,069	
Forfeited	(13,601)	
Outstanding at Vested	(237,704)	
Outstanding at December 31, 2017	548,005	0.3
Granted	178,543	
Forfeited	(1,335)	
Vested	(547,920)	
Outstanding at December 31, 2018	177,293	2.2
Restricted stock exercisable at December 31, 2018	—	

At December 31, 2018, there was $2,771 of unrecognized compensation expense remaining related to our service-based restricted stock awards. The unrecognized compensation cost is expected to be recognized over a weighted average period of 2.2 years. All restricted stock granted prior to May 2014 vested upon our IPO and the remaining grants under the 2007 Plan vested six months after the IPO.

Stock-based compensation expense on restricted stock amounted to $3,185, $3,478 and $1,251 for the years ended December 31, 2018, 2017 and 2016, respectively. Due to our limited operating history and lack of marketability, prior to our IPO, discounts of 15% and 15% were applied when estimating the stock-based compensation for restricted stock awards granted in 2017 and 2016.

An additional $1,986 and $2,000 of stock-based compensation expense was incurred in 2018 and 2017, respectively, due to the accelerated vesting of restricted shares related to our IPO.

Warrants

Our warrant activity and related information are summarized below:

	Warrants	Weighted-Average Exercise Price
Outstanding at January 1, 2016	44,101	$ 27.03
Outstanding at December 31, 2016	44,101	$ 27.03
Outstanding at December 31, 2017	44,101	$ 27.03
Forfeited or expired	(37,311)	$ 26.89
Outstanding at December 31, 2018	6,790	$ 27.81

For all periods presented, the warrants were issued at exercise prices ranging from $26.27 to $30.97 per share. The warrants generally have a 10-year term. No warrants have been exercised during each of the three years in the period ended December 31, 2018. At inception and as of December 31, 2018 and 2017, no fair value was assigned to the warrants.

NOTE 10 – NET LOSS PER SHARE

The following is a reconciliation of basic and diluted net loss per share attributable to common stockholders:

	Year Ended December 31,		
	2018	2017	2016
Net loss	$ (12,025)	$ (8,932)	$ (6,572)
Accretion of cumulative dividends of redeemable preferred stock to redemption value	—	(4,563)	(5,876)
Forfeiture of 50% of Series B Preferred Stock accumulated dividends	—	5,965	—
Series A Preferred Stock preference payment in common stock	—	(16,000)	$ —
Net loss attributable to common stockholders - basic and diluted	$ (12,025)	$ (23,530)	$ (12,448)
Weighted average number of shares - basic and diluted	12,567,387	4,017,330	1,744,356
Net loss per share attributable to common stockholders - basic and diluted	$ (0.96)	$ (5.86)	$ (7.14)

Our basic and diluted net loss per share is computed using the two-class method. The two-class method is an earnings allocation that determines net income per share for each class of common stock and participating securities according to their participation rights in dividends and undistributed earnings or losses. Non-vested restricted stock that includes non-forfeitable rights to dividends are considered participating securities. Series A and B preferred stock include rights to participate in dividends and distributions to common stockholders on an if-converted basis, and accordingly are also considered participating securities. During periods of undistributed losses however, no effect is given to our participating securities since they are not contractually obligated to share in the losses.

Because we have incurred a net loss for all periods presented, diluted net loss per common share is the same as basic net loss per common share. The following contingently issuable and convertible equity shares were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive for all periods presented (shares for the redeemable convertible preferred shares were determined based on the applicable conversation ratio of 1:1):

	Year Ended December 31,		
	2018	2017	2016
Redeemable convertible preferred stock - Series A	—	—	670,000
Redeemable convertible preferred stock - Series B	—	—	2,979,475
Restricted stock	177,293	548,005	677,241
Stock options	112,094	176,959	248,201
Warrants	6,790	44,101	44,101
	296,177	769,065	4,619,018

NOTE 11 – BUSINESS SEGMENT

Operating segments are defined as components of an enterprise for which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. We have one operating and reporting segment, OrthoPediatrics, which designs, develops and markets anatomically appropriate implants and devices for children with orthopedic problems. Our chief operating decision-maker, our Chief Executive Officer, reviews financial information presented on a consolidated basis for purposes of making operating decisions and assessing financial performance, accompanied by disaggregated revenue information by product category. We do not assess the performance of our individual product categories on measures of profit or loss, or other asset-based metrics. Therefore, the information below is presented only for revenue by category and geography.

Product sales attributed to a country or region includes product sales to hospitals, physicians and distributors and is based on the final destination where the products are sold. No individual customer accounted for more than 10% of total product sales for any of the periods presented. No customer accounted for more than 10% of consolidated accounts receivable as of December 31, 2018 or 2017.

Product sales by source were as follows:

Product sales by geographic location:	Year Ended December 31, 2018	2017	2016
U.S.	$ 43,461	$ 34,909	$ 28,839
International	14,098	10,711	8,459
Total	$ 57,559	$ 45,620	$ 37,298

Product sales by category:	Year Ended December 31, 2018	2017	2016
Trauma and deformity	$ 39,695	$ 32,801	$ 26,844
Scoliosis	16,662	11,585	9,349
Sports medicine/other	1,202	1,234	1,105
Total	$ 57,559	$ 45,620	$ 37,298

No individual country with sales originating outside of the United States accounted for more than 10% of consolidated revenue for the years ended December 31, 2018, 2017 and 2016.

NOTE 12 - RELATED PARTY TRANSACTIONS

In addition to the debt and credit agreements and mortgage with Squadron and its affiliate (refer to Note 6), we have used, or currently use, FMI Hansa Medical Products, LLC (“FMI”) and Structure Medical, LLC (“Structure Medical”) as two of our suppliers. Each of these entities is affiliated with Squadron. In 2017, FMI merged with and into Structure Medical. We do not have long-term contracts with either supplier. Our aggregate payments to Structure and FMI were $4,026, $4,081 and $1,769 for the years ended December 31, 2018, 2017 and 2016, respectively.

NOTE 13 - EMPLOYEE BENEFIT PLAN

We have a defined-contribution plan, OrthoPediatrics 401(k) Retirement Plan (the “401(k) Plan”), which includes a cash or deferral (Section 401(k)) arrangement. The 401(k) Plan covers those employees who meet certain eligibility requirements and elect to participate. Employee contributions are limited to the annual amounts permitted under the Internal Revenue Code. The 401(k) Plan allows us to make a discretionary matching contribution. Discretionary matching contributions are determined annually by management. Effective January 1, 2018, we have elected to match our employees' 401(k) contributions up to 3% of employees' salary. For the year ended December 31, 2018, we matched $196 of our employees' 401(k) contributions.

NOTE 14 – COMMITMENTS AND CONTINGENCIES

From time to time, we are involved in various legal proceedings arising in the ordinary course of our business. On January 20, 2017, K2M, Inc. filed suit against us in the United States District Court for the District of Delaware (*K2M, Inc. v. OrthoPediatrics Corp. et al.*, Case No. 1:17-cv-0061) seeking unspecified damages for alleged infringement of U.S. Patent No. 9,532,816. The complaint was amended on August 21, 2017 to add, among other things, a claim of patent infringement regarding U.S. Patent No. 9,655,664. These patents relate to certain instruments used in our RESPONSE™ spine systems, which represent a portion of our total scoliosis portfolio. We have denied these claims and responded with counterclaims seeking declaratory relief that the patents in question are both invalid and not infringed. The parties attended a court-ordered mediation on October 24, 2017, which did not resolve the dispute, but as we move forward with this matter we welcome constructive discussions on a negotiated settlement. Nevertheless, we view our case as particularly strong and will continue to vigorously defend this matter. On January 8 and 22, 2018, we filed our first and second petitions for *inter partes review* ("IPR") with the United States Patent and Trademark Office's Patent Trial and Appeal Board ("PTAB") to challenge the patentability of U.S. Patent No. 9,532,816 (OrthoPediatrics Corp., v. K2M, Inc., *Inter Partes* Case No. IPR2018-00429 and IPR2018-00521). On June 28, 2018, the PTAB instituted the subject IPRs and set a trial date of February 20, 2019 for both IPRs. Due to inclement weather, the subject February 20 hearing was postponed and took place on February 21, 2019. To date, PTAB has not rendered a decision concerning the subject IPRs. Additionally, the parties have agreed to stay the above-referenced district court proceedings pending the outcome of the subject IPR proceedings. The Court ordered the stay on July 10, 2018. Moreover, on August 21, 2018, we

filed three petitions with PTAB to challenge the patentability of the above-referenced U.S. Patent No. 9,655,664 (OrthoPediatrics Corp., v. K2M, Inc., Inter Partes Case Nos. IPR2018-01546, IPR2018-01547, and IPR2018-01548). On February 14 and 22, 2019 PTAB declined to initiate IPR Case Nos. IPR2018-01546 and IPR2018-01547, respectively. Although we believe that the K2M lawsuit is without merit and will vigorously defend the claims asserted against us, intellectual property litigation can involve complex factual and legal questions, and an adverse resolution of this proceeding could have a material adverse effect on our business, operating results and financial condition.

We are not presently a party to any other legal proceedings the outcome of which, if determined adversely to us, would individually or in the aggregate materially affect our financial position or results of operations or cash flows.

As of December 31, 2018, we are contracted to pay royalties to individuals and entities that provide research and development services, which range from 0.5% to 20% of sales. Additionally, we have minimum royalty commitments of $500 annually through 2026.

We have products in development that have milestone payments and royalty commitments. In any development project, there are significant variables that will affect the amount and timing of these payments and as of December 31, 2018, we have not been able to determine the amount and timing of payments. We do not anticipate these future payments will have a material impact on our financial results.

NOTE 15. QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The quarterly financial data presented should be read in conjunction with the consolidated financial statements and related notes.

	Three Months Ended			
	Mar. 31, 2018	Jun. 30, 2018	Sep. 30, 2018	Dec. 31, 2018
Net revenue	$ 12,094	$ 15,077	$ 15,820	$ 14,568
Gross profit	8,919	11,270	11,977	10,514
Operating loss	(4,395)	(2,120)	(1,172)	(1,866)
Net loss	(5,000)	(2,692)	(1,865)	(2,468)
Net loss attributable to common stockholders	(5,000)	(2,692)	(1,865)	(2,468)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.41)	$ (0.21)	$ (0.15)	$ (0.19)

	Three Months Ended			
	Mar. 31, 2017	Jun. 30, 2017	Sep. 30, 2017	Dec. 31, 2017
Net revenue	$ 9,762	$ 11,802	$ 12,375	$ 11,681
Gross profit	7,415	8,712	9,491	8,832
Operating loss	(837)	(677)	(754)	(4,204)
Net loss	(1,285)	(1,266)	(1,536)	(4,845)
Net loss attributable to common stockholders	(2,711)	(2,720)	(3,021)	(15,078)
Net loss per share attributable to common stockholders - basic and diluted	$ (1.55)	$ (1.56)	$ (1.70)	$ (1.41)

NOTE 16. SUBSEQUENT EVENTS

Effective January 1, 2019, we expanded our international operations in Belgium and the Netherlands selling direct to local hospitals.

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

In connection with its audits for the two most recent fiscal years ended December 31, 2018, there have been no disagreements with the Company's independent registered public accounting firm on any matter of accounting principles or practices, financial statement disclosure or audit scope or procedure, nor have there been any changes in accountants.

ITEM 9A. CONTROLS AND PROCEDURES

At the end of the period covered by this report (the "Evaluation Date"), the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of its disclosure controls and procedures pursuant to Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 ("Exchange Act"). Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based upon that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that, as of the Evaluation Date, the Company's disclosure controls and procedures are effective. Disclosure controls and procedures are controls and procedures that are designed to ensure that information required to be disclosed in Company reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms.

Management's Report on Internal Control over 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, and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. 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. Management is responsible for establishing and maintaining adequate internal control over financial reporting for the company.

Management has used the framework set forth in the report entitled Internal Control-Integrated Framework (2013 framework) published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), known as COSO, to evaluate the effectiveness of our internal control over financial reporting. Based

on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2018. For as long as we remain an "emerging growth company" we are exempt from the auditor attestation requirement in the assessment of the effectiveness of our internal control over financial reporting.

There has been no change in 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

None

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

We will provide information that is responsive to this Item 10 regarding executive compensation in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Information About Directors,” “Section 16 (a) Beneficial Ownership Reporting Compliance” and possibly elsewhere therein. That information is incorporated in this Item 10 by reference.

ITEM 11. EXECUTIVE COMPENSATION

We will provide information that is responsive to this Item 11 regarding executive compensation in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Executive Compensation,” and possibly elsewhere therein. That information is incorporated in this Item 11 by reference.

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

We will provide information that is responsive to this Item 12 regarding ownership of securities by certain beneficial owners in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report, in either case under the caption “Security Ownership of Certain Beneficial Owners and Management and Related Stockholders,” and possibly elsewhere therein. That information is incorporated in this Item 12 by reference.

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

We will provide information that is responsive to this Item 13 regarding transactions with related parties and director independence in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this annual report, in either case under the caption “Certain Relationships and Related Transactions,” and possibly elsewhere therein. That information is incorporated in this Item 13 by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

We will provide information that is responsive to this Item 14 regarding principal accounting fees and services in our definitive proxy statement or in an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this annual report, in either case under the caption “Principal Accountant Fees and Services,” and possibly elsewhere therein. That information is incorporated in this Item 14 by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

FINANCIAL INFORMATION

(a) 1. The following financial statements of OrthoPediatrics Corp. are filed as part of this document under Item 8 hereof:

Report of Independent Registered Public Accounting Firm
Consolidated balance sheets at December 31, 2018 and 2017
Consolidated statements of operations, years ended December 31, 2018, 2017 and 2016
Consolidated statements of comprehensive loss, years ended December 31, 2018, 2017 and 2016
Consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit), years ended December 31, 2018, 2017 and 2016
Consolidated statements of cash flows, years ended December 31, 2018, 2017 and 2016
Notes to consolidated financial statements

(a) 2. Financial statement schedules:

All schedules are omitted because they are not applicable or not required, or because the required information is included in the consolidated financial statements or related notes.

(a) 3. Exhibits:

Exhibit No:	Ref	Description of Exhibits:
3.1		Amended and Restated Certificate of Incorporation of OrthoPediatrics Corp. (Incorporated by reference to Exhibit 3.1 of registrant's Form 8-K filed on October 16, 2017) (SEC File No. 001-38242)
3.2		Amended and Restated Bylaws of OrthoPediatrics Corp. (Incorporated by reference to Exhibit 3.2 of registrant's Form 8-K filed on October 16, 2017) (SEC File No. 001-38242)
4.1		Specimen stock certificate evidencing the shares of common stock (Incorporated by reference to Exhibit 4.1 of registrant's Amendment No. 3 to Form S-1 filed on October 2, 2017) (SEC File No. 333-212076)
4.2		Registration Rights Agreement, by and between the registrant and Squadron, dated as of May 30, 2014 (Incorporated by reference to Exhibit 4.2 of registrant's Form S-1 filed on June 16, 2016) (SEC File No. 333-212076)
4.3		First Amendment to Registration Rights Agreement, by and between the registrant and Squadron, dated October 16, 2017 (Incorporated by reference to Exhibit 10.2 of registrant's Form 8-K filed on October 16, 2017) (SEC File No. 001-38242)
4.4		Stockholders Agreement, by and between the registrant and Squadron, dated October 16, 2017 (Incorporated by reference to Exhibit 10.1 of registrant's Form 8-K filed on October 16, 2017) (SEC File No. 001-38242)
10.1		Form of Director and Executive Office Indemnification and Advancement Agreement (Incorporated by reference to Exhibit 10.1 of registrant's Amendment No. 3 to Form S-1 filed on October 2, 2017) (SEC File No. 001-38242)
10.2	*	OrthoPediatrics Corp. Amended and Restated 2007 Equity Incentive Plan (Incorporated by reference to Exhibit 10.2 of registrant's Form S-1 filed on June 16, 2016) (SEC File No. 333-212076)
10.3	*	OrthoPediatrics Corp. 2017 Incentive Award Plan (Incorporated by reference to Exhibit 10.3 of registrant's Amendment No. 3 to Form S-1 filed on October 2, 2017) (SEC File No. 333-212076)
10.4	*	OrthoPediatrics Corp. Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.4 of registrant's Amendment No. 3 to Form S-1 filed on October 2, 2017) (SEC File No. 333-212076)
10.5	*	Employment Agreement, by and between the registrant and Mark C. Throdahl, dated as of July 31, 2014 (Incorporated by reference to Exhibit 10.5 of registrant's Form S-1 filed on June 16, 2016) (SEC File No. 333-212076)
10.6	*	Employment Agreement, by and between the registrant and Fred L. Hite, dated as of February 1, 2015 (Incorporated by reference to Exhibit 10.6 of registrant's Form S-1 filed on June 16, 2016) (SEC File No. 333-212076)
10.7	*	Employment Agreement, by and between the registrant and David R. Bailey, dated as of July 31, 2014 (Incorporated by reference to Exhibit 10.7 of registrant's Form S-1 filed on June 16, 2016) (SEC File No. 333-212076)
10.8	*	Employment Agreement, by and between the registrant and Gregory A. Odle, dated as of July 31, 2014 (Incorporated by reference to Exhibit 10.8 of registrant's Form S-1 filed on June 16, 2016) (SEC File No. 333-212076)
10.9	*	Employment Agreement, by and between the registrant and Daniel J. Gerritzen, dated as of July 31, 2014 (Incorporated by reference to Exhibit 10.9 of registrant's Form S-1 filed on June 16, 2016) (SEC File No. 333-212076)
10.10	*	Form of OrthoPediatrics Corp. Restricted Stock Award Agreement (Incorporated by reference to Exhibit 10.3 of registrant's Form 8-K filed on October 16, 2017) (SEC File No. 001-38242)

10.11		Third Amended and Restated Loan Agreement, by and among the registrant, its subsidiaries and Squadron, dated as of April 26, 2017 (Incorporated by reference to Exhibit 10.10 of registrant's Amendment No. 1 to Form S-3 filed on August 10, 2017) (SEC File No. 333-212076)
10.12		Amended and Restated Term Note A, by and among the registrant, its subsidiaries and Squadron, dated as of April 26, 2017 (Incorporated by reference to Exhibit 10.11 of registrant's Amendment No. 1 to Form S-3 filed on August 10, 2017) (SEC File No. 333-212076)
10.13		Term Note B, by and among the registrant, its subsidiaries and Squadron, dated as of April 26, 2017 (Incorporated by reference to Exhibit 10.12 of registrant's Amendment No. 1 to Form S-3 filed on August 10, 2017) (SEC File No. 333-212076)
10.14		Fourth Amended and Restated Loan Agreement, by and among the registrant, its subsidiaries and Squadron, dated as of December 31, 2017 (Incorporated by reference to Exhibit 10.1 of registrant's Form 8-K filed on January 8, 2018) (SEC File No. 001-38242)
10.15		Second Amended and Restated Term Note A, by and among the registrant, its subsidiaries and Squadron, dated as of December 31, 2017 (Incorporated by reference to Exhibit 10.2 of registrant's Form 8-K filed on January 8, 2018) (SEC File No. 001-38242)
10.16		Revolving Note, by and among the registrant, its subsidiaries and Squadron, dated as of December 31, 2017 (Incorporated by reference to Exhibit 10.3 of registrant's Form 8-K filed on January 8, 2018) (SEC File No. 001-38242)
10.17		Underwriting Agreement between the registrant and the various underwriters named therein, dated December 7, 2018 (Incorporated by reference to Exhibit 1.1 of registrant's Form 8-K filed on December 7, 2018) (SEC File No. 001-38242)
21.1	+	Subsidiaries of the registrant
23.1	+	Consent of Deloitte & Touche LLP, independent registered public accounting firm
24.1	+	Limited Power of Attorney
31.1	+	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	+	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	+	Certifications of Chief Executive Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	+	Certifications of Chief Financial Officer pursuant to 18 U.S.C Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	++	XBRL Instance Document
101.SCH	++	XBRL Taxonomy Extension Schema Document
101.CAL	++	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	++	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	++	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	++	XBRL Taxonomy Extension Presentation Linkbase Document

* Exhibits that describe or evidence management contracts or compensatory plans or arrangements required to be filed as Exhibits to this Report.

+ Exhibits that are filed with this Report (other than through incorporation by reference to other disclosures or exhibits).

++ Furnished and not filed herewith.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15 (d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 7th day of March, 2019.

OrthoPediatrics Corp.

By: /s/ Mark C. Throdahl
Mark C. Throdahl,
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report on Form 10-K has been signed by the following persons on behalf of the registrant and in the capacities indicated, on this 7th day of March, 2019.

/s/ Mark C. Throdahl
Mark C. Throdahl
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Fred L. Hite
Fred L. Hite
Chief Financial Officer
(Principal Financial and Accounting Officer)

*/s/ Terry D. Schlotterback **
Terry D. Schlotterback
Director

*/s/ Bernie B. Berry **
Bernie B. Berry
Director

*/s/ Stephen F. Burns **
Stephen F. Burns
Director

*/s/ Bryan W. Hughes **
Bryan W. Hughes
Director

*/s/ Marie C. Infante **
Marie C. Infante
Director

*/s/ David R. Pelizzon **
David R. Pelizzon
Director

*/s/ Harold Ruf **
Harold Ruf
Director

*/s/ Kevin L. Unger **
Kevin L. Unger
Director

*/s/ Samuel D. Riccitelli **
Samuel D. Riccitelli
Director

* By Daniel J. Gerritzen as Attorney-in Fact pursuant to a Limited Power of Attorney executed by the directors listed above, which Power of Attorney is being filed with the Securities and Exchange Commission as an exhibit hereto.

/s/ Daniel J. Gerritzen

Daniel J. Gerritzen

As Attorney-in-Fact
March 7, 2019

Subsidiaries of OrthoPediatrics Corp.
As of December 31, 2018

Name of Subsidiary	Jurisdiction of Formation
Domestic Subsidiaries:	
OrthoPediatrics US Distribution Corp.	Delaware
International Subsidiaries:	
OrthoPediatrics EU Limited	United Kingdom
OrthoPediatrics AUS PTY LTD	Australia
OrthoPediatrics NZ Limited	New Zealand

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-220973 on Form S-8 and Registration Statement No. 333-228103 on Form S-3 of our report dated March 7, 2019 relating to the financial statements of OrthoPediatrics Corp. appearing in this Annual Report on Form 10-K of OrthoPediatrics Corp. for the year ended December 31, 2018.

/s/ DELOITTE & TOUCHE LLP

Indianapolis, Indiana

March 7, 2019

LIMITED POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS that the undersigned directors and officers of OrthoPediatrics Corp., a Delaware corporation (the "Corporation"), hereby constitute and appoint Fred L. Hite and Daniel J. Gerritzen, or either of them acting singly, as the true and lawful agent and attorney-in-fact of the undersigned with full power and authority in said agent and attorney-in-fact to sign for the undersigned and in their respective names as directors and officers of the Corporation on the Annual Report on Form 10-K of the Corporation to be filed with the Securities and Exchange Commission, Washington, D.C., under the Securities Exchange Act of 1934, as amended, and to sign any amendment to such Annual Report on Form 10-K, hereby ratifying and confirming all acts taken by such agent and attorney-in-fact, as herein authorized.

Dated: March 7, 2019

/s/ Mark C. Throdahl
Mark C. Throdahl
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Fred L. Hite
Fred L. Hite
Chief Financial Officer
(Principal Financial and Accounting Officer)

/s/ Terry D. Schlotterback
Terry D. Schlotterback
Director

/s/ Bernie B. Berry
Bernie B. Berry
Director

/s/ Stephen F. Burns
Stephen F. Burns
Director

/s/ Bryan W. Hughes
Bryan W. Hughes
Director

/s/ Marie C. Infante
Marie C. Infante
Director

/s/ David R. Pelizzon
David R. Pelizzon
Director

/s/ Harold Ruf
Harold Ruf
Director

/s/ Kevin L. Unger
Kevin L. Unger
Director

/s/ Samuel D. Riccitelli
Samuel D. Riccitelli
Director

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark C. Throdahl, certify that:

1. I have reviewed this Annual Report on Form 10-K of OrthoPediatrics Corp.;

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

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

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

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

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

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

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

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

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

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

/s/ Mark C. Throdahl

Mark C. Throdahl
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 7, 2019

CERTIFICATION PURSUANT TO RULE 13a-14(a)/15d-14(a)
OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Fred L. Hite, certify that:

1. I have reviewed this Annual Report on Form 10-K of OrthoPediatrics Corp.;

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

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

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

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

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

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

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

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

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

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

/s/ Fred L. Hite

Fred L. Hite
Chief Financial Officer
(Principal Financial Officer)

Date: March 7, 2019

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of OrthoPediatrics Corp. (the "Company") for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Mark C. Throdahl, President and Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

This certificate is being furnished solely for purposes of Section 906 and is not being filed as part of the Report.

/s/ Mark C. Throdahl

Mark C. Throdahl
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 7, 2019

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of OrthoPediatrics Corp. (the "Company") for the period ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Fred L. Hite, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

This certificate is being furnished solely for purposes of Section 906 and is not being filed as part of the Report.

/s/ Fred L. Hite

Fred L. Hite
Chief Financial Officer
(Principal Financial Officer)

Date: March 7, 2019