
2019
Annual Report
ORTHOFIX MEDICAL INC.
SYDNEY 2000
ORTHOFIX®

Cover photo: Orthofix Spine Patient Laura Wilkinson displays her 2000 Olympic Gold Medal, 2004 World Cup Gold Medal, 2005 World Championship Gold Medal, and other medals.

Orthofix Patient Laura Wilkinson Goes For Olympic Glory Once Again

Laura Wilkinson made history at the 2000 Olympics when she became the first American woman since 1964 to win a Gold Medal in platform diving. Laura continued to make history when she became the first woman to win all three world titles in platform diving (the 2004 World Cup, the 2005 World Championship, and the 2000 Olympic Games).

After she was diagnosed with cervical disc degeneration in 2018, Laura had a successful fusion surgery using an Orthofix cervical plate system to stabilize her spine in combination with the Trinity ELITE™ allograft to aid in bone fusion. During her recovery, Laura wore an Orthofix CervicalStim™ device to stimulate bone growth at the fusion site. After six months of recovery and wearing the CervicalStim device, Laura was deemed fully fused by her physician. Soon she was back in the water and proceeded to secure a spot to compete during the Olympic trials.

Orthofix is a proud sponsor of Laura's quest for the Summer Olympics in Tokyo, now postponed to summer 2021.

Letter to our shareholders

Jon Serbousek

I write this letter to you in the midst of the global health crisis of COVID-19. I am hopeful that by the time you receive it, we will have started to "flatten the curve" to bring COVID-19 under control. We here at Orthofix are working hard to ensure patients and health care providers continue to receive the highest quality products and service they need, when they need them. We are doing so while working to keep our employees and communities safe. Although Orthofix is well positioned financially, this is an unprecedented challenge for all of us in the medical device industry. Orthofix has been in existence for 40 years, we are resilient, and we are dedicated to improving the lives of patients around the world.

After joining Orthofix in August 2019, I spent a significant amount of time talking with our global teams, as well as with our many surgeon customers, distributor partners, and hospital advisors. As a result of these conversations, and despite the COVID-19 challenges, I am even more enthusiastic today about the opportunity in front of us than when I first joined the company.

Prior to 2018, Orthofix was organized into four divisions focused on specialty groups. In mid-2018 under the prior leadership, Orthofix initiated a reorganization into two businesses. This initiative realigned the legacy businesses of Bone Growth Therapies, Biologics, Spinal Implants, and Motion Preservation into a single Global Spine business unit while maintaining the structure of our Global Extremities business. The goal of this reorganization was to centralize and align the company in order to better leverage our products and solutions across our businesses and present ourselves more effectively to our unique Spine and Extremity customers. Orthofix started on this journey two years ago, positioning itself for the future. The company began this journey with the successful acquisition and integration of Spinal Kinetics in 2018, followed by the U.S. Food and Drug Administration (FDA) approval of the M6-C™ artificial cervical disc in 2019. I am honored to assume the role of Orthofix's President and CEO and excited at the opportunity to continue shaping the future of this great company. In 2020 and the years ahead, I look forward to capitalizing on the investments we are making now.

A Winning Product Portfolio

First and foremost, we currently have well-defined market and technology leadership positions in bone growth stimulation therapies, cellular-based allografts, artificial disc replacement, and extremity deformity correction products. There is opportunity for us to enhance and build around these strong offerings. Additionally, we have the most comprehensive offering of cervical spine solutions, and with the recently announced acquisition of the FITBONE® intramedullary lengthening system, we will be the only company offering both internal and external limb-lengthening options. Collectively, these are impressive positions for a company our size.

Apart from our product and technology strengths, the talented team at Orthofix has done a great job creating a solid business foundation from which we can grow. With our strong infrastructure, legal, finance, accounting, order-to-cash, and compliance programs, Orthofix is well positioned to build and execute commercially.

Transformation

In 2020, we have embarked on an ambitious strategic plan—our road map for business transformation. Our plan is not to change where we are going, but how we will do it. While this transformation won't happen overnight, our strategic plan is built around four pillars that we believe will accelerate our growth and take Orthofix to the next level:

- Structure and Leadership
- Operational Execution
- Product Innovation and Differentiation
- Commercial Channel Development

Structure and Leadership

The Orthofix of today is strongly aligned around the two platforms mentioned above that will propel us forward: Spine and Extremities. These businesses share many strategic leverage points, enabling us to maximize revenues across our entire organization.

While Orthofix continued to deliver on our commitment to bringing innovative products to the market in 2019, I want to acknowledge that we did not fully deliver on our growth expectations last year. Our sales growth was lower than expected due to a number of factors, but two of the primary limitations were the distraction from the CEO transition combined with key leadership departures in the Spine business. As a result, we experienced a great deal of organizational uncertainty and lacked a clear path forward. Filling some of the vacancies and adding to our talented leadership team has been a key focus for me since I arrived at Orthofix, and I am

"All of our patients may not be Olympic Gold Medalists like Laura Wilkinson, but we're proud to help them on their journeys."

very pleased with the progress we have made in this area. I firmly believe that investing in the people who work in our business and on our technologies is just as important as investing in the technology itself. Today we have enhanced our expertise and solidified our leadership team by bringing on seasoned executives that we believe will give us a huge advantage in the marketplace. Combining these new additions and roles with the existing strong Orthofix talent will position us for success, and I look forward to this team coalescing as we execute commercially.

Operational Execution

Operational execution for Orthofix means we will work hard to ensure that we are providing our high-quality products and tissues to our customers WHEN they want it and HOW they want it. The WHEN entails optimizing our supply chain, and the HOW will be driven by being more focused on our customers' needs. We are creating the view that everyone at Orthofix owns the total customer experience. This will have benefits not only near term, but down the road as we work to create an agile, competitive culture focused on flawless execution and winning.

Product Innovation and Differentiation

It is easy to talk about new product innovation but executing on these initiatives requires a focused plan. There are market trends today that are creating unmet needs that require solutions. We are going to be laser focused on both developing and acquiring high-value products and procedural solutions that solve these unmet needs.

As we focus on accelerating our new product innovation cycle, we will also invest in our Clinical and Regulatory execution with the launch of our M6-C artificial cervical disc two-level study to expand our future market opportunity. Post-market studies in our Spine and Extremities businesses are also planned.

On the inorganic front, we will continue to be disciplined acquirers of assets that are strong strategic fits that we can purchase at a reasonable price, thereby adding significant value. As mentioned above, we started 2020 with a targeted acquisition of the FITBONE intramedullary lengthening system for limb lengthening of the femur and tibia bones. Additionally, this transaction brings other potential applications of the technology, which are in development, including the FITSPINE® system for early onset scoliosis.

Both our acquisitions of Spinal Kinetics and the FITBONE technology are good examples of the types of deals that we are looking to execute on. In both cases, we acquired differentiated products that strengthen our portfolio and represent areas where Orthofix can add substantial value to the market. We believe that both of these acquisitions will drive revenue growth in the future.

Commercial Channel Development

With the leadership teams we have recently created in both the Spine and Extremity businesses, we intend to transform and invest in our Commercial Channels. Over the next 24 months and beyond, we will focus on adding or developing long-term, strategic sales partners. These partners will share in our vision for differentiation and growth and sell multiple Orthofix product lines. This will enable us to realize inherent synergies across our product lines and realize sustained growth. The fundamental thread to our sales partners is that we will be highly aligned to collectively grow our businesses together over the long-term.

The Path Forward

Our global team has a unified vision for the future. We have set a course to strengthen our core businesses and better serve our customers. Orthofix already has a strong margin profile for its size and scale. By investing to accelerate our organic growth rate and achieving scale in our businesses, we see a pathway to ultimately produce higher margins and free cash flow generation three to five years down the road.

On behalf of the Board of Directors and all of us at Orthofix, we thank our shareholders for the continued support and trust you place in us. Together, we will continue to grow the business for a successful future.

I would also like to thank all of our Orthofix team members for their strong work ethic through a year of change, and during the current period of uncertainty around the globe. Whether working directly with products, customers or patients, or supporting our business in other ways, our team makes it possible for Orthofix to improve the lives of patients around the world. The future for Orthofix is bright.

Sincerely,

Jon Serbousek
President and Chief Executive Officer
Orthofix Medical Inc.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2019

or

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

For the transition period from _____ to _____.

Commission File Number: 0-19961

ORTHOFIX MEDICAL INC.

(Exact name of registrant as specified in its charter)

Delaware	**98-1340767**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3451 Plano Parkway, Lewisville, Texas	**75056**
(Address of principal executive offices)	**(Zip Code)**

(214) 937-2000

(Registrant's telephone number, including area code)

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

Common Stock, $0.10 par value	**OFIX**	**Nasdaq Global Select Market**
(Title of Class)	**(Trading Symbol)**	**(Name of Exchange on Which Registered)**

Securities registered pursuant to Section 12(g) of the Act: None

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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	☐	Emerging Growth Company	☐
Non-accelerated filer	☐	Smaller reporting company	☐		

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

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

The aggregate market value of registrant's common stock held by non-affiliates, based upon the closing price of the common stock on the last business day of the fiscal quarter ended June 30, 2019, as reported by the Nasdaq Global Select Market, was approximately $995.8 million.

As of February 20, 2020, 19,179,120 shares of common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain sections of the registrant's definitive proxy statement to be filed with the Commission in connection with the Orthofix Medical Inc. 2020 Annual General Meeting of Shareholders are incorporated by reference in Part III of this Annual Report.

Orthofix Medical Inc.

Form 10-K for the Year Ended December 31, 2019
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Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended ("the Exchange Act"), and Section 27A of the Securities Act of 1933, as amended, relating to our business and financial outlook, which are based on our current beliefs, assumptions, expectations, estimates, forecasts and projections. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "projects," "intends," "predicts," "potential," or "continue" or other comparable terminology. These forward-looking statements are not guarantees of our future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict, including the risks described in Part I, Item 1A, "Risk Factors." Therefore, our actual outcomes and results may differ materially from those expressed in these forward-looking statements. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to further update any such statement, to reflect new information, the occurrence of future events or circumstances or otherwise.

Trademarks

Solely for convenience, our trademarks and trade names in this Annual Report are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that we will not assert, to the fullest extent under applicable law, our rights thereto.

PART I

Item 1. Business

In this Annual Report, the terms "we," "us," "our," "Orthofix," "the Company" and "our Company" refer to the combined operations of Orthofix Medical Inc. and its consolidated subsidiaries and affiliates, unless the context requires otherwise.

Company Overview

We are a global medical device company focused on musculoskeletal products and therapies. Our mission is to improve patients' lives by providing superior reconstruction and regenerative musculoskeletal solutions to physicians worldwide. Headquartered in Lewisville, Texas, our spine and orthopedic extremities products are distributed in more than seventy countries via our sales representatives and distributors.

We have administrative and training facilities in the United States ("U.S."), Italy, Brazil, the United Kingdom ("U.K."), France, and Germany, and manufacturing facilities in the U.S. and Italy. We directly distribute products in the U.S., Italy, the U.K., Germany, and France. In several of these and other markets, we also distribute our products through independent distributors.

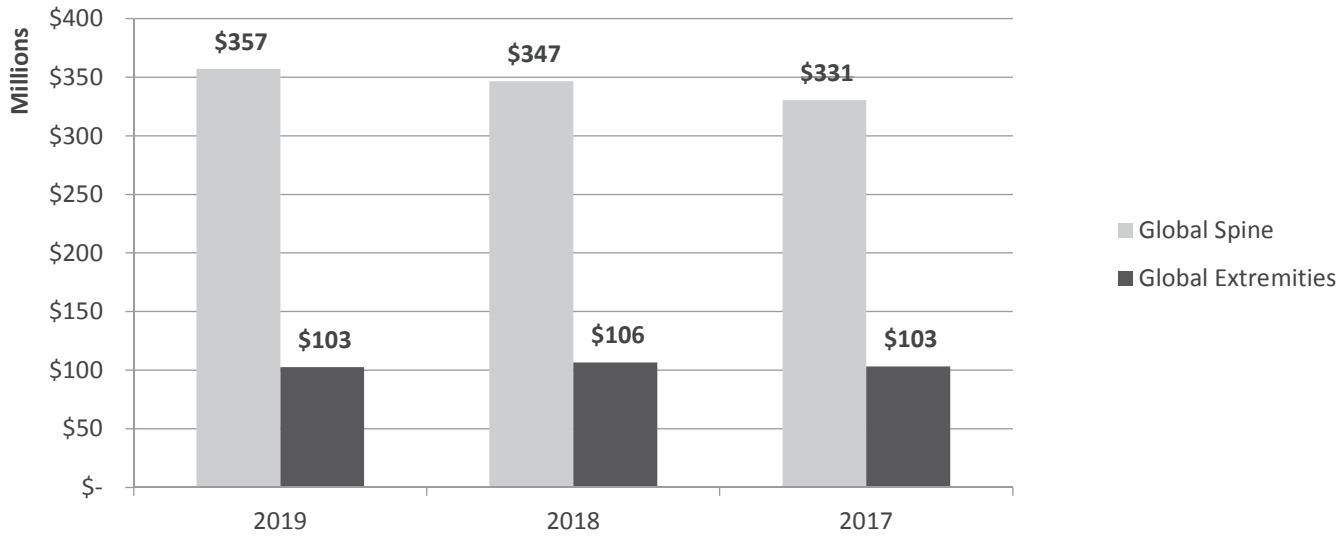
The Company originally was formed in 1987 in Curaçao and is now a corporation operating under the laws of the State of Delaware. In 2018, the Company completed a change in its jurisdiction of organization from Curaçao to the State of Delaware and changed its name to "Orthofix Medical Inc."

Available Information and Orthofix Website

Our filings with the Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Annual Proxy Statement on Schedule 14A, any registration statements, and amendments to those reports, are available free of charge on our website as soon as reasonably practicable after they are filed with, or furnished to, the SEC. Information on our website or connected to our website is not incorporated by reference into this Annual Report. Our website is located at www.orthofix.com. Our SEC filings are also available on the SEC website at www.sec.gov.

Business Segments

We manage our business by our two reporting segments, Global Spine and Global Extremities, which accounted for 78% and 22%, respectively, of our total net sales in 2019. The chart below presents net sales, which includes product sales and marketing service fees, by reporting segment for each of the years ended December 31, 2019, 2018, and 2017.



Financial information regarding our reportable business segments and certain geographic information is included in Part II, Item 7 of this Annual Report under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," and Note 15 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Global Spine

The Global Spine reporting segment is largely represented by three product categories, i) Bone Growth Therapies, ii) Spinal Implants, and iii) Biologics. Our strategies within the Global Spine reporting segment for each of these product categories, and the principal products within each of these categories, are described below in further detail:

Bone Growth Therapies

Within the Bone Growth Therapies product category of the Global Spine reporting segment, we manufacture, distribute, and provide support services for market-leading bone growth stimulation devices that enhance bone fusion. These class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in the cervical and lumbar spine as well as a therapeutic treatment for non-spinal, appendicular fractures that have not healed (nonunions). These devices utilize Orthofix's patented pulsed electromagnetic field ("PEMF") technology, the safety and efficacy of which is supported by basic mechanism of action data in the scientific literature, as well as published data from level one randomized controlled clinical trials. The devices are compatible with the STIM onTrack mobile application, which includes a first-to-market feature that enables physicians to remotely view and assess patient adherence to treatment protocols and patient reported outcome measures. We currently have research and a clinical study underway to identify potential clinical indications for treating rotator cuff tears. We sell our Bone Growth Therapies products almost exclusively in the U.S. using distributors and direct sales representatives to sell and deliver our devices to hospitals, healthcare providers, and patients.

Bone Growth Therapies Strategy

Our strategy for the Bone Growth Therapies product category is to expand patient access to bone growth therapy devices that deliver noninvasive treatment for promoting healing in fractured bones and spinal fusions. Our key strategies in this product category are to:

- Promote competitive advantages of our recently launched products and STIM onTrack mobile app
- Support adoption and reimbursement with:
    - North American Spine Society's ("NASS") Coverage Policy Recommendation
    - Post-market clinical research
- Continue to invest in expanding our sales force
- Bring to market new PEMF products addressing unmet clinical needs

Bone Growth Therapies Products

The following table and discussion identify our principal Bone Growth Therapies products by trade name and describe their primary applications:

Product	Primary Application
CervicalStim Spinal Fusion Therapy	PEMF non-invasive cervical spinal fusion therapy used to enhance bone growth
SpinalStim Spinal Fusion Therapy	PEMF non-invasive lumbar spinal fusion therapy used to enhance bone growth
PhysioStim Bone Healing Therapy	PEMF non-invasive appendicular skeleton healing therapy used to enhance bone growth in nonunion fractures

Spinal Therapy

Our bone growth therapy devices used in spinal applications are designed to enhance bone growth and the success rate of certain spinal fusions by stimulating the body's own natural healing mechanism post-surgically. These non-invasive portable devices are intended to be used as part of a home treatment program prescribed by a physician.

We offer two spinal fusion therapy devices: the SpinalStim and CervicalStim devices. Our stimulation products use a PEMF technology designed to enhance the growth of bone tissue following surgery and are placed externally over the site to be healed. Research data shows that our PEMF signal induces mineralization and results in a process that stimulates new regeneration at the spinal fusion site. Some spine fusion patients are at greater risk of not achieving a solid fusion of new bone around the fusion site. These patients typically have one or more risk factors such as smoking, obesity, or diabetes, or their surgery involves the revision of a failed fusion or the fusion of multiple levels of vertebrae in one procedure. For these patients, post-surgical bone growth therapy has been shown to significantly increase the probability of fusion success.

The SpinalStim device is a non-invasive spinal fusion stimulator system that has been commercially available in the U.S. since 1990. It is designed for the treatment of the lumbar region of the spine. The device uses proprietary technology and a wavelength to generate a PEMF signal. The U.S. Food and Drug Administration (the "FDA") has approved the SpinalStim system as a spinal fusion adjunct to increase the probability of fusion success and as a non-operative treatment for salvage of failed spinal fusion at least nine months post-operatively.

Our CervicalStim product remains the only FDA-approved bone growth stimulator on the market indicated for use as an adjunct to cervical spine fusion surgery in patients at high-risk for non-fusion. The FDA approved this device in 2004 and it has been commercially available in the U.S. since 2005.

In 2016, the NASS issued first-of-its-kind coverage recommendations for electrical bone growth stimulators. These evidence-based coverage policy recommendations support the use of PEMF devices as an adjunct to spinal fusion surgery in high-risk patients. The NASS coverage policy recommends coverage of the use of electrical stimulation for spinal fusion healing in all regions of the spine, including cervical and lumbar regions. The validation of PEMF electrical stimulation from this leading surgical society has and is expected to continue to further support our efforts to expand the availability and use of the therapy to the many patients who can benefit from it.

In 2017, we announced FDA and European Commission CE mark approval for our next-generation SpinalStim and CervicalStim bone growth stimulators. The CervicalStim and SpinalStim systems available in the U.S. are accompanied by a new application for mobile devices called STIM onTrack. The mobile app includes a first-to-market feature that enables physicians to remotely view patient adherence to prescribed treatment protocols and patient reported outcome measures. Designed for use with smartphones and other mobile devices, the STIM onTrack tool helps patients follow their prescription with daily treatment reminders and a device usage calendar. The app is free and available through the iTunes App Store. In addition to the app, the next-generation bone growth stimulators include patient enhancements aimed at improving fit, comfort, and ease of use.

Orthopedic Therapy

Our PhysioStim bone healing therapy products use PEMF technology similar to that used in our spine stimulators. The primary difference is that the PhysioStim devices are designed for use on the appendicular skeleton.

A bone's regenerative power results in most fractures healing naturally within a few months. However, in the presence of certain risk factors, some fractures do not heal or heal slowly, resulting in "nonunions." Traditionally, orthopedists have treated such nonunion conditions surgically, often by means of a bone graft with fracture fixation devices, such as bone plates, screws, or intramedullary rods. These are examples of "invasive" treatments. Our patented PhysioStim bone healing therapy products are designed to use a low level of PEMF signals to noninvasively activate the body's natural healing process. The devices are anatomically designed, allowing ease of placement, patient mobility, and the ability to cover a large treatment area.

In 2018, we announced the FDA and European Commission CE mark approval for our next-generation PhysioStim bone growth stimulator. Similar to the next-generation CervicalStim and SpinalStim systems, the PhysioStim device is also accompanied by the STIM onTrack mobile app, enabling physicians treating patients with nonunion fractures to remotely view and assess patient adherence to prescribed treatment protocols and patient reported outcome measures. In addition to the app, the next-generation PhysioStim devices also include patient enhancements aimed at improving fit, comfort, and ease of use.

Future Applications

We have sponsored research at the University of Pennsylvania, Cleveland Clinic, New York University, and University of California San Francisco, where scientists conducted animal and cellular studies to identify the mechanisms of action of our PEMF signals on bone and tendon and efficacy of healing. From these efforts, many studies have been published in peer-reviewed journals. Among other insights, the studies illustrate positive effects of PEMF on callus formation and bone strength as well as proliferation and

differentiation of cells involved in regeneration and healing. Furthermore, we believe that the research work with Cleveland Clinic and the University of Pennsylvania, allowing for characterization and visualization of the Orthofix PEMF waveform, is paving the way for signal optimization for a variety of new applications and indications. This collection of pre-clinical data, along with additional clinical data, could represent new clinical indication opportunities for our regenerative stimulation solutions.

Spinal Implants

Within the Spinal Implants product category of the Global Spine reporting segment, we design, develop and market a portfolio of motion preservation and fixation implant products used in surgical procedures of the spine. We distribute these products globally through a network of distributors and sales representatives to sell spine products to hospitals and healthcare providers.

Spinal Implants Strategy

Our vision for the Spinal Implants product category is to become a first choice for surgeons, healthcare providers, and payers by demonstrating strength in partnership. Our key strategies in this product category are:

- Accelerate training and market acceptance in the U.S. for our M6-C artificial cervical disc
- Continue creating differentiated products
- Provide exceptional training and education programs for sales representatives and surgeons
- Acquire or license products, technologies and companies to further expand the Spinal Implants portfolio

Spinal Implants Products

The following table and discussion identify our key Spinal Implants products by trade name and describe their primary applications:

Product	Primary Application
M6-C Artificial Cervical Disc	A next-generation artificial disc developed to replace an intervertebral disc damaged by cervical disc degeneration; the only artificial cervical disc that mimics the anatomic structure of a natural disc by incorporating an artificial viscoelastic nucleus and fiber annulus into its design
M6-L Artificial Lumbar Disc	A next-generation artificial disc developed to replace an intervertebral disc damaged by lumbar disc degeneration; the only artificial lumbar disc that mimics the anatomic structure of a natural disc by incorporating an artificial viscoelastic nucleus and fiber annulus into its design
FORZA XP Expandable Spacer System	A titanium expandable spacer system for Posterior Lumbar Interbody Fusion (“PLIF”) and Transforaminal Lumbar Interbody Fusion (“TLIF”) procedures featuring a large graft window with the ability to pack post expansion in situ
CETRA Anterior Cervical Plate System	An anterior cervical plate system offering a low profile plate with an intuitive locking mechanism, large graft windows, a high degree of screw angulation, and simplified instrumentation
CONSTRUX Mini PEEK / Titanium Composite (“PTC”) Spacer System	A cervical interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a Polyetheretherketones (“PEEK”) core to maintain imaging characteristics
FORZA PTC Spacer System	A posterior lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics
PILLAR SA PTC PEEK Spacer System	A standalone Anterior Lumbar Interbody Fusion (“ALIF”) lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics

Product	Primary Application
FIREBIRD / FIREBIRD NXG Spinal Fixation System	A system of rods, crossbars, and modular pedicle screws designed to be implanted during a posterior lumbar spine fusion procedure
JANUS Midline Fixation Screw	An addition to the Firebird Spinal Fixation System designed to achieve more cortical bone purchase in the medial to lateral trajectory, when compared to traditional pedicle screws, and that provides surgeons with the option of a midline approach
Connector System for revisions	A comprehensive system to reduce the complexity of revising and extending existing spinal constructs; this eliminates the need to remove existing hardware while providing stability at adjacent levels
CENTURION Posterior Occipital Cervico-Thoracic ("POCT") System	A multiple component system comprised of a variety of non-sterile, single use components made of titanium alloy or cobalt chrome that allow the surgeon to build a spinal implant construct
FIREBIRD SI	A minimally invasive screw system that is intended for fixation of sacroiliac joint disruptions in skeletally mature patients
FIREBIRD Deformity Correction System	An extension to the Firebird Spinal Fixation System that provides additional instrument and implant options for complex thoracolumbar spine procedures
PHOENIX Minimally Invasive Spinal Fixation System	A multi-axial extended reduction screw body used with the Firebird Spinal Fixation System designed to be implanted during a posterior thoracolumbar spine fusion procedure
LONESTAR Cervical Stand Alone ("CSA")	A stand-alone spacer system designed to provide the biomechanical strength to a traditional or minimal invasive Anterior Cervical Discectomy and Fusion ("ACDF") procedure with less disruption of patient anatomy and to preserve the anatomical profile
SKYHAWK Lateral Interbody Fusion System & Lateral Plate System	Provides a complete solution for the surgeon to perform a Lateral Lumbar Interbody Fusion, an approach to spinal fusion in which the surgeon accesses the intervertebral disc space using a surgical approach from the patient's side that disturbs fewer structures and tissues
FORZA Spacer System	PEEK interbody devices for PLIF and TLIF procedures

Motion Preservation Solutions

In 2018, we acquired Spinal Kinetics Inc., a privately held developer and manufacturer of artificial cervical and lumbar discs, namely the M6-C cervical and M6-L lumbar artificial discs, which are used to treat patients suffering from degenerative disc disease of the spine. The M6 discs are the only artificial discs that mimic the anatomic structure of a natural disc by incorporating an artificial viscoelastic nucleus and fiber annulus into their design. Like a natural disc, this unique construct allows for shock absorption at the implanted level, as well as provides a controlled range of motion when the spine transitions in its combined complex movements. Both discs have European Commission CE mark approval and prior to 2019, had historically been exclusively distributed outside the U.S. In February 2019, we received FDA approval of the M6-C artificial cervical disc to treat patients with cervical disc degeneration. We released the M6-C artificial cervical disc in the U.S. in 2019 through a controlled market launch accompanied by an extensive training and education curriculum for surgeons. As of December 31, 2019, we have recorded $4.1 million in motion preservation sales within the U.S. market. In addition, we are in the planning phase of a 2-level investigational device exemption study for the M6-C artificial cervical disc, which we plan to initiate in 2020.

Spinal Repair Solutions

We provide a wide array of implants designed for use primarily in cervical, thoracic, and lumbar fusion surgeries. These implants are made of either metal or a thermoplastic compound called PEEK. The majority of the implants that we offer are made of titanium metal. The Spinal Fixation System, the Firebird Spinal Fixation System, the Phoenix Minimally Invasive Spinal Fixation System, the Ascent, Ascent LE, and the Centurion POCT Systems are sets of rods, cross connectors and screws that are implanted during

posterior fusion procedures. The Firebird Modular and pre-assembled Spinal Fixation Systems are designed to be used in either open or minimally-invasive posterior lumbar fusion procedures with our ProView MAP System. To complement our plates, rods and screw fixation options we offer an entire portfolio of cervical and thoracolumbar PEEK interbody devices within our Pillar and Forza product lines. This interbody portfolio includes two stand-alone devices, Lonestar and Pillar SA, as well as the Construx Mini PTC system, a novel titanium composite spacer, which offers a superior alternative to other plasma spray coated options currently available on the market. We also offer specialty plates and screws that are used in less common procedures, and as such, are not manufactured by many device makers.

Biologics

Within the Biologics product category of the Global Spine reporting segment, we provide a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This product category specializes in the marketing of regeneration tissue forms and distributes MTF Biologics ("MTF") tissues to hospitals and healthcare providers, primarily in the U.S., through a network of independent distributors and sales representatives. Our partnership with MTF allows us to exclusively market the Trinity ELITE and Trinity Evolution tissue forms for musculoskeletal defects to enhance bony fusion.

Biologics Strategy

In order to drive further adoption and use of our products, our strategy for the Biologics product category is to educate physicians, both directly and through our sales force, of the surgical and patient benefits of using our portfolio of regenerative tissues and products to augment their surgical procedures and results. Our key strategies in this product category are to:

- Leverage sales channels of our spine and extremities businesses to expand coverage
- Continue to leverage the surgeon-preferred Trinity ELITE characteristics and clinical evidence
- Continue to expand and promote the breadth of the portfolio with offerings such as fiberFUSE
- Accelerate new tissue development projects with MTF

Biologics Products

The following table and discussion identify the principal Biologics products by trade name and describe their primary applications:

Product	Primary Application
Trinity ELITE	A fully moldable allograft with viable cells used during surgery that is designed to enhance the success of a spinal fusion or bone fusion procedure
Trinity Evolution	An allograft with viable cells used during surgery that is designed to enhance the success of a spinal fusion or bone fusion procedure
AlloQuent Structural Allografts	Interbody devices made of cortical bone (or cortical-cancellous grafts) that are designed to restore the space that has been lost between two or more vertebrae due to a degenerated disc during a spinal fusion procedure
Collage Synthetic Osteoconductive Scaffold	A synthetic bone void filler
fiberFUSE	An allograft comprised of a mixture of cancellous bone and demineralized cortical bone that creates a natural scaffold for revascularization, cellular ingrowth, and new bone formation
VersaShield	A thin hydrophilic amniotic membrane designed to serve as a wound or tissue covering for a variety of surgical demands

The regenerative solutions offered as part of the Biologics product category's portfolio include solutions for a variety of musculoskeletal defects used in spinal and extremity orthopedic procedures.

Regenerative Solutions

The premier biologics tissues we market include the Trinity ELITE and Trinity Evolution tissue forms, which are cortical cancellous allografts that contain viable cells and are used during surgery in the treatment of musculoskeletal defects for bone reconstruction and repair. These allografts are intended to offer a viable alternative to an autograft procedure, as harvesting autograft has been shown to add risk of an additional surgical procedure and related patient discomfort in conjunction with a repair surgery.

To provide structural support and facilitate bone growth in spine fusion procedures, we offer a full line of AlloQuent allograft structural spacers derived from human cadaveric bone. These spacers are used to restore the height lost between vertebral bodies when discs are removed in fusion procedures and to facilitate spine fusion.

We offer the Collage product as an osteoconductive scaffold and a bone graft substitute product. The product is a combination synthetic bone graft substitute comprised of beta tri-calcium phosphate and type 1 bovine collagen.

The fiberFUSE tissue is the newest biologics tissue form with handling characteristics analogous to Trinity ELITE and expands the offering to address a broader scope of surgical applications. This tissue offering was developed by MTF in close collaboration to expand the Orthofix portfolio and provides an opportunity to serve a great number of clinical indications addressed by surgeons.

We also market the VersaShield tissue form, a thin hydrophilic amniotic membrane designed to serve as a wound or tissue covering for a variety of surgical demands. Amniotic tissue forms derived from donated human placenta are used in a wide variety of applications and are valued for their healing properties, scar reduction and anti-adhesion characteristics. The VersaShield tissue is derived from the human placental layers, amnion and chorion, thin elastic membranes that allow the tissue to conform to the surface of the surgical site.

We receive marketing fees through our collaboration with MTF for the Trinity ELITE, Trinity Evolution, fiberFUSE, and VersaShield tissues. MTF processes the tissues, maintains inventory, and invoices hospitals and surgery centers and other points of care for service fees, which are submitted by customers via purchase orders. We have exclusive worldwide rights to market the Trinity ELITE and Trinity Evolution tissue forms. We market the VersaShield tissue under a private label brand via a non-exclusive marketing agreement for the tissue form.

To date, our Biologics products are offered primarily in the U.S. market due in part to restrictions on providing U.S. human donor tissue in other countries.

Global Extremities

The Global Extremities reporting segment offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This reporting segment specializes in the design, development, and marketing of the Company's orthopedic products used in fracture repair, deformity correction, and bone reconstruction procedures. We distribute these products through a global network of distributors and sales representatives to sell our orthopedic products to hospitals and healthcare providers.

Global Extremities Strategy

Our strategy for the Global Extremities reporting segment is to continue to provide highly valued external and internal temporary to definitive fixation devices used in fracture repair, deformity correction, and bone reconstruction. Our key strategies in this segment are:

- Geographic market & product focus on:
    - Pediatrics & deformity correction worldwide
    - Foot & ankle in the U.S.
    - Trauma in selected geographies
- Promote the advantages of our JuniOrtho pediatric portfolio and support tools
- Leverage the market acceptance of the TL-Hex platform
- Close on the FITBONE asset acquisition transaction and Integrate the FITBONE business

- Continue the strong pace of new product launches
- Acquire or license products, technologies and companies to support these market opportunities.

Global Extremities Products

The following table and discussion identify the principal Global Extremities products by trade name and describe their primary applications:

Product	Primary Application
External Fixator	External fixation and internal fixation, including the Sheffield Ring, limb-lengthening systems, DAF, ProCallus, XCaliber and Gotfried P.C.C.P
Eight-Plate + Guided Growth System	The 2nd generation plate for treatment for bowed legs or knock knees of children
LRS Advanced Limb Reconstruction System	External fixation for limb lengthening and corrections of deformity
TrueLok	Ring fixation system for trauma, limb lengthening, and deformity correction
TL-HEX TrueLok Hexapod System ("TL-HEX")	Hexapod external fixation system for trauma and deformity correction with associated software
HEX RAY	An innovative software to manage pre-operation and post-operation planning in connection with the TL-HEX system
Galaxy Fixation System	External fixation system for temporary and definitive fracture fixation, including anatomical specific clamps
VeroNail Trochanteric Nailing System	Trochanteric titanium nailing system for hip fractures
Centronail Titanium Nailing System	Complete range of intramedullary nails including the Humeral Nail
Ankle Hind Foot Nailing System ("AHN")	An extension of the Centronail range of intramedullary nails
Chimaera Hip Fracture System	A strong, versatile hip nail that allows fixation to be adapted to the type of fracture being treated
Agile Nail	A small rigid intramedullary nail to treat adolescent patients
MJ FLEX	An innovative elastic nail with a unique design to be used in pediatric patients
OSCAR	Ultrasonic bone cement removal
Ankle Hindfoot Nail ("AHN")	A differentiated solution for hindfoot fusions
Contours Lapidus Plating System ("LPS")	A plate design contoured specifically for a tarsometatarsal ("TMT") fusion
Contours VPS Volar Plating System III	The 3rd generation of plates to treat distal radius fractures
RIVAL Foot & Ankle System	A comprehensive offering of foot and ankle solutions across the range of two plating lines, Rival VIEW and Rival REDUCE, accompanied by Rival BITE, an extensive portfolio of headed cannulated and headless compression screws

We provide internal and external fixation solutions for extremity repair and deformity correction, both for adults and children. Our fracture repair products consist of fixation devices designed to stabilize a broken bone until it can heal. With these devices, we can treat simple and complex fracture patterns, along with achieving deformity corrections.

External Fixation

External fixation devices are used to stabilize fractures and offer an ideal treatment for complex fractures, fractures near the joints, and in patients with known risk factors or co-morbidities. The treatment method entails the use of bone screws and/or wires which are inserted percutaneously into the bone and stabilized with an external device. The treatment is minimally invasive and allows external manipulation of the bone to obtain and maintain final bone alignment (reduction). The bone is fixed in this way until healing. External fixation devices may also be used temporarily in complex trauma cases to stabilize the fracture prior to treating it definitively. In these situations, the device offers rapid fracture stabilization, which is important in life saving as well as limb salvage procedures.

The Galaxy Fixation System is a modular external fixation system indicated for fracture treatment in the upper and lower limbs. The system incorporates a streamlined combination of clamps, with both pin-to-bar and bar-to-bar coupling capabilities, offering a complete range of applications, including specific anatomic units for the elbow, shoulder, and wrist. It is designed both for temporary and definitive fracture fixation. It is also available in sterile kits for convenience and ease of use.

The XCaliber external fixator, made of lightweight radiolucent material, offers improved X-ray visualization of the fracture and alignment. It is available in three configurations for the treatment of long bone fractures, fractures near joints, and ankle fractures. XCaliber fixators are supplied pre-assembled, ready to use, in sterile kits to decrease time in the operating room.

The LRS Advanced Limb Reconstruction System uses callus distraction to lengthen bone in a variety of procedures, including monofocal lengthening and corrections of deformity. Its multifocal procedures include bone transport, simultaneous compression and distraction at different sites, bifocal lengthening, and correction of deformities with shortening.

The TrueLok Ring Fixation System is a surgeon-designed, lightweight external fixation system for limb lengthening and deformity correction. In essence, a ring fixation construct consists of circular rings and semi-circular external supports centered on the patient's limb and secured to the bone by crossed, tensioned wires and half pins. The rings are connected externally to provide stable bone fixation. The main external connecting elements are threaded rods, linear distractors, or hinges and angular distractors, which allow the surgeon to adjust the relative position of rings to each other. The ring positions are manipulated either acutely or gradually in precise increments to perform the correction of the deformity, limb lengthening, or bone segment transportation as required by the surgeon. Created with pre-assembled function blocks, the TrueLok products are a simple, stable, versatile ring fixation system.

The TL-HEX System is a hexapod-based system designed at Texas Scottish Rite Hospital for Children as a three-dimensional bone segment reposition module to augment the previously developed TrueLok frame. The system consists of circular and semi-circular external supports secured to the bones by wires and half pins and interconnected by six struts. This allows multi-planar adjustment of the external supports. The rings' positions are adjusted either rapidly or gradually in precise increments to perform bone segment repositioning in three-dimensional space. All the basic components from the TrueLok Ring Fixation System (wire and half pin fixation bolts, posts, threaded rods, plates, and other assembly components and instrumentation) can be utilized with the TL-HEX system; therefore, external supports from both systems can be connected to each other when building fixation blocks.

The addition of HEX-Ray software to the TL-HEX platform allows a unique and realistic representation of the case using real x-rays and providing more accurate and user-friendly management of the surgery. The software is intended to help the surgeon save time by avoiding undesired corrections and mistakes related to software management.

Linked to the TrueLok and TL-HEX lines, we have also developed an app to support the patient. The patient is an active part in the healing process and the app is designed to improve the communication and connection with the hospital staff by saving time, optimizing the number of visits to the clinic, and supporting the patient with motivational messages and an online tutorial to sort out the most common issues. Also related to the TrueLok and TL-HEX lines, but specifically developed for younger patients, we created the Edugame, an online app to help patients learn by playing a virtual game. It has been developed with psychologist involvement in order to deliver useful information in an effective way.

Our proprietary XCaliber bone screws are designed to be compatible with our external fixators and reduce inventory for our customers. Some of these screws are covered with hydroxyapatite, a mineral component of bone that reduces superficial inflammation of soft tissue and improves bone grip. Other screws in this proprietary line do not include the hydroxyapatite coating, but offer different advantages, such as patented thread designs for better adherence in hard or poor quality bone. We also offer

cylindrical screws, which are geared towards the trauma applications of the Galaxy Fixation System. We believe we have a full line of bone screws to meet the demands of the market.

In 2017, we introduced JuniOrtho, a brand identity for extremity fixation pediatric products. JuniOrtho is a range of products and resources dedicated to pediatrics and young adults with bone fractures and deformities that brings together our expertise and products in the pediatric space.

Internal Fixation

Internal fixation devices come in various sizes, depending on the bone that requires treatment, and consist of either long rods, commonly referred to as nails, or plates that are attached with the use of screws. A nail is inserted into the medullary canal of a fractured long bone of the human arm or leg (e.g., humerus, femur, or tibia). Alternatively, a plate is attached by screws to an area such as a broken wrist, hip, or foot. Examples of our internal fixation devices include:

- The Chimaera Hip Nailing System, which is indicated for the treatment of hip fractures. The Chimaera hip nail is designed to offer improvements over currently available nails by taking advantage of decades of knowledge in hip nailing. The result is a strong, versatile nail that allows fixation to be adapted to the type of fracture being treated. An all-in-one dedicated instrument tray contains a color-coded instrument set designed for increased precision during the surgical steps as well as intuitive instrument selection.
- The VeroNail Trochanteric Nailing System, which is indicated for the treatment of hip fractures. The nail design is minimally-invasive to reduce surgical trauma and allow patients to begin walking again shortly after the operation. It uses a dual screw configuration that we believe provides more stability than previous single screw designs.
- The Centronail Titanium Nailing System, which comprises a range of titanium nails to stabilize fractures in the femur, tibia, and humerus. The system offers improved mechanical distal targeting and minimal instrumentation to optimize inventory.
- The Ankle Hindfoot Nail, which is an arthrodesis nailing system designed to improve upon the stability, simplicity, and flexibility of current hindfoot nails.
- The Agile Nail, which is designed to treat femoral fractures in patients where a small rigid nail is needed. Its unique design requires less inventory and is the smallest titanium nail currently available in the market. This provides further benefits such as reduced invasiveness and lightness.
- The MJ Flex, which is an elastic nail system that innovates a technique considered to be the gold standard in the treatment of pediatric fractures. The unique shape of the nail offers improved strength, better visibility, more rigidity, and potentially a reduced usage of x-rays. The system is available in different sizes, both in titanium and stainless steel.
- The RIVAL Foot & Ankle System, which is a comprehensive offering of foot and ankle solutions across the range of two plating lines, Rival VIEW and Rival REDUCE, accompanied by Rival BITE, an extensive portfolio of headed cannulated and headless compression screws. The system is comprised of titanium plates and screws for the stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, and toes.

In addition to treating bone fractures, we also design, manufacture and distribute devices intended to treat congenital bone conditions, such as angular deformities (e.g., bowed legs in children), or degenerative diseases, as well as conditions resulting from a previous trauma. An example of a product offered in this area is the Eight-Plate Guided Growth System.

Product Development

Our primary research and development facilities are located in Verona, Italy and Lewisville, Texas. We work with leading hospital research institutions, as well as with MTF, physicians, and other consultants, on the long-term scientific planning and evolution of our products and therapies. Several of the products that we market have been developed through these collaborations. In addition, we periodically receive suggestions for new products and product enhancements from the scientific and medical community, some of which result in us entering into assignment or license agreements with physicians and third parties.

In 2019, 2018, and 2017, we incurred $34.6 million, $33.2 million, and $29.7 million, respectively, of research and development expense.

FITBONE Asset Acquisition

On February 3, 2020, we entered into an Asset Purchase Agreement (the "Purchase Agreement") with Wittenstein SE ("Wittenstein"), a privately-held German-based company, to acquire assets associated with the FITBONE intramedullary lengthening system for limb lengthening of the femur and tibia bones. Under the terms of the Purchase Agreement, as consideration for the acquired assets, we will pay $18 million in cash consideration and will enter into manufacturing supply contract with Wittenstein. The acquisition is anticipated to close by the end of the first quarter of 2020, subject to customary closing conditions.

Patents, Trade Secrets, Assignments and Licenses

We rely on a combination of patents, trade secrets, assignment and license agreements, and non-disclosure agreements to protect our proprietary intellectual property. We own numerous U.S. and foreign patents, have numerous pending patent applications, and have license rights under patents held by third parties. Our primary products are patented in the major markets in which they are sold. No assurance can be given that pending patent applications will result in issued patents, that patents issued or assigned to or licensed by us will not be challenged or circumvented by competitors, or that such patents will be found to be valid or sufficiently broad to protect our technology or to provide us with any competitive advantage or protection. Third parties might also obtain patents that would require assignments to or licensing by us to conduct our business. We rely on confidentiality and non-disclosure agreements with employees, consultants, and other parties to protect, in part, trade secrets and other proprietary technology.

We obtain assignments or licenses of varying durations for certain of our products from third parties. We typically acquire rights under such assignments or licenses in exchange for lump-sum payments or arrangements under which we pay a percentage of sales to the licensor. However, while assignments or licenses to us generally are irrevocable, no assurance can be given that these arrangements will continue to be made available to us on terms that are acceptable to us, or at all. The terms of our license and assignment agreements vary in length from a specified number of years to the life of product patents or the economic life of the product. These agreements generally provide for royalty payments and termination rights in the event of a material breach.

Compliance and Ethics Program

It is a fundamental policy of our Company to conduct business in accordance with the highest ethical and legal standards. We have a comprehensive compliance and ethics program, which is overseen by our Chief Ethics and Compliance Officer who reports directly to our Chief Executive Officer and the Compliance Committee of the Board of Directors. The program is intended to promote lawful and ethical business practices throughout our domestic and international businesses. It is designed to prevent and detect violations of applicable federal, state, and local laws in accordance with the standards set forth in guidance issued by the U.S. Department of Justice ("Evaluation of Corporate Compliance Programs" (updated April 2019)), the Office of Inspector General (HCCA-OIG "Measuring Compliance Program Effectiveness: A Resource Guide" (March 2017)) and the U.S. Sentencing Commission ("Effective Compliance and Ethics Programs" (November 2014)). Key elements of the program include:

- Organizational oversight by senior-level personnel responsible for the compliance function within our Company;
- Written standards and procedures, including a Corporate Code of Conduct;
- Methods for communicating compliance concerns, including anonymous reporting mechanisms;
- Investigation and remediation measures to ensure prompt response to reported matters and timely corrective action;
- Compliance education and training for employees and contracted business associates;
- Auditing and monitoring controls to promote compliance with applicable laws and assess program effectiveness;
- Disciplinary guidelines to enforce compliance and address violations;
- Due diligence reviews of high risk intermediaries and exclusion lists screening of employees and contracted business associates; and
- Risk assessments to identify areas of compliance risk.

Government Regulation

Classification and Approval of Products by the FDA and other Regulatory Authorities

Our research, development, and clinical programs, and our manufacturing and marketing operations, are subject to extensive regulation in the U.S. and other countries. Most notably, all of our products sold in the U.S. are subject to the Federal Food, Drug, and Cosmetic Act and the Public Health Services Act as implemented and enforced by the FDA. The regulations that cover our products and facilities vary widely from country to country. The amount of time required to obtain approvals or clearances from regulatory authorities also differs from country to country.

Unless an exemption applies, each medical device we commercially distribute in the U.S. is covered by premarket notification ("510(k)") clearance, letter to file, approval of a premarket approval application ("PMA"), or some other approval from the FDA. The FDA classifies medical devices into one of three classes, which generally determine the type of FDA approval required. Devices deemed to pose low risk are placed in class I, while devices that are considered to pose moderate risk are placed in class II, and devices deemed to pose the greatest risks requiring more regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, or devices deemed not substantially equivalent to a device that previously received 510(k) clearance (as described below), are placed in class III. Our Spinal Implants and Global Extremities products are, for the most part, class II devices and the instruments used in conjunction with these products are generally class I. Our Bone Growth Therapies products and the M6-C artificial cervical disc are classified as class III by the FDA, and have been approved for commercial distribution in the U.S. through the PMA process.

The medical devices we develop, manufacture, distribute, and market are subject to rigorous regulation by the FDA and numerous other federal, state, and foreign governmental authorities. The process of obtaining FDA clearance and other regulatory approvals to develop and market a medical device, particularly from the FDA, can be costly and time-consuming, and there can be no assurance such approvals will be granted on a timely basis, if at all. While we believe we have obtained all necessary clearances and approvals for the manufacture and sale of our products and that they are in material compliance with applicable FDA and other material regulatory requirements, there can be no assurance that we will be able to continue such compliance.

To market our devices within the member states of the European Union ("E.U."), we are required to comply with the European Medical Device Directives. Under the European Medical Device Directives, all medical devices must bear the CE mark. To obtain authorization to affix the CE mark to our products, a recognized European Notified Body must assess our quality systems and the product's conformity to the requirements of the European Medical Device Directives. We are subject to an annual inspection by a Notified Body for compliance with these requirements.

In 2017, the E.U. adopted the E.U. Medical Device Regulation (Council Regulations 2017/745) which imposes stricter requirements for the marketing and sale of medical devices, including new quality system and post-market surveillance requirements. The regulation provides a transition period until May 2020 for currently-approved medical devices to meet the additional requirements and for certain devices this transition period can be extended until May 2024. After this transition period, all medical devices marketed in the E.U. will require certification according to these new requirements. Complying with this new regulation will require us to incur significant costs over the transition period and failure to meet the requirements of the regulation could adversely impact our business in the EU and other countries that utilize or rely on E.U. requirements for medical device registrations.

Within our Biologics product category, we market tissue for bone repair and reconstruction under the brand names Trinity ELITE, Trinity Evolution, and fiberFUSE, our allogeneic bone matrices comprised of cancellous bone containing viable stem cells and a demineralized cortical bone component. These allografts are regulated under the FDA's Human Cell, Tissues and Cellular and Tissue-Based Products, or HCT/P, regulatory paradigm and not as a medical device, biologic, or a drug. The Biologics product category also distributes certain surgical implant products known as "allograft" products that are derived from human tissues and which are used for bone reconstruction or repair and are surgically implanted into the human body. These tissues are regulated by the FDA as minimally-manipulated tissue and are covered by the FDA's "Good Tissues Practices" regulations, which cover all stages of allograft processing. There can be no assurance our suppliers will continue to meet applicable regulatory requirements or that those requirements will not be changed in ways that could adversely affect our business. Further, there can be no assurance these products will continue to be made available to us or that applicable regulatory standards will be met or remain unchanged. Moreover, products derived from human tissue or bones are from time to time subject to recall for certain administrative or safety reasons and we may be affected by one or more such recalls. For a further description of some of these risks, see Item 1A of this Annual Report under the heading "Risk Factors."

Certain Other Product and Manufacturing Regulations

After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include: product listing and establishment registration; Quality System Regulation ("QSR"), which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all aspects of the manufacturing process; labeling regulations and governmental prohibitions against the promotion of products for uncleared, unapproved, or off-label uses or indications; clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices; approval of product modifications that affect the safety or effectiveness of one of our PMA approved devices; Medical Device Adverse Event Reporting regulations, which require that manufacturers report to the FDA and other foreign governmental agencies if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur; post-approval restrictions or conditions, including post-approval study commitments; post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; the FDA's recall authority, whereby it can ask, or under certain conditions, order device manufacturers to recall a product from the market that is in violation of governing laws and regulations; regulations pertaining to voluntary recalls; and notices of corrections or removals.

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA and European Notified Bodies to determine our compliance with the FDA's QSR and other international regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as fines and civil penalties against us, our officers, our employees, or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. In addition to FDA inspections, all manufacturing facilities of the Company are subject to annual Notified Body inspections.

Moreover, governmental authorities outside the U.S. have become increasingly stringent in their regulation of medical devices. Our products may become subject to more rigorous regulation by non-U.S. governmental authorities in the future. U.S. or non-U.S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. For a description of some of these risks, see Item 1A of this Annual Report under the heading "Risk Factors."

Accreditation Requirements

Our subsidiary, Orthofix Inc., has been accredited by the Accreditation Commission for Health Care, Inc. ("ACHC") for medical supply provider services with respect to durable medical equipment, prosthetics, orthotics, and supplies ("DMEPOS"). ACHC, a private, not-for-profit corporation, which is certified to ISO 9001:2000 standards, was developed by home care and community-based providers to help companies improve business operations and quality of patient care. Although accreditation is generally a voluntary activity where healthcare organizations submit to peer review their internal policies, processes, and patient care delivery against national standards, the Centers for Medicare and Medicaid Services ("CMS") required DMEPOS suppliers to become accredited. We believe that by attaining accreditation, Orthofix Inc. has demonstrated its commitment to maintain a higher level of competency and strive for excellence in its products, services, and customer satisfaction.

Third-Party Payor Requirements

Our products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid, and Tricare, or private insurance plans and healthcare networks. Third-party payors may deny reimbursement if they determine that a device provided to a patient or used in a procedure does not meet applicable payment criteria or if the policyholder's healthcare insurance benefits are limited. Also, non-government third-party payors are increasingly challenging the medical necessity and prices paid for our products and services. The Medicare program is expected to continue to implement a new payment mechanism for certain DMEPOS items via the implementation of its competitive bidding program. Bone growth therapy devices are currently exempt from this competitive bidding process.

Laws Regulating Healthcare Fraud and Abuse; State Healthcare Laws

Our sales and marketing practices are also subject to a number of U.S. laws regulating healthcare fraud and abuse such as the federal Anti-Kickback Statute and the federal Physician Self-Referral Law (known as the "Stark Law"), the Civil False Claims Act, and

the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as well as numerous state laws regulating healthcare and insurance. These laws are enforced by the Office of Inspector General within the U.S. Department of Health and Human Services, the U.S. Department of Justice, and other federal, state, and local agencies. Among other things, these laws and others generally (1) prohibit the provision of anything of value in exchange for the referral of patients for, or the purchase, order, or recommendation of, any item or service reimbursed by a federal healthcare program, (including Medicare and Medicaid); (2) require that claims for payment submitted to federal healthcare programs be truthful; (3) prohibit the transmission of protected healthcare information to persons not authorized to receive that information; and (4) require the maintenance of certain government licenses and permits.

Laws Protecting the Confidentiality of Health Information

U.S. federal and state laws protect the confidentiality of certain health information, in particular individually identifiable information such as medical records, and restrict the use and disclosure of that protected information. At the federal level, the Department of Health and Human Services promulgates health information privacy and security rules under HIPAA. These rules protect health information by regulating its use and disclosure, including for research and other purposes. Failure of a HIPAA “covered entity” to comply with HIPAA regarding such “protected health information” could constitute a violation of federal law, subject to civil and criminal penalties. Covered entities include healthcare providers (including certain of those that sell devices or equipment) that engage in particular electronic transactions, including, as we do, the transmission of claims to health plans. Consequently, health information that we access, collect, analyze, and otherwise use and/or disclose includes protected health information that is subject to HIPAA. As noted above, many state laws also pertain to the confidentiality of health information. Such laws are not necessarily preempted by HIPAA, in particular those state laws that afford greater privacy protection to the individual than HIPAA. These state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

In the European Union, the General Data Protection Regulation (“GDPR”), which became enforceable in May 2018, includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data.

These laws and regulations impact the ways in which we use and manage personal data, protected health information, and our information technology systems. They also impact our ability to move, store, and access data across geographic boundaries. Compliance with these requirements may require changes in business practices, complicate our operations, and add complexity and additional management and oversight needs. They also may complicate our clinical research activities, as well as product offerings that involve transmission or use of clinical data.

Physician Payments Sunshine Provision of the Affordable Care Act

The Physician Payments Sunshine Provision of the Affordable Care Act (Section 6002) (the “Sunshine Act”), which was enacted in 2010 and became subject to final CMS rules in 2013, requires public disclosure to the United States government of payments to physicians and teaching hospitals, including in-kind transfers of value such as gifts or meals. The Act also provides penalties for non-compliance. The Act requires that we file an annual report on March 31st of a calendar year for the transfers of value incurred for the prior calendar year.

In 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the “SUPPORT Act”) was signed into law. The SUPPORT Act expands the reporting obligation under the Sunshine Act to include payments and other transfers of value made to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives. These expanded reporting obligations are effective for payments reported in 2022, with payment tracking beginning in 2021. Non-compliance with the Sunshine Act or SUPPORT Act is subject to civil monetary penalties.

In addition to the Sunshine Act, as expanded by the SUPPORT Act, we seek to comply with other international and individual state transparency laws, like Massachusetts and Vermont.

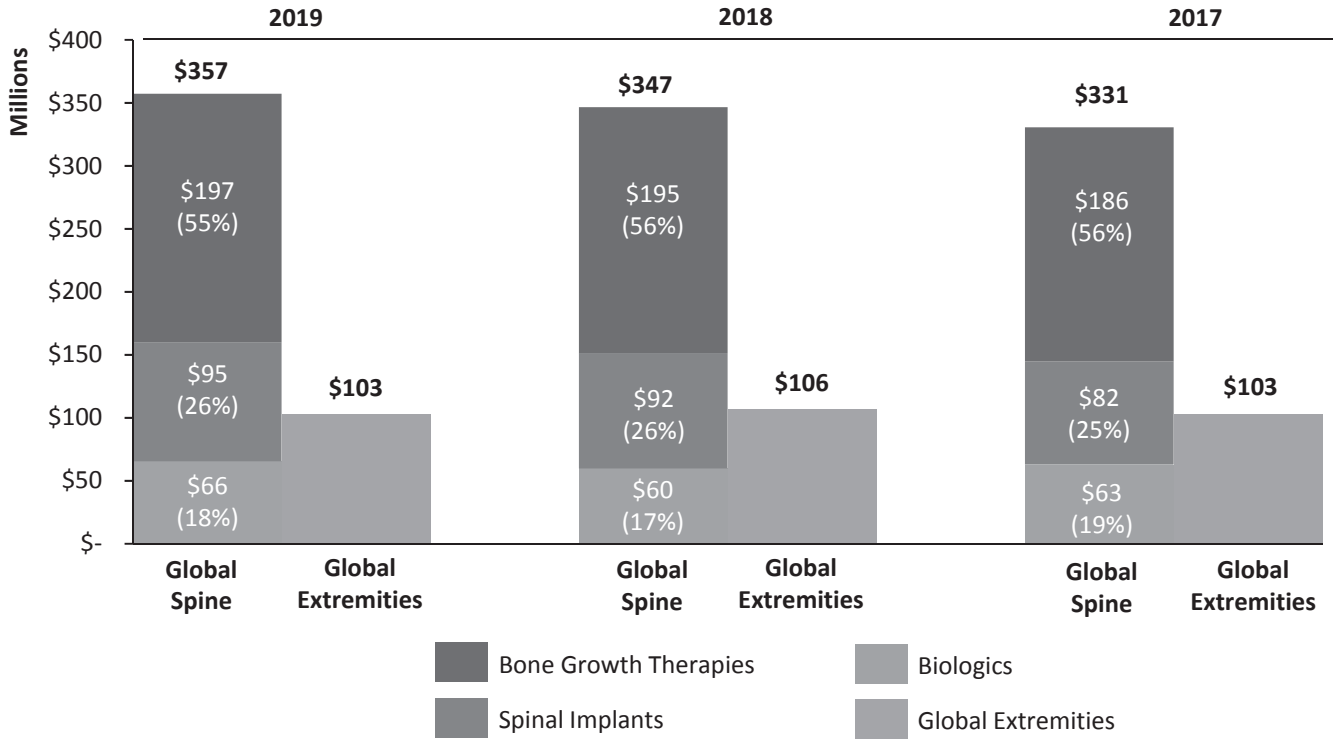
Sales, Marketing and Distribution

General Trends

We believe that demographic trends, principally in the form of a better informed, more active, and aging population in the major healthcare markets of the U.S., Western Europe, and Japan, together with opportunities in emerging markets such as the Asia-Pacific Region and Latin America, as well as our focus on innovative products, will continue to have a positive effect on the demand for our products.

Reporting Segments and Product Categories

Our revenues are generated from the sales of products in our two reporting segments, Global Spine and Global Extremities. Further, our Global Spine reporting segment is comprised of three primary product categories: Bone Growth Therapies, Spinal Implants, and Biologics. See the following chart for the distribution of sales between each of our reporting segments and product categories for each of the years ended December 31, 2019, 2018, and 2017.



Sales Network

We have a broad sales network comprised of direct sales representatives, sales agents, and distributors. This established sales network provides us with a platform to introduce new products and expand sales of existing products. We distribute our products worldwide in more than 70 countries.

In our largest market, the U.S., our sales network is generally comprised of four sales forces, each addressing one of our primary product categories; however, many independent distributors sell products for more than one of our product categories. Within our Global Spine reporting segment, a hybrid distribution network of direct sales representatives and independent distributors sells products in our Bone Growth Therapies product category, while primarily independent distributors sell products in our Spinal Implants and Biologics product categories. In the U.S., our Global Extremities reporting segment products are primarily sold by independent distributors.

Outside the U.S., we employ direct sales representatives and contract with independent distributors. In order to provide support to our independent sales network, we have sales and product specialists who regularly visit independent distributors to provide training and product support.

Marketing and Product Education

We market and sell our products principally to physicians, hospitals, ambulatory surgery centers, integrated health delivery systems, and other purchasing organizations.

We support our sales force through specialized training workshops in which physicians and sales specialists participate. We also produce marketing and training materials, including materials outlining surgical procedures, for our customers, sales force, and distributors in a variety of languages using printed, video, and multimedia formats. We require all of our sales force, direct and independent, to undergo extensive product, policy, and compliance training to ensure adherence to our standards, policies, and applicable law.

To provide additional advanced training for physicians, consistent with the AdvaMed Code of Ethics ("AdvaMed Code") and the MedTech Europe Code of Ethical Business Practice ("MedTech Code"), we organize regular multilingual teaching seminars in multiple locations. Those places include our facility in Verona, Italy, various locations in Latin America, and in Lewisville, Texas. In recent years, thousands of surgeons from around the world attended these product education seminars, which have included a variety of lectures from specialists, as well as demonstrations and hands-on workshops.

Competition

Our Bone Growth Therapies product category competes principally with similar products marketed by Zimmer Biomet, Inc.; DJO Global; and Bioventus. The Biologics HCT/P and Spinal Implants products we market compete with products marketed by Medtronic, Inc.; DePuy Synthes, a division of Johnson and Johnson; Stryker Corp.; Zimmer Biomet, Inc.; NuVasive, Inc.; Globus Medical Inc.; and various smaller public and private companies. For Global Extremities devices, our principal competitors include DePuy Synthes; Zimmer Biomet, Inc.; Stryker Corp.; Smith & Nephew plc; and Wright Medical Group N.V.

We believe that we enhance our competitive position by focusing on product features such as ease of use, versatility, cost, and patient acceptability, together with value-added services, such as the STIM onTrack mobile app, HEX RAY software, and our JuniOrtho educational products and services. We attempt to avoid competing based solely on price. Overall cost and medical effectiveness, innovation, reliability, value-added service, and training are the most prevalent methods of competition in the markets for our products, and we believe we compete effectively.

Manufacturing and Sources of Supply

We generally design, develop, assemble, test and package our stimulation, orthopedic, and spinal implant products, and subcontract the manufacture of a substantial portion of the component parts and instruments. We design and develop our AlloQuent Allograft HCT/Ps and subcontract its manufacturing. Through subcontracting a portion of our manufacturing, we attempt to maintain operating flexibility in meeting demand while focusing our resources on product development, education, and marketing, as well as quality assurance standards. Although certain of our key raw materials are obtained from a single source, we believe alternate sources for these materials are available. Further, we believe an adequate inventory supply is maintained to avoid product flow interruptions. Historically, we have not experienced difficulty in obtaining the materials necessary to meet our production schedules.

The Trinity ELITE, Trinity Evolution, and fiberFUSE HCT/Ps, for which we have exclusive marketing rights, are allograft tissue forms that are supplied to customers by MTF in accordance with orders received directly from us. MTF sources, processes, and packages the tissue forms and is the sole supplier of the Trinity ELITE and Trinity Evolution HCT/Ps to our customers.

Our products are currently manufactured and assembled in the U.S. and Italy. We believe our plants comply in all material respects with the requirements of the FDA and all relevant regulatory authorities outside the U.S. For a description of the laws to which we are subject, see Item 1, "Business", under the subheadings "Corporate Compliance and Ethics Program" and "Government Regulation." We actively monitor each of our subcontractors in order to maintain manufacturing and quality standards and product specification conformity.

Employees

At December 31, 2019, we had 1,055 employees worldwide. Of these, 774 were employed in the U.S. and 281 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 196 at December 31, 2019, are governed by the provisions of a National Collective Labor Agreement setting forth mandatory minimum standards for labor relations in the metal mechanic workers industry. We are not a party to any other collective bargaining agreement. We believe we have good relations with our employees.

Item 1A. Risk Factors

In addition to the other information contained in this Annual Report and the exhibits hereto, you should carefully consider the risks described below. These risks are not the only ones that we may face. Additional risks not presently known to us or that we currently consider immaterial may also impair our business operations. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below or elsewhere in this Annual Report. Investing in our common stock involves a high degree of risk and if any of these risks or uncertainties occur, the trading price of our common stock could decline and you could lose part or all of your investment.

Risks Related to our Legal and Regulatory Environment

If we fail to maintain an effective system of internal controls or discover material weaknesses in our internal control over financial reporting, we may not be able to report our financial results accurately or detect fraud, which could harm our business and the trading price of our common stock.

Effective internal controls are necessary for us to produce reliable financial reports and are important in our effort to prevent financial fraud. We are required to periodically evaluate the effectiveness of the design and operation of our internal controls. As has occurred in several years prior, these evaluations may result in the conclusion that enhancements, modifications, or changes to our internal controls are necessary or desirable. While management evaluates the effectiveness of our internal controls on a regular basis, these controls may not always be effective. There are inherent limitations on the effectiveness of internal controls, including collusion, management override, and failure of human judgment. Because of this, control procedures are designed to reduce rather than eliminate business risks. If we fail to maintain an effective system of internal controls or if management or our independent registered public accounting firm were to discover material weaknesses in our internal controls, we may be unable to produce reliable financial reports or prevent fraud, which could harm our financial condition and operating results, and could result in a loss of investor confidence and a decline in our stock price.

We have previously settled violations of the Foreign Corrupt Practices Act and any future violations could further subject us to adverse consequences.

In 2013, we self-reported to the U.S. Department of Justice (the "DOJ") and the SEC an internal investigation of improper payments by our Brazilian subsidiary, Orthofix do Brasil Ltda., regarding non-compliance by such subsidiary with the Foreign Corrupt Practices Act (the "FCPA"). This followed a prior matter that we self-reported to the DOJ and SEC in 2011, and settled in 2012, involving FCPA-related non-compliance by our then Mexican subsidiary, Promeca S.A. de C.V. In January 2017, we consented to a cease-and-desist order with the SEC to settle the Brazil-related violations, pursuant to which we agreed to pay approximately $6.1 million in disgorgement and penalties, and agreed to retain an independent compliance consultant for one year to review and test our FCPA compliance program. Our engagement of the independent compliance consultant concluded on March 16, 2018.

The FCPA and similar anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to foreign government officials for the purpose of obtaining or retaining business. The FCPA also imposes accounting standards and requirements on U.S. publicly traded entities and their foreign affiliates, which are intended to prevent the diversion of corporate funds to the payment of bribes and other improper payments. Because of the predominance of government-sponsored healthcare systems around the world, many of our customer relationships outside of the United States are with governmental entities and are therefore subject to such anti-bribery laws.

In connection with our self-reported FCPA violations, we instituted extensive remediation measures, including terminating employees as well as relationships with third-party representatives and distributors, conducting a global review of our anti-corruption and anti-bribery program, implementing regular audits of our third-party distributors and sales agents, developing and implementing new global accounting policies to provide further structure and guidance to foreign subsidiaries, establishing an internal audit function, improving the quality of personnel in our Compliance department, and implementing enhanced anti-corruption compliance training for employees and certain third parties. However, notwithstanding these efforts to make FCPA-related compliance a priority, our compliance policies and procedures may not always protect us from reckless or criminal acts committed by our employees, distributors, or agents.

Any failure to comply with applicable legal and regulatory obligations in the United States or abroad could adversely affect us in a variety of ways that include, but are not limited to, significant criminal, civil, and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions on certain business activities, disgorgement and other remedial measures, disruptions of our operations, and significant management distraction. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities. Any reduction in international sales, or our failure to further develop our international markets, could have a material adverse effect on our business, results of operations and financial condition.

We are subject to federal and state healthcare fraud, abuse, and anti-self-referral laws, and could face substantial penalties if we are determined not to have fully complied with such laws.

Healthcare fraud and abuse regulations by federal and state governments impact our business. Healthcare fraud and abuse laws potentially applicable to our operations include:

- the federal Anti-Kickback Statute, which prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce the purchase or recommendation of an item or service reimbursable under a federal healthcare program (such as the Medicare or Medicaid programs);
- the federal Stark law, which prohibits physician self-referral, specifically a referral by a physician of a Medicare or Medicaid patient to an entity providing designated health services if the physician or an immediate family member has a financial relationship with that entity;
- federal false claims laws, which prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal government payors that are false or fraudulent; and
- state and non-U.S. laws analogous to each of the above federal laws, such as anti-kickback and false claims laws that may apply to items or services reimbursed by non-governmental or non-U.S. governmental third-party payors, including commercial insurers.

Due to the breadth of some of these laws, there can be no assurance that we will not be found to be in violation of any such laws, and as a result we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, or the exclusion from participation in federal, non-U.S. or state healthcare programs. Any penalties could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Reimbursement policies of third parties, cost containment measures, and healthcare reform could adversely affect the demand for our products and limit our ability to sell our products.

Our products are sold either directly by us or by independent sales representatives to customers or to our independent distributors and purchased by hospitals, healthcare providers, and patients. These products may be reimbursed by third-party payors, such as government programs, including Medicare, Medicaid, and Tricare, or private insurance plans and healthcare networks. Major third-party payors for medical services in the U.S. and internationally continue to work to contain health care costs and are increasingly challenging the policies and the prices charged for medical products and services. Any medical policy developments that eliminate, reduce, or materially modify coverage of our reimbursement rates for our products could have an impact on our ability to sell our products. In addition, third-party payors may deny reimbursement if they determine that a device or product provided to a patient or used in a procedure does not meet applicable payment criteria or if the policyholder's healthcare insurance benefits are limited. These policies and criteria may be revised from time-to-time.

Limits put on reimbursement could make it more difficult to buy our products and substantially reduce, or possibly eliminate, patient access to our products. In addition, should governmental authorities continue to enact legislation or adopt regulations that affect third-party coverage and reimbursement, access to our products and coverage by private or public insurers may be reduced with a consequential material adverse effect on our sales and profitability.

CMS, in its ongoing implementation of the Medicare program, periodically reviews medical study literature to determine how the literature addresses certain procedures and therapies in the Medicare population. The impact that this information could have on Medicare coverage policy for our products is currently unknown, but we cannot provide assurances that the resulting actions will not restrict Medicare coverage for our products. There can be no assurance that we or our distributors will not experience significant reimbursement problems in the future related to these or other proceedings. Globally, our products are sold in many

countries, such as the U.K., Germany, France, and Italy, which have publicly funded healthcare systems. The ability of hospitals supported by such systems to purchase our products is dependent, in part, upon public budgetary constraints. Any increase in such constraints may have a material adverse effect on our sales and collection of accounts receivable from such sales.

As required by law, CMS has continued efforts to implement a competitive bidding program for selected durable medical equipment, prosthetic, orthotic supplies ("DMEPOS") items paid for by the Medicare program. In this program, Medicare rates are based on bid amounts for certain products in designated geographic areas, rather than the Medicare fee schedule amount. Bone growth stimulation products are currently exempt from this competitive bidding process. We cannot predict which products from any of our businesses may ultimately be affected or whether or when the competitive bidding process may be extended to our businesses. There can be no assurance that the implementation of the competitive bidding program will not have an adverse impact on the sales of some of our products.

We and certain of our suppliers may be subject to extensive government regulation that increases our costs and could limit our ability to market or sell our products.

The medical devices we manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state, and foreign governmental authorities. These authorities regulate the development, approval, classification, testing, manufacturing, labeling, marketing, and sale of medical devices. Likewise, our use and disclosure of certain categories of health information may be subject to federal and state laws, implemented and enforced by governmental authorities that protect health information privacy and security. For a description of these regulations, see Item 1, "Business," under the subheading "Government Regulation."

The approval or clearance by governmental authorities, including the FDA in the U.S., is generally required before any medical devices may be marketed in the U.S. or other countries. We cannot predict whether, in the future, the U.S. or foreign governments may impose regulations that have a material adverse effect on our business, financial condition, results of operations, or cash flows. The process of obtaining FDA clearance and approvals to develop and market a medical device can be costly, time-consuming, and subject to the risk that such clearances or approvals will not be granted on a timely basis, if at all. The regulatory process may delay or prohibit the marketing of new products and impose substantial additional costs if the FDA lengthens review times for new devices. The FDA has the ability to change the regulatory classification of a cleared or approved device from a higher to a lower regulatory classification, or to reclassify an HCT/P, either of which could materially adversely impact our ability to market or sell our devices. For example, the FDA included Class III bone growth stimulator products in its 2015 strategic priority work plan, as part of a list of 21 product categories it would review for possible down classification. Shortly after the issuance of the work plan, we and other manufacturers of bone growth stimulator products submitted a public comment letter opposing the possible down classification. The FDA did not respond to the comment letter and has not taken any action with respect to the bone growth stimulator product category since publication of the 2015 work plan. If a down classification were to occur and new entrants to the market were able to create technologies with comparable efficacy to our devices, our Bone Growth Therapies products could face additional competition, which could negatively affect our future sales.

In addition, we may be subject to compliance actions, penalties, or injunctions if we are determined to be promoting the use of our products for unapproved or off-label uses, or if the FDA challenges one or more of our determinations that a product modification did not require new approval or clearance by the FDA. Device manufacturers are permitted to promote products solely for the uses and indications set forth in the approved product labeling. A number of enforcement actions have been taken against manufacturers that promote products for "off-label" uses, including actions alleging that federal health care program reimbursement of products promoted for "off-label" uses are false and fraudulent claims to the government. The failure to comply with "off-label" promotion restrictions can result in significant administrative obligations and costs, and potential penalties from, and/or agreements with, the federal government.

We and certain of our suppliers also are subject to announced and unannounced inspections by the FDA to determine our compliance with FDA's QSR and other regulations. If the FDA were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agency could institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as: fines and civil penalties against us, our officers, our employees, or our suppliers; unanticipated expenditures to address or defend such actions; delays in clearing or approving, or refusal to clear or approve, our products; withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies; product recall or seizure; interruption of production; operating restrictions; injunctions; and criminal prosecution. The FDA also has the authority to request repair, replacement, or refund of the cost of any medical device manufactured or distributed by us. Any of the foregoing actions could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition, results of operations, or cash flows.

Moreover, governmental authorities outside the U.S. have become increasingly stringent in their regulation of medical devices, and our products may become subject to more rigorous regulation by non-U.S. governmental authorities in the future. U.S. or non-U.S. government regulations may be imposed in the future that may have a material adverse effect on our business and operations. The European Commission ("EC") has harmonized national regulations for the control of medical devices through European Medical Device Directives with which manufacturers must comply. Under these new regulations, manufacturing plants must have received a full Quality Assurance Certification from a "Notified Body" in order to be able to sell products within the member states of the European Union. This Certification allows manufacturers to stamp the products of certified plants with a "CE" mark. Products covered by the EC regulations that do not bear the CE mark cannot be sold or distributed within the European Union. We have received certification for all currently existing manufacturing facilities.

The impact of the Affordable Care Act and other United States healthcare reform legislation on us remains uncertain.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (or collectively the "ACA"), made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. The ACA is far-reaching and is intended to expand access to health insurance coverage, improve quality, and reduce costs over time. Among other things, the ACA:

- establishes 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; and

- implements 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.

Certain legislative changes to and regulatory changes under the ACA occurred in the 115th United States Congress. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the individual mandate, beginning in 2019, as well as the tax on generous employer-sponsored employee-sponsored healthcare plans.

In addition, U.S. government agencies continue efforts to modify provisions of the ACA. For example, CMS began permitting states to impose work requirements on persons covered by Medicaid expansion plans; certain federal subsidies to insurers have ended; and certain short-term insurance plans not offering the full array of ACA benefits have been allowed to extend in duration. Some of these changes are being challenged in U.S. courts and so their long-term impact remains uncertain. This changing federal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal law, and potential modification or repeal of these laws, will ultimately affect the industry. Any future changes to the ACA or other such legislation, depending on their nature, could have an adverse effect on our ability to maintain or increase sales of any of our products and achieve profitability.

We are subject to differing customs and import/export rules in several jurisdictions in which we operate.

We import and export our products to and from a number of different countries around the world. These product movements involve subsidiaries and third parties operating in jurisdictions with different customs and import/export rules and regulations. Customs authorities in such jurisdictions may challenge our treatment of customs and import/export rules relating to product shipments under aspects of their respective customs laws and treaties. If we are unsuccessful in defending our treatment of customs and import/export classifications, we may be subject to additional customs duties, fines, or penalties that could adversely affect our profitability.

In addition, changes in U.S. or foreign policies regarding international trade could also negatively impact our business. The enactment of or increases in tariffs, or other such charges, on specific products that we sell or with which our products compete, may have an adverse effect on our business or on our results of operations.

Risks Related to our Business and Industry

Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if a group purchasing organization or similar entity excludes us from being a supplier.

Because healthcare costs have risen significantly over the past decade, numerous initiatives and reforms have been launched by legislators, regulators, and third-party payors to curb these costs. As a result, there has been a consolidation trend in the healthcare industry to create larger companies, including medical device companies and hospitals, each with greater market power. As the healthcare industry consolidates, competition to provide products and services to industry participants has become and may continue to become more intense. This has resulted and may continue to result in greater pricing pressures and the exclusion of certain suppliers from important markets as group purchasing organizations ("GPOs"), independent delivery networks, and large single accounts continue to use their market power to consolidate purchasing decisions and as larger manufacturers use their broad offerings to secure exclusive arrangements. If a GPO were to exclude us from their supplier list, our net sales could be adversely impacted. We expect that market demand, government regulation, third-party reimbursement policies, and societal pressures will continue to change the worldwide healthcare industry, which may exert further downward pressure on the prices of our products.

The industry in which we operate is highly competitive. New developments by others could make our products or technologies non-competitive or obsolete.

The medical devices industry is highly competitive. We compete with a large number of companies, many of which have significantly greater financial, manufacturing, marketing, distribution, and technical resources than we do. Many of our competitors may be able to develop products and processes competitive with, or superior to, our own. Furthermore, we may not be able to successfully develop or introduce new products that are less costly or offer better performance than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. For more information regarding our competitors, see Item 1, "Business," under the subheading "Competition."

In addition, the orthopedic medical device industry in which we compete is undergoing, and is characterized by, rapid and significant technological change. We expect competition to intensify as technological advances are made. New technologies and products developed by other companies are regularly introduced into the market, which may render our products or technologies non-competitive or obsolete.

Our ability to market products successfully depends, in part, upon the acceptance of the products not only by consumers, but also by independent third parties.

Our ability to market our products successfully depends, in part, on the acceptance of the products by independent third parties (including hospitals, physicians, other healthcare providers, and third-party payors) as well as patients. Unanticipated side effects or unfavorable publicity concerning any of our products could have an adverse effect on our ability to maintain hospital approvals or achieve acceptance by prescribing physicians, managed care providers and other retailers, customers, and patients.

Our allograft and mesenchymal stem cell allografts could expose us to certain risks that could disrupt our business.

Our Biologics business markets allograft tissues that are derived from human cadaveric donors, and our ability to market the tissues depends on our supplier continuing to have access to donated human cadaveric tissue, as well as the maintenance of high standards by the supplier in its processing methodology. The supply of such donors is inherently unpredictable and can fluctuate over time. The allograft tissues are regulated under the FDA's HCT/P regulatory paradigm and not as a medical device, biologic, or drug. There can be no assurance that the FDA will not at some future date re-classify the allograft tissues, and the reclassification of this product from a human tissue to a medical device could have adverse consequences for us or for the supplier of this product and make it more difficult or expensive for us to conduct this business by requiring premarket clearance or approval as well as compliance with additional post-market regulatory requirements.

We may not be able to successfully introduce new products to the market, and market opportunities that we expect to develop for our products may not be as large as we expect.

We plan to continue to make improvements in our products, to develop new products, and to introduce our products into new markets. Despite our planning, the process of developing and introducing new products (including product enhancements) is inherently complex and uncertain, and involves risks, including the ability of such new products to satisfy customer needs, gain broad market acceptance (including by physicians), and obtain regulatory approvals. These events can depend on the product

achieving broad clinical acceptance, the level of third-party reimbursement, and the introduction of competing technologies, among other things. In addition, these risks make it inherently difficult to forecast and predict the future net sales of our products. If the market opportunities that we expect to develop for our products, including new products, are not as large as we expect, it could adversely affect our ability to grow our business.

Growing our business requires that we properly educate and train physicians regarding the distinctive characteristics, benefits, safety, clinical efficacy, and cost-effectiveness of our products.

Acceptance of our products depends in part on our ability to (i) educate the medical community as to the distinctive characteristics, benefits, safety, clinical efficacy, and cost-effectiveness of our products compared to alternative products, procedures, and therapies, and (ii) train physicians in the proper use and implementation of our products. This is particularly true in instances of newly launched products or in the introduction of a product into a new market, such as our launch of the M6-C artificial cervical disc within the U.S. We support our sales force and distributors through specialized training workshops in which surgeons and sales specialists participate. We also produce marketing materials, including materials outlining surgical procedures, for our sales force and distributors in a variety of languages using printed, video, and multimedia formats. To provide additional advanced training for surgeons, consistent with the AdvaMed Code and the MedTech Code, we organize regular multilingual teaching seminars in multiple locations. However, we may not be successful in our efforts to educate the medical community and properly train physicians. If physicians are not properly trained, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes, patient injury, negative publicity, or lawsuits against us. In addition, a failure to educate the medical community regarding our products may impair our ability to achieve market acceptance of our products.

We may be adversely affected by any disruption in our information technology systems, which could adversely affect our cash flows, operating results, and financial condition.

Our operations are dependent upon our information technology systems, which encompass all of our major business functions. We rely upon such information technology systems to manage and replenish inventory, to fill and ship customer orders on a timely basis, to coordinate our sales activities across all of our products and services, and to coordinate our administrative activities. A substantial disruption in our information technology systems for any prolonged time period (arising from, for example, system capacity limits from unexpected increases in our volume of business, outages, or delays in our service) could result in delays in receiving inventory and supplies or filling customer orders and adversely affect our customer service and relationships. Our systems might be damaged or interrupted by natural or man-made events, or by computer viruses, physical or electronic break-ins, and similar disruptions affecting the global Internet. There can be no assurance that such delays, problems, or costs will not have a material adverse effect on our cash flows, operating results, and financial condition.

As our operations grow in both size and scope, we will continuously need to improve and upgrade our systems and infrastructure while maintaining the reliability and integrity of our systems and infrastructure. An expansion of our systems and infrastructure may require us to commit substantial financial, operational, and technical resources before the volume of our business increases, with no assurance that the volume of business will increase. Any such upgrades to our systems and information technology, or new technology, now and in the future, require that our management and resources be diverted from our core business to assist in compliance with those requirements. There can be no assurance that the time and resources our management will need to devote to these upgrades, service outages, or delays due to the installation of any new or upgraded technology (and customer issues therewith), or the impact on the reliability of our data from any new or upgraded technology will not have a material adverse effect on our cash flows, operating results and financial condition.

A significant portion of our operations run on a single Enterprise Resource Planning (“ERP”) platform. To manage our international operations efficiently and effectively, we rely heavily on our ERP system, internal electronic information and communications systems, and on systems or support services from third parties. Any of these systems are subject to electrical or telecommunications outages, computer hacking, or other general system failure. It is also possible that future acquisitions will operate on different ERP systems and that we could face difficulties in integrating operational and accounting functions of new acquisitions. Difficulties in upgrading or expanding our ERP system or system-wide or local failures that affect our information processing could adversely affect our cash flows, operating results, and financial condition.

We may be adversely affected by a failure or compromise from a cyberattack or data breach, which could have an adverse effect on our business

We rely on information technology systems to perform our business operations, including processing, transmitting and storing electronic information, and interacting with customers, suppliers, healthcare payors, and other third parties. Like other medical device companies, the size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, or other significant disruption. Our information systems require an ongoing commitment of significant resources to maintain, protect, and enhance existing systems and develop new systems to keep pace with continuing changes in information processing technology, evolving systems and regulatory standards, the increasing need to protect financial or personal information related to patients and customers, and changing customer patterns.

For example, third parties may attempt to hack into our products to obtain data relating to patients or disrupt performance of our products or to access our proprietary information. Any failure by us to maintain or protect our information technology systems and data integrity, including from cyber-attacks, intrusions or other breaches, could result in the unauthorized access to patient data and personally identifiable information, theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. In the U.S., Federal and State privacy and security laws require certain of our operations to protect the confidentiality of personal information including patient medical records and other health information. In Europe, the Data Protection Directive requires us to manage individually identifiable information in the EU and, the new General Data Protection Regulation may impose fines of up to four percent of our global revenue in the event of violations. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data. We believe that we meet the expectations of applicable regulations and that the ongoing costs of compliance with such rules are not material to our business but could become material due to new regulations. There is no guarantee that we will be able to comply with these regulations, or otherwise avoid the negative reputational and other affects that might ensue from a significant data breach or failure to comply with applicable data privacy regulations, each of which could have significant adverse effects on our business, financial condition, or results of operations.

In recent years, companies around the world are seeing a surge in wire transfer “phishing” attacks that attempt to trick employees into wiring money from company bank accounts to criminals’ bank accounts. In some cases, companies have lost millions of dollars to such relatively simple attacks, and these funds often are not recovered. While we take efforts to train employees to be cognizant of these types of attacks and take appropriate precautions, the level of technological sophistication being used by attackers has increased in recent years, and a successful attack against us could lead to the loss of significant funds.

We are dependent on third-party manufacturers for many of our products.

We contract with third-party manufacturers to produce many of our products, like many other companies in the medical device industry. If we or any such manufacturer fail to meet production and delivery schedules, it can have an adverse impact on our ability to sell such products. Further, whether we directly manufacture a product or utilize a third-party manufacturer, shortages and spoilage of materials, labor stoppages, product recalls, manufacturing defects and other similar events can delay production and inhibit our ability to bring a new product to market in timely fashion. For example, the supply of the Trinity ELITE and Trinity Evolution allografts are derived from human cadaveric donors, and our ability to market the tissues depends on MTF continuing to have access to donated human cadaveric tissue, as well as, the maintenance of high standards by MTF in its processing methodology.

Termination of our existing relationships with our independent sales representatives or distributors could have an adverse effect on our business.

We sell our products in many countries through independent distributors. Generally, our independent sales representatives and our distributors have the exclusive right to sell our products in their respective territories. The terms of these agreements vary in length, generally from one to ten years. Under the terms of our distribution agreements, each party has the right to terminate in the event of a material breach by the other party and we generally have the right to terminate if the distributor does not meet agreed sales targets or fails to make payments on time. Any termination of our existing relationships with independent sales representatives or distributors could have an adverse effect on our business unless and until commercially acceptable alternative distribution arrangements are put in place. In addition, we operate in areas of the world that have been or may be disproportionately affected by recessions or disasters and we bear risk that existing or future accounts receivable may be uncollected if these distributors or hospitals experience disruptions to their business that cause them to discontinue paying ongoing accounts payable or become insolvent.

We depend on our senior management team.

Our success depends upon the skill, experience, and performance of members of our senior management team, who have been critical to the management of our operations and the implementation of our business strategy. We do not have key man insurance on our senior management team, and the loss of one or more key executive officers could have a material adverse effect on our operations and development. Further, any turnover in our senior management team could adversely affect our operating results and cash flows.

In order to compete, we must attract, retain and motivate key employees, and our failure to do so could have an adverse effect on our results of operations.

In order to compete, we must attract, retain and motivate executives and other key employees, including those in managerial, technical, sales, marketing, research, development, finance, information and technology, and other support positions. Hiring and retaining qualified executives, engineers, technical staff and sales representatives are critical to our business, and competition for experienced employees in the medical device industry can be intense. To attract, retain, and motivate qualified executives and key employees, we utilize stock-based incentive awards, such as employee stock options, restricted stock, and restricted stock units. Certain awards vest based upon the passage of time while others vest upon the achievement of certain performance-based or market-based conditions. If the value of such stock awards does not appreciate as measured by the performance of the price of our common stock and ceases to be viewed as a valuable benefit, our ability to attract, retain, and motivate our employees could be adversely impacted, which could negatively affect our results of operations and/or require us to increase the amount we expend on cash and other forms of compensation.

Our business is subject to economic, political, regulatory and other risks associated with international sales and operations.

Because we sell our products in many different countries, our business is subject to risks associated with conducting business internationally. We anticipate that net sales from international operations will continue to represent a substantial portion of our total net sales. In addition, a number of our manufacturing facilities and suppliers are located outside the U.S. Accordingly, our future results could be harmed by a variety of factors, including:

- changes in a specific country's or region's political or economic conditions;
- trade protection measures and import or export licensing requirements or other restrictive actions by foreign governments;
- tariff increases and import or export restrictions
- consequences from changes in tax or customs laws;
- difficulty in staffing and managing widespread operations;
- differing labor regulations;
- differing protection of intellectual property;
- unexpected changes in regulatory requirements; and
- violation by our independent agents of the FCPA or other anti-bribery or anti-corruption laws.

Risks Related to our Intellectual Property

We depend on our ability to protect our intellectual property and proprietary rights, but we may not be able to maintain the confidentiality, or assure the protection, of these assets.

Our success depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. If we fail to protect our intellectual property adequately, competitors may manufacture and market products similar to, or that compete directly with, ours. Numerous patents covering our technologies have been issued to us, and we have filed, and expect to continue to file, patent applications seeking to protect newly developed technologies and products in various countries, including the U.S. Some patent applications in the U.S. are maintained in secrecy until the patent is issued. Because the publication of discoveries tends to follow their actual discovery by several months, we may not be the first to invent, or file patent applications on any of our discoveries. Patents may not be issued with respect to any of our patent applications and existing or future patents issued to, or licensed by, us and may not provide adequate protection or competitive advantages for our products. Patents that are issued may be challenged, invalidated, or circumvented by our competitors. Furthermore, our patent

rights may not prevent our competitors from developing, using, or commercializing products that are similar or functionally equivalent to our products.

We also rely on trade secrets, unpatented proprietary expertise, and continuing technological innovation that we protect, in part, by entering into confidentiality agreements with assignors, licensees, suppliers, employees, and consultants. These agreements may be breached and there may not be adequate remedies in the event of a breach. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of confidentiality agreements. Moreover, our trade secrets and proprietary technology may otherwise become known or be independently developed by our competitors. If patents are not issued with respect to our products arising from research, we may not be able to maintain the confidentiality of information relating to these products. In addition, if a patent relating to any of our products lapses or is invalidated, we may experience greater competition arising from new market entrants.

Third parties may claim that we infringe on their proprietary rights and may prevent us from manufacturing and selling certain of our products.

There has been substantial litigation in the medical device industry with respect to the manufacture, use, and sale of new products. These lawsuits relate to the validity and infringement of patents or proprietary rights of third parties. We may be required to defend against allegations relating to the infringement of patent or proprietary rights of third parties. Any such litigation could, among other things:

- require us to incur substantial expense, even if we are successful in the litigation;
- require us to divert significant time and effort of our technical and management personnel;
- result in the loss of our rights to develop or make certain products; and
- require us to pay substantial monetary damages or royalties in order to license proprietary rights from third parties or to satisfy judgments or to settle actual or threatened litigation.

Although patent and intellectual property disputes within the orthopedic medical devices industry have often been settled through assignments, licensing, or similar arrangements, costs associated with these arrangements may be substantial and could include the long-term payment of royalties. Furthermore, the required assignments or licenses may not be made available to us on acceptable terms. Accordingly, an adverse determination in a judicial or administrative proceeding or a failure to obtain necessary assignments or licenses could prevent us from manufacturing and selling some products or increase our costs to market these products.

Risks Related to Litigation and Product Liability Matters

We may be subject to product and other liability claims that may not be covered by insurance and could require us to pay substantial sums. Moreover, fluctuations in insurance expense could adversely affect our profitability.

We are subject to an inherent risk of, and adverse publicity associated with, product liability and other liability claims, whether or not such claims are valid. We maintain product liability insurance coverage in amounts and scope that we believe are reasonable and adequate. There can be no assurance, however, that product liability or other claims will not exceed our insurance coverage limits or that such insurance will continue to be available on reasonable, commercially acceptable terms, or at all. A successful product liability claim that exceeds our insurance coverage limits could require us to pay substantial sums and could have a material adverse effect on our financial condition.

In addition to product liability insurance coverage, we hold a number of other insurance policies, including directors' and officers' liability insurance, property insurance, and workers' compensation insurance. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely impacted.

Risks Related to Potential Acquisitions and Divestitures

Our efforts to identify, pursue, and implement new business opportunities (including acquisitions) may be unsuccessful and may have an adverse effect on our business.

Our growth depends, in large part, on our ability to identify, pursue, and implement new business opportunities that expand our product offerings, capabilities, and geographic presence, and we compete with other medical device companies for these opportunities. Our efforts to identify such opportunities focus primarily on potential acquisitions of new businesses, products or

technologies, licensing arrangements, commercialization arrangements, and other transactions with third parties. We may not be able to identify business opportunities that meet our strategic criteria or are acceptable to us or our shareholders. Even if we are able to identify acceptable business opportunities, we may not be able to pursue or implement such business opportunities (or, in the case of acquisitions or other transactions, complete such acquisitions or other transactions) in a timely manner or on a cost-effective basis (or at all), and we may not realize the expected benefits of such business opportunities. If we are not able to identify, pursue, and implement new business opportunities, it will adversely affect our ability to grow our business.

In addition, pursuing and implementing new business opportunities (particularly acquisitions) may involve significant costs and entail risks, uncertainties and disruptions to our business, especially where we have limited experience as a company developing or marketing a particular product or technology or operating in a particular geographic region. We may be unable to integrate a new business, product, or technology effectively, or we may incur significant charges related to an acquisition or other business opportunity (for example, amortization of acquired assets or asset impairment charges), which may adversely affect our business, financial condition, and results of operations. Newly acquired technology or products may require additional development efforts prior to commercial sale, including clinical testing and approval by the FDA and applicable foreign regulatory authorities; such additional development efforts may involve significant expense and ultimately be unsuccessful. Any cross-border acquisitions or transactions may involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks, and the particular economic, political and regulatory risks associated with specific countries. To the extent we issue additional equity in connection with acquisitions, this may dilute our existing shareholders.

We may incur significant costs or retain liabilities associated with disposition activity.

We may from time to time sell, license, assign or otherwise dispose of or divest assets, the stock of subsidiaries or individual products, product lines or technologies, which we determine are no longer desirable for us to own, some of which may be material. Any such activity could result in us incurring costs and expenses from these efforts, some of which could be significant, as well as retaining liabilities related to the assets or properties disposed of even though, for instance, the income-generating assets have been disposed of. These costs and expenses may be incurred at any time and may have a material impact on our results of operations.

Risks Related to Our Financial Results and Need for Financing

Our quarterly operating results may fluctuate.

Our quarterly operating results have fluctuated significantly in the past. Our future quarterly operating results may fluctuate significantly, and we may experience losses depending on a number of factors, including the extent to which our products continue to gain or maintain market acceptance, the rate and size of expenditures incurred as we expand our domestic and establish our international sales and distribution networks, the timing and level of reimbursement for our products by third-party payors, the extent to which we are subject to government regulation or enforcement, the valuation of certain assets and liabilities, and other factors, many of which are outside our control.

We face risks related to foreign currency exchange rates.

Because some of our revenue, operating expenses, assets and liabilities are denominated in foreign currencies, we are subject to foreign exchange risks that could adversely affect our operations and reported results. To the extent that we incur expenses or earn revenue in currencies other than the U.S. Dollar, any change in the values of those foreign currencies relative to the U.S. Dollar could cause our profits to decrease or our products to be less competitive against those of our competitors. To the extent that our current assets denominated in foreign currency are greater or less than our current liabilities denominated in foreign currencies, we have potential foreign exchange exposure. The fluctuations of foreign exchange rates during 2019 have had an unfavorable impact of $4.7 million on net sales outside of the U.S. Although we seek to manage our foreign currency exposure by matching non-dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we may enter into currency hedges from time to time.

Our global operations may expose us to tax risks

We are subject to taxes in the U.S. and numerous foreign jurisdictions. Significant judgment and interpretation of tax laws are required to estimate our tax liabilities. Tax laws and rates in various jurisdictions may be subject to significant change as a result of political and economic conditions. Our effective income tax rate could be adversely affected by changes in those tax laws; changes in

the mix of earnings among tax jurisdictions; changes in the valuation of our deferred tax assets and liabilities; and the resolution of matters arising from tax audits.

Certain of our subsidiaries sell products directly to other Orthofix subsidiaries or provide marketing and support services to other Orthofix subsidiaries. These intercompany sales and support services involve subsidiaries operating in jurisdictions with differing tax rates, and we must determine the appropriate allocation of income to each jurisdiction based on current interpretations of complex income tax regulations. Tax authorities in these jurisdictions may challenge our treatment of such intercompany transactions. If we are unsuccessful in defending our treatment of intercompany transactions, we may be subject to additional tax liability, interest, or penalty, which could adversely affect our profitability.

We maintain a $300 million secured revolving credit facility secured by a pledge of substantially all of our property.

On October 25, 2019, we and certain of our wholly-owned subsidiaries (collectively, the "Borrowers") entered into a Second Amended and Restated Credit Agreement (the "Amended Credit Agreement"). The Amended Credit Agreement provides for a $300 million secured revolving credit facility maturing on October 25, 2024, and amends and restates the previous $125 million secured revolving credit facility. No amounts have been drawn on the credit facility as of the date hereof, but the Company may draw on this facility in the future.

Certain of our subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of any obligations under the Amended Credit Agreement. The obligations with respect to the Amended Credit Agreement are secured by a pledge of substantially all of the personal property assets of the Borrowers and each of the Guarantors, including accounts receivables, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their respective subsidiaries.

The Amended Credit Agreement contains customary affirmative and negative covenants, including limitations on our ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness, and enter into affiliate transactions. In addition, the Amended Credit Agreement contains financial covenants requiring us to maintain, on a consolidated basis as of the last day of any fiscal quarter, a total net leverage ratio of not more than 3.5 to 1.0 (which ratio can be permitted to increase to 4.0 to 1.0 for no more than 4 fiscal quarters following a material acquisition) and an interest coverage ratio of at least 3.0 to 1.0. The Amended Credit Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Facility may be accelerated and/or the lenders' commitments terminated.

We believe that we are in compliance with the covenants, and there were no events of default, at December 31, 2019 (and in prior periods). However, there can be no assurance that we will be able to meet such financial covenants in future fiscal quarters. The failure to do so could result in an event of default under such agreement, which could have a material adverse effect on our financial position in the event that we have significant amounts drawn under the facility at such time.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal facilities as of December 31, 2019 are as follows:

Facility	Location	Approx. Square Feet	Ownership
Manufacturing, warehousing, distribution, research and development, and administrative facility for Corporate and all reporting segments	Lewisville, TX	140,000	Leased
Manufacturing, warehousing, distribution, research and development, and administrative facility for motion preservation	Sunnyvale, CA	25,000	Leased
Research and development, component manufacturing, quality control and training facility for fixation products and sales management, distribution and administrative facility for Italy	Verona, Italy	38,000	Owned
International distribution center for Orthofix products	Verona, Italy	18,000	Leased
Mechanical workshop for Orthofix products	Verona, Italy	9,000	Leased
Sales management, distribution and administrative facility for United Kingdom	Maidenhead, England	5,580	Leased
Sales management, distribution and administrative facility for Brazil	São Paulo, Brazil	22,000	Leased
Sales management, distribution and administrative facility for France	Arcueil, France	8,500	Leased
Sales management, distribution and administrative facility for Germany	Ottobrunn, Germany	18,300	Leased

Item 3. Legal Proceedings

For a description of our material pending legal proceedings, refer to Note 12 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market for Our Common Stock

Our common stock is traded on the Nasdaq Global Select Market under the symbol "OFIX." As of February 20, 2020, we had 318 holders of record of our common stock. The closing price of our common stock on February 20, 2020 was $45.36. The following table shows the high and low sales prices for our common stock for each of the two most recent fiscal years.

	High	Low
2018		
First Quarter	$ 61.00	$ 51.01
Second Quarter	61.86	51.38
Third Quarter	61.98	50.41
Fourth Quarter	63.57	48.00
2019		
First Quarter	$ 74.44	$ 47.79
Second Quarter	57.85	48.02
Third Quarter	55.17	48.77
Fourth Quarter	54.02	39.75

Dividends

We have not paid dividends to holders of our common stock in the past and have no present intention to pay dividends in the foreseeable future. Additionally, we have restrictions on the ability to pay dividends in certain circumstances pursuant to our Amended Credit Agreement. We currently intend to retain all of our consolidated earnings to finance the continued growth of our business.

In the event that we decide to pay a dividend to holders of our common stock in the future with dividends received from our subsidiaries, we may, based on prevailing rates of taxation, be required to pay additional withholding and income tax on such amounts.

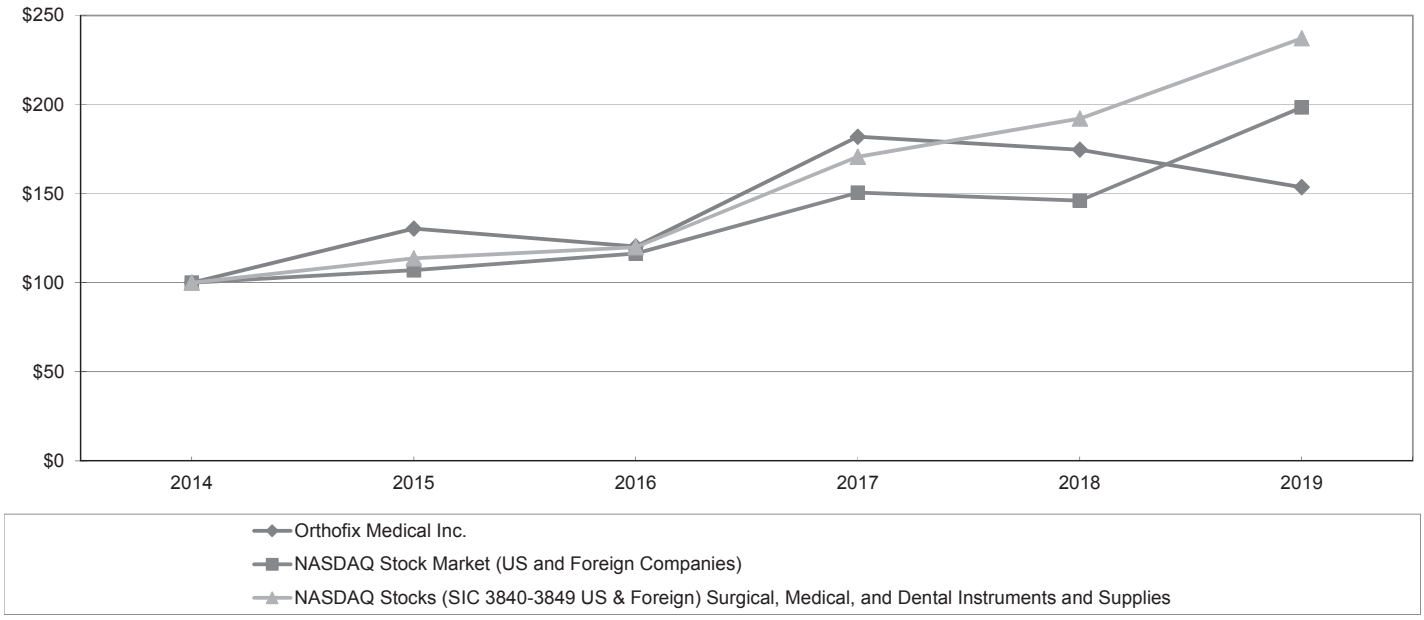
Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of 2019.

Performance Graph

The following performance graph is not deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C or to the liabilities of Section 18 of the Exchange Act. This information will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except to the extent we specifically incorporate this information by reference.

The graph below compares the five-year total shareholder return on Orthofix common stock with the returns of two indexes: the Nasdaq Stock Market and Nasdaq stocks for surgical, medical, and dental instruments and supplies. The graph assumes that you invested $100 in Orthofix Common Stock and in each of the indexes on December 31, 2014. Points on the graph represent the performance as of the last business day of each of the years indicated.



Item 6. Selected Financial Data

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

	Year ended December 31,				
(U.S. Dollars, in thousands, except margin and per share data)	2019	2018	2017	2016	2015
Consolidated operating results					
Net sales	$ 459,955	$ 453,042	$ 433,823	$ 409,788	$ 396,489
Gross profit	359,348	356,414	340,786	321,935	309,964
Gross margin	78%	79%	79%	79%	78%
Operating income (loss) (1)	(18,784)	30,094	40,811	21,067	9,225
Net income (loss) from continuing operations	(28,462)	13,811	7,291	3,497	(2,342)
Net loss from discontinued operations	—	—	(1,068)	(441)	(467)
Net income (loss) (2)	$ (28,462)	$ 13,811	$ 6,223	$ 3,056	$ (2,809)
Net income (loss) per common share – basic					
Net income (loss) from continuing operations	$ (1.51)	$ 0.73	$ 0.40	$ 0.19	$ (0.12)
Net loss from discontinued operations	—	—	(0.06)	(0.02)	(0.03)
Net income (loss)	$ (1.51)	$ 0.73	$ 0.34	$ 0.17	$ (0.15)
Net income (loss) per common share – diluted					
Net income (loss) from continuing operations	$ (1.51)	$ 0.72	$ 0.39	$ 0.19	$ (0.12)
Net loss from discontinued operations	—	—	(0.05)	(0.02)	(0.03)
Net income (loss)	$ (1.51)	$ 0.72	$ 0.34	$ 0.17	$ (0.15)

(1) Includes the following:

- Legal, accounting, and other professional fees incurred in 2019, 2018, 2017, 2016, and 2015 of $0.2 million, $1.1 million, $3.4 million, $2.0 million, and $9.1 million, respectively, in connection with the accounting review and restatements (incurred through March 2015) and legal fees associated with the SEC Investigation, a related securities class action complaint and Brazil subsidiary compliance review. In addition, the Company received an insurance settlement related to these matters of approximately $6.1 million in 2017
- Charges related to U.S. Government resolutions in 2016 of $14.4 million

(2) Dividends have not been paid in any of the years presented

	As of December 31,				
(U.S. Dollars, in thousands)	2019	2018	2017	2016	2015
Consolidated financial position					
Total assets	$ 495,620	$ 466,641	$ 405,354	$ 372,103	$ 400,222
Long-term debt	—	—	—	—	—
Shareholders' equity	327,631	335,397	296,608	263,477	290,311

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

The following discussion and analysis of our financial condition and result of operations should be read in conjunction with "Forward-Looking Statements" and our consolidated financial statements and notes thereto appearing elsewhere in this Annual Report. The discussion and analysis below is focused on our 2019 and 2018 financial results, including comparisons of our year-over-year performance between these years. Discussion and analysis of our 2017 fiscal year specifically, as well as the year-over-year comparison of our 2018 financial performance to 2017, is located in Part II, Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on February 25, 2019, which is available on our website at www.orthofix.com and the SEC's website at www.sec.gov.

Executive Summary

We are a global medical device company focused on musculoskeletal products and therapies. Headquartered in Lewisville, Texas, we have two reporting segments: Global Spine and Global Extremities. Our products are distributed by our sales representatives and distributors in more than 70 countries.

Notable highlights and accomplishments in 2019 include the following:

- Net sales were $460.0 million, an increase of 1.5% on a reported basis and 2.5% on a constant currency basis
- Increase in Biologics net sales of 9.7% compared to the prior year, as we believe we now have the #1 market-share position within the U.S. Cellular Allograft segment per SmartTRAK following the product category's strong performance in 2019
- Net loss was $28.5 million, a decrease $42.3 million from the prior year, primarily driven by increases in acquisition-related amortization and remeasurement and sales and marketing expenses
- Obtained approval in February 2019 from the U.S. Food and Drug Administration ("FDA") for our M6-C artificial cervical disc acquired from Spinal Kinetics, Inc. ("Spinal Kinetics") and achieved $4.1 million in net sales in the U.S. following approval
- Changed our reporting segments to Global Spine and Global Extremities to optimize our structure and better serve our surgeon customers
- Successful transition of Chief Executive Officer and Global Spine President positions

Results of Operations

The following table presents certain items in our consolidated statements of operations as a percent of net sales:

	Year ended December 31,		
	2019 (%)	2018 (%)	2017 (%)
Net sales	100.0	100.0	100.0
Cost of sales	21.9	21.3	21.4
Gross profit	78.1	78.7	78.6
Sales and marketing	48.6	45.4	45.7
General and administrative	18.6	18.4	16.6
Research and development	7.5	7.3	6.9
Acquisition-related amortization and remeasurement	7.5	1.0	—
Operating income (loss)	(4.1)	6.6	9.4
Net income (loss) from continuing operations	(6.2)	3.0	1.7
Net loss from discontinued operations	—	—	(0.3)
Net income (loss)	(6.2)	3.0	1.4

Net Sales by Reporting Segment

The following table provides net sales by major product category by reporting segment:

				Percentage Change			
				2019/2018	2019/2018 Constant Currency	2018/2017	2018/2017 Constant Currency
(U.S. Dollars, in thousands)	2019	2018	2017	Reported		Reported	
Bone Growth Therapies	$ 197,181	$ 195,252	$ 185,900	1.0%	1.0%	5.0%	5.0%
Spinal Implants	94,544	91,658	81,957	3.1%	3.8%	11.8%	11.9%
Biologics	65,496	59,684	62,724	9.7%	9.7%	-4.8%	-4.8%
Global Spine	357,221	346,594	330,581	3.1%	3.2%	4.8%	4.9%
Global Extremities	102,734	106,448	103,242	-3.5%	0.3%	3.1%	0.9%
Net sales	$ 459,955	$ 453,042	$ 433,823	1.5%	2.6%	4.4%	3.9%

Global Spine

Global Spine offers the following products categories:

- Bone Growth Therapies, which manufactures, distributes, sells, and provides support services for market leading devices that enhance bone fusion. Bone Growth Therapies uses distributors and sales representatives to sell its devices and provide associated services to hospitals, healthcare providers, and patients.
- Spinal Implants, which designs, develops and markets a broad portfolio of motion preservation and fixation implant products used in surgical procedures of the spine. Spinal Implants distributes its products globally through a network of distributors and sales representatives to sell spine products to hospitals and healthcare providers.
- Biologics, which provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. Biologics markets its tissues to hospitals and healthcare providers, primarily in the U.S., through a network of employed and independent sales representatives.

2019 Compared to 2018

Net sales increased $10.6 million or 3.1%

- Bone Growth Therapies net sales increased $1.9 million or 1.0%, primarily driven by a 2.8% increase in order volume during the year, partially offset by customer sales mix and product mix changes
- Spinal Implants net sales increased $2.9 million or 3.1%, primarily driven by an increase of $7.6 million in motion preservation net sales, which includes a full 12 months of sales in 2019 as compared to only eight months in the prior year due to the acquisition of Spinal Kinetics in 2018 and our launch into the U.S. market in April 2019 following FDA approval for the M6-C artificial cervical disc; this increase was partially offset by a decrease in legacy Spine Fixation sales of $4.7 million, primarily resulting from disruptions in our U.S. distribution channel as we upgrade our legacy sales force with new, high-potential sales partners
- Biologics net sales increased $5.8 million or 9.7%, primarily due to distribution added during the last year as volume increased related to Trinity tissues by 12.4%, partially offset by a low single-digit price decline as well as a contractual reduction in the marketing services fee we receive from MTF Biologics, which became effective during the first quarter of 2018

Global Extremities

Global Extremities offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. Global Extremities distributes its products globally through a network of distributors and sales representatives to sell orthopedic products to hospitals and healthcare providers.

2019 Compared to 2018

Net sales decreased $3.7 million, or 3.5%

- Decrease of $4.1 due to the changes in foreign currency exchange rates, which had a negative impact on net sales
- Increase of $0.4 largely attributed to variability in the timing of orders from our international stocking distributors and growth in our global direct-sales markets

Gross Profit

				Percentage Change	
(U.S. Dollars, in thousands)	**2019**	**2018**	**2017**	**2019/2018**	**2018/2017**
Net sales	$ 459,955	$ 453,042	$ 433,823	1.5%	4.4%
Cost of sales	100,607	96,628	93,037	4.1%	3.9%
Gross profit	$ 359,348	$ 356,414	$ 340,786	0.8%	4.6%
Gross margin	78.1%	78.7%	78.6%	-0.6%	0.1%

2019 Compared to 2018

Gross profit increased $2.9 million, or 0.8%

- Primarily due to the growth in net sales, partially offset by gross margin decreasing from 78.7% in 2018 to 78.1% in 2019
- Increase of $0.7 million attributable to a decrease in acquisition-related inventory fair market value adjustments for Spinal Kinetics

Sales and Marketing Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2019**	**2018**	**2017**	**2019/2018**	**2018/2017**
Sales and marketing	$ 223,676	$ 205,527	$ 198,370	8.8%	3.6%
As a percentage of net sales	48.6%	45.4%	45.7%	3.2%	-0.3%

2019 Compared to 2018

Sales and marketing expense increased $18.1 million

- Increase largely attributable to increases in headcount, training, and education costs, and increased marketing efforts to support growth and the launch of the M6-C artificial cervical disc in the U.S.
- Further increases relate to higher variable compensation rates in our Global Spine segment to support growth

General and Administrative Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2019**	**2018**	**2017**	**2019/2018**	**2018/2017**
General and administrative	$ 85,607	$ 83,251	$ 71,905	2.8%	15.8%
As a percentage of net sales	18.6%	18.4%	16.6%	0.2%	1.8%

2019 Compared to 2018

General and administrative expense increased $2.4 million

- Increase of $9.9 million attributable to succession and transition charges, including acceleration of certain share-based compensation expense, relating to the retirement, transition, or termination of certain named executive officers and from targeted restructuring activities

- Partially offset by a decrease of $3.9 million associated with strategic investments, largely due to diligence and integration costs related to the acquisition of Spinal Kinetics and expenses associated with our change in jurisdiction of organization from Curaçao to the State of Delaware (the "Domestication") in 2018
- Further offset by a decrease of $4.1 million in certain compensation expenses, such as share-based compensation expense, excluding the impact of succession and transition charges

Research and Development Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2019**	**2018**	**2017**	**2019/2018**	**2018/2017**
Research and development	$ 34,637	$ 33,218	$ 29,700	4.3%	11.8%
As a percentage of net sales	7.5%	7.3%	6.9%	0.2%	0.4%

2019 Compared to 2018

Research and development expense increased $1.4 million

- Increase largely attributable to the Spinal Kinetics acquisition and the regulatory efforts associated with the FDA premarket approval of the M6 artificial cervical disc, which was obtained in February of 2019
- Increase of $1.0 million related to costs to comply with recent medical device reporting regulations in the European Union

Acquisition-related Amortization and Remeasurement

				Percentage Change	
(U.S. Dollars, in thousands)	**2019**	**2018**	**2017**	**2019/2018**	**2018/2017**
Acquisition-related amortization and remeasurement	$ 34,212	$ 4,324	$ —	691.2%	100.0%
As a percentage of net sales	7.5%	1.0%	0.0%	6.5%	1.0%

2019 Compared to 2018

Acquisition-related amortization and remeasurement increased $29.9 million

- Increase of $26.1 million related to the remeasurement of contingent milestone payments associated with the Spinal Kinetics acquisition that become due upon the achievement of certain revenue targets and upon FDA approval of the M6-C artificial cervical disc, which occurred in the first quarter of 2019
- The fair value associated with the contingent revenue-based milestones increased significantly in 2019, largely attributable to the initial success observed in the launch of the M6-C artificial cervical disc in the U.S. market, as our long-term forecasts of net sales now indicate a greater likelihood of achieving the contingent revenue-based milestones
- Increase of $3.8 million related to the amortization of intangible assets acquired through business combinations or asset acquisitions; of this amount, $2.9 million of the increase is attributable to the Spinal Kinetics acquisition, which includes amortization of acquired in-process research and development costs following the achievement of the FDA milestone

Non-operating Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2019**	**2018**	**2017**	**2019/2018**	**2018/2017**
Interest expense, net	$ (122)	$ (828)	$ (416)	-85.3%	99.0%
Other expense, net	(8,143)	(6,381)	(4,004)	27.6%	59.4%

Non-operating income and expense largely consists of interest income and expense, transaction gains and losses from changes in foreign currency exchange rates, changes in fair value related to our equity holdings in Bone Biologics, Inc. ("Bone Biologics"), and other-than-temporary impairments on the debt security of eNeura, Inc. ("eNeura") that was settled on October 25, 2019. Foreign exchange gains and losses are primarily a result of several of our foreign subsidiaries holding trade and intercompany payables or receivables in currencies (most notably the U.S. Dollar) other than their functional currency.

2019 Compared to 2018

Other expense, net, increased $1.8 million

- Increase of $6.5 million associated with an other-than-temporary impairment of the eNeura debt security, which was settled in 2019
- Partially offset by a net decrease of $3.1 million relating to impairment and changes in fair value of our equity holdings and warrants in Bone Biologics during 2018 that did not recur in 2019
- Partially offset by an decrease of $1.9 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement loss of $1.4 million in 2019 compared to a loss of $3.3 million in 2018

Income Taxes

				Percentage Change	
(U.S. Dollars, in thousands)	**2019**	**2018**	**2017**	**2019/2018**	**2018/2017**
Income tax expense	$ 1,413	$ 9,074	$ 29,100	-84.4%	-68.8%
Effective tax rate	-5.2%	39.7%	80.0%	-44.9%	-40.3%

2019 Effective Tax Rate

The decrease in the effective tax rate during the year was primarily a result of the decrease in income before income taxes, full year benefit of our Domestication completed in 2018, and statute expirations and effective settlement of uncertain tax positions, offset by non-deductible executive compensation and non-deductible increase in contingent consideration. The primary factors affecting our tax rate for 2019 are as follows:

- Non-deductible increases in the fair value of contingent consideration
- Statute expirations and effective settlement of uncertain tax positions
- Executive compensation that is not deductible as a result of the Tax Act
- State taxes and foreign income taxed at differing rates

2018 Effective Tax Rate

The decrease in the effective tax rate during the year was primarily a result of the decrease in income before income taxes, the reduction of the US statutory tax rate from 35% to 21%, and the 2017 charge from recording the impact of the Tax Cuts and Jobs Act (the “Tax Act”) that did not recur in 2018. The primary factors affecting our tax rate for 2018 are as follows:

- Current period losses in jurisdictions where we do not currently receive a tax benefit
- State taxes and foreign income taxed at differing rates
- Benefits of deductible equity compensation in excess of financial statement impact

Segment Review

In conjunction with our change in reporting segments in 2019, we also changed the performance measure used to evaluate segment performance from Non-GAAP net margin, an internal metric that we defined as gross profit less sales and marketing expense, to EBITDA. When compared to the prior year, EBITDA decreased $44.6 million, largely driven by the fluctuations discussed above, but primarily attributable to changes in acquisition-related amortization and remeasurement and sales and marketing expense.

The following table reconciles EBITDA to income (loss) before income taxes:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
Global Spine	$ 39,528	$ 76,545	$ 84,034
Global Extremities	7,496	9,453	7,143
Corporate	(49,252)	(43,626)	(34,246)
Total EBITDA	(2,228)	42,372	56,931
Depreciation and amortization	(24,699)	(18,659)	(20,124)
Interest expense, net	(122)	(828)	(416)
Income (loss) before income taxes	$ (27,049)	$ 22,885	$ 36,391

Liquidity and Capital Resources

Cash, cash equivalents, and restricted cash at December 31, 2019 was $70.4 million compared to $72.2 million at December 31, 2018.

	Year Ended December, 31,		
(U.S. Dollars, in thousands)	2019	2018	Change
Net cash from operating activities	$ 32,033	$ 49,918	$ (17,885)
Net cash from investing activities	(22,924)	(60,998)	38,074
Net cash from financing activities	(10,688)	2,993	(13,681)
Effect of exchange rate changes on cash and restricted cash	(207)	(881)	674
Net change in cash, cash equivalents, and restricted cash	$ (1,786)	$ (8,968)	$ 7,182

The following table presents free cash flow, a non-GAAP financial measure, which is calculated by subtracting capital expenditures from net cash from operating activities.

	Year Ended December, 31,		
(U.S. Dollars, in thousands)	2019	2018	Change
Net cash from operating activities	$ 32,033	$ 49,918	$ (17,885)
Capital expenditures	(20,524)	(15,256)	(5,268)
Free cash flow	$ 11,509	$ 34,662	$ (23,153)

Operating Activities

Cash flows from operating activities decreased $17.9 million

- Decrease in net income of $42.3 million
- Net increase of $46.8 million for non-cash gains and losses, primarily related to changes in fair value of contingent consideration, depreciation and amortization, share-based compensation expense, and deferred income taxes
- Net decrease of $22.4 million relating to changes in working capital, primarily attributable to changes in inventories and trade accounts receivable

Two of our primary working capital accounts are trade accounts receivable and inventory. Day's sales in receivables were 66 days at December 31, 2019 compared to 59 days at December 31, 2018, largely due to a delay in payment from certain third party payors. Inventory turns were 1.2 times as of December 31, 2019 compared to 1.3 times at December 31, 2018, primarily resulting from increases in inventory and instruments in 2019 to support certain product launches.

Investing Activities

Cash flows from investing activities increased $38.1 million

- Increase of $44.3 million associated with cash paid in relation to the Spinal Kinetics acquisition in 2018, net of cash acquired
- Increase of $4.0 million related to the settlement of the eNeura debt security in 2019

- Increase of $0.9 million associated with the acquisition of certain intangible assets in transactions with former distributors and from our additional investment of $0.5 million in Bone Biologics in 2018
- Partially offset by $6.4 million associated with cash paid in relation to the acquisition of certain assets of Options Medical LLC, one of our former distributors, in 2019
- Further offset by an increase in capital expenditures of $5.3 million compared to the prior year, largely relating to the buildup of instruments to support new product launches, such as our launch of the M6-C artificial cervical disc in the U.S.

Financing Activities

Cash flows from financing activities decreased $13.7 million

- Decrease of $13.7 million associated with our payment of the FDA Milestone associated with the Spinal Kinetics acquisition in 2019, which represents the acquisition-date fair value attributable to the FDA Milestone liability originally recognized
- Decrease of $1.4 million associated with debt issuance costs, largely attributable to costs incurred in 2019 associated with our Second Amended and Restated Credit Agreement (the "Amended Credit Agreement")
- Decrease of $0.4 million attributable to principal payments made in 2019 relating to our finance lease and $0.9 million attributable to other financing cash flows, which primarily relate to deferred payments made in association with the acquisition of certain intangible assets in transactions with former distributors
- Partially offset by an increase in net proceeds of $2.7 million from the issuance of common shares

Credit Facilities

On October 25, 2019, we entered into a Second Amended and Restated Credit Agreement (the "Amended Credit Agreement"), which provides for a five year $300 million secured revolving credit facility. The Amended Credit Agreement has a maturity date of October 25, 2024, and amends and restates the previous $125 million secured revolving credit facility.

Borrowings under the Amended Credit Agreement may be used for, among other things, working capital and other general corporate purposes (including share repurchases, permitted acquisitions and permitted payments of dividends and other distributions). As of December 31, 2019, we have not made any borrowings under the Amended Credit Agreement. For additional information regarding the credit facility, see Note 10 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

We had no borrowings and an unused available line of credit of €5.5 million ($6.2 million and $6.3 million) at December 31, 2019 and 2018, respectively, on our Italian line of credit. This unsecured line of credit provides us the option to borrow amounts in Italy at rates which are determined at the time of borrowing.

Other

For information regarding Contingencies, see Note 12 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Spinal Kinetics Acquisition and Contingent Consideration

As part of the consideration for the Spinal Kinetics acquisition, we agreed to milestone payments in the future of up to $60.0 million in cash. One milestone payment was for $15.0 million upon FDA approval of Spinal Kinetics' M6-C artificial cervical disc (the "FDA Milestone"). During the first quarter of 2019, we obtained FDA approval of the M6-C artificial cervical disc for patients suffering from cervical disease degeneration and the FDA Milestone payment was triggered. We paid the $15.0 million FDA Milestone payment on February 14, 2019 from cash on hand.

The remaining two milestones are comprised of revenue-based milestone payments of up to $45.0 million in connection with future sales of the M6-C artificial cervical disc and the M6-L artificial lumbar disc. The fair value of the contingent consideration arrangement as of December 31, 2019 was $42.7 million; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration. At December 31, 2019, we classified $14.7 million of the liability attributable to the revenue-based milestones within other current liabilities, as we expect to pay one of the revenue-based milestones in the next twelve months, and the remaining $28.0 million within other long-term liabilities. For additional discussion of this matter, see Note 12 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

FITBONE Asset Acquisition

On February 3, 2020, we entered into an Asset Purchase Agreement (the "Purchase Agreement") with Wittenstein SE ("Wittenstein"), a privately-held German-based company, to acquire assets associated with the FITBONE intramedullary lengthening system for limb lengthening of the femur and tibia bones. Under the terms of the Purchase Agreement, as consideration for the acquired assets, we will pay $18 million in cash consideration and will enter into manufacturing supply contract with Wittenstein.

The acquisition is anticipated to close by the end of the first quarter of 2020, subject to customary closing conditions.

Debt Security

Until October of 2019, we held a debt security of eNeura, a privately held medical technology company that is developing devices for the treatment of migraines. The debt security was originally set to mature on March 4, 2019. On March 1, 2019, we entered into an Amended and Restated Senior Secured Promissory Note with eNeura (the "Restructured Debt Security") to restructure the debt security, which extended the maturity date to the earlier of (i) March 4, 2022, (ii) the effective date of a change in control, or (iii) the effective date of an initial public offering by eNeura. As consideration for the extension, eNeura issued to us a Warrant to Purchase Common Stock (the "Warrant"), exercisable at $0.01 per share over a ten year contractual term.

During the third quarter of 2019, we engaged in negotiations with eNeura to settle the Restructured Debt Security and on October 25, 2019, we settled the Restructured Debt Security for a $4.0 million cash payment and agreed to transfer the Warrant to eNeura. As such, prior to its settlement, we determined the Restructured Debt Security and Warrant were impaired and adjusted the carrying value of the Restructured Debt Security to $4.0 million, its settlement value, by recording a net other-than-temporary impairment of $6.5 million in other expense, net, which includes a reclassification of the related unrealized gains included in accumulated other comprehensive income (loss) of $5.2 million.

Brazil

In 2018, the Federal Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority inspected the offices of more than 30 companies, including the Company's office in São Paulo, as part of an investigation into tender irregularities in the medical device industry. Before doing so, the authorities obtained a court order affecting the Company's (and other companies') local bank accounts resulting in the freezing of the Company's cash. On April 3, 2019, our appeal regarding the freezing of our local bank accounts was heard by the Brazil Federal Court of Appeals of Rio de Janeiro, in which the Court ordered the unfreezing of our cash. Approximately $2.5 million was then returned without any restrictions in April 2019. As such, this balance has been reclassified from restricted cash to cash and cash equivalents as of December 31, 2019.

In September 2019, in relation to an ongoing legal dispute with a former Brazilian distributor, approximately $0.7 million of our cash in Brazil was frozen upon request to satisfy a judgment. Although we are appealing the judgment, this cash has been reclassified to restricted cash.

For additional discussion regarding these matters, see Note 12 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Unremitted Foreign Earnings

Prior to the Domestication, as an entity incorporated in Curaçao, "foreign earnings" referred to both U.S. and non-U.S. earnings. As a result of the Domestication, only income sourced outside of the U.S. is considered unremitted foreign earnings. Unremitted foreign earnings decreased from $50.4 million at December 31, 2018 to $49.2 million at December 31, 2019, due to currency translation. As a result of the 2017 Tax Act, current year earnings have been deemed to be repatriated. Our investment in foreign subsidiaries continues to be indefinite in nature, however, we may periodically repatriate a portion of these earnings to the extent that we do not incur significant additional tax liability.

Contractual Obligations

The following table sets forth our contractual obligations as of December 31, 2019:

	Payments Due by Period				
(U.S. Dollars, in thousands)	Total	2020	2021 - 2023	2024	2025 and thereafter
Operating leases	$ 6,234	$ 1,979	$ 3,426	$ 143	$ 686
Finance leases	32,547	1,013	4,327	1,501	25,706
Total (1)(2)	$ 38,781	$ 2,992	$ 7,753	$ 1,644	$ 26,392

(1) Associated with the acquisition of Spinal Kinetics, we may be required to make conditional revenue-based milestone payments of up to $45.0 million in connection with future sales of the M6-C artificial cervical disc and M6-L artificial lumbar disc. We expect to make a $15.0 million payment related to these contingent milestones in 2020 and a $30.0 million payment in 2021; however, the timing of cash settlement, if any, could vary from these estimates. Accordingly, these contingent payments have been excluded from the contractual obligations table above. For further information regarding these contingent payments, see Note 11 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

(2) We may be required to make payments related to our uncertain tax positions. However, we are unable to reliably estimate the timing of cash settlement, if any, with the respective taxing authorities. Accordingly, unrecognized tax benefits, including interest and penalties, of $23.5 million as of December 31, 2019 have been excluded from the contractual obligations table above. For further information, see Note 19 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Off-balance Sheet Arrangements

As of December 31, 2019, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, cash flows, liquidity, capital expenditures or capital resources that are material to investors. In addition, we do not consider the backlog of firm orders to be material.

Critical Accounting Estimates

Our discussion of operating results is based upon the consolidated financial statements and accompanying notes. The preparation of these statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. On an ongoing basis, we evaluate these estimates, which are based on historical experience and various other assumptions that management believe to be reasonable under the circumstances at that point in time. Actual results may differ, significantly at times, from these estimates.

We believe the estimates described below are the most critical in preparing our consolidated financial statements. We have reviewed these critical accounting estimates with the Audit Committee of the Board of Directors.

Revenue Recognition

The process for recognizing revenue involves significant assumptions and judgments for certain of our revenue streams. Revenue recognition policies are “critical accounting estimates” because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net sales, gross margin, operating income, EBITDA, and net income.

Bone Growth Therapies revenue is largely attributable to the U.S. and is comprised of third-party payor transactions and wholesale revenue.

For revenue derived from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors, such as Medicare, in connection with the sale of our stimulation products, we recognize revenue when the stimulation product is fitted to and accepted by the patient and all applicable documents that are

required by the third-party payor have been obtained. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

Wholesale revenue is related to the sale of our bone growth stimulators directly to physicians and other healthcare providers. Wholesale revenues are recognized upon shipment and receipt of a confirming purchase order, which is when the customer obtains control of the promised goods.

Biologics revenue is largely attributable to the U.S. and is primarily related to a collaborative arrangement with MTF. We have exclusive global marketing rights and receive marketing fees from MTF based on products distributed by MTF. MTF is considered the principal in these arrangements; therefore, we recognize these marketing service fees on a net basis upon shipment of the product to the customer.

Spinal Implants and Global Extremities products are distributed world-wide, with U.S. sales largely comprised of commercial revenue and international sales derived from commercial sales and through stocking distributor arrangements.

Commercial revenue is largely related to the sale of our Spinal Implants and Global Extremities products to hospital customers. Commercial revenues are recognized when these products have been utilized and a confirming purchase order has been received from the hospital.

Stocking distributors purchase our products and then re-sell them directly to customers, such as hospitals. For revenue derived from stocking distributor agreements, prior to the adoption of ASU 2014-09, *Revenue from Contracts with Customers* ("Topic 606"), i.e. for all periods presented prior to January 1, 2018, we recognized revenue once the product was delivered to the end customer (the "sell-through method"). Because we did not have reliable information about when our distributors sold the product through to end customers, we used cash collection from distributors as a basis for revenue recognition under the sell-through method. Additionally, when we sold to these distributors, we considered whether to match the related cost of sales expense with revenue or to recognize expense upon shipment. In making this assessment, we considered the financial viability of our distributors based on their creditworthiness to determine if collectability of amounts sufficient to realize the costs of the products shipped was reasonably assured at the time of shipment to these distributors. In instances where the distributor was determined to be financially viable, we deferred the costs of sales until the revenue was recognized.

Subsequent to the adoption of Topic 606, effective January 1, 2018, for revenue derived from stocking distributor arrangements, we recognize revenue upon shipment and receipt of a confirming purchase order, which is when the distributor obtains control of the promised goods. The transaction price is estimated based upon our historical collection experience with the stocking distributor. To derive this estimate, we analyze twelve months of historical invoices by stocking distributor and the subsequent collections on those invoices, for a period of up to 24 months subsequent to the invoice date. This percentage, which is specific to each stocking distributor, is then used to calculate the transaction price. Cost of sales is also recorded upon transfer of control of the product to the customer, which is when the Company's performance obligation has been satisfied.

Allowance for Doubtful Accounts and Contractual Allowances

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. Historical collections, write-offs, and payor reimbursement experience are integral parts of the estimation process related to reserves for doubtful accounts and the establishment of contractual allowances. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses. Revisions to contractual allowances are recorded as an adjustment to net sales. Our estimates are periodically tested against actual collection experience. We believe our allowance for doubtful accounts is sufficient to cover customer credit risks; however, a 10% change in our allowance for doubtful accounts as of December 31, 2019 would result in an increase or decrease to sales and marketing expense of $0.4 million. Additionally, we believe our estimate to establish contractual allowances is sufficient to cover customer credit risks; however, a 10% change in our reserve for contractual allowances as of December 31, 2019 would result in an increase or decrease to net sales of $0.6 million. Our allowance for doubtful accounts and estimation of contractual allowances are "critical accounting estimates" because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net sales, gross margin, operating income, EBITDA, net income, and trade accounts receivable.

Inventory Allowances

Reserves for excess, slow moving, and obsolete inventory are calculated as the difference between the cost of inventory and market value, and are based on assumptions and judgments about new product launch periods, overall product life cycles, forecasted demand, and market conditions. In the event of a decrease in demand for our products, excess product production, or a higher incidence of inventory obsolescence, we could be required to increase our inventory reserves, which would increase cost of sales and decrease gross profit. We regularly evaluate our exposure for inventory write-downs. If conditions or assumptions used in determining the market value or forecasted demand change, additional inventory adjustments in the future may be necessary. Our inventory allowance is a "critical accounting estimate" because changes in the assumptions used to develop the estimate could materially affect key financial measures, including gross profit, operating income, EBITDA, net income, and inventory.

Valuation of Intangible Assets

Our intangible assets are comprised primarily of patents, acquired or developed technology, licensing arrangements, trademarks, and in-process research and development ("IPR&D"). We make significant judgments in relation to the valuation of intangible assets resulting from business combinations or asset acquisitions. Intangible assets acquired in a business combination that are used for IPR&D activities are considered to have indefinite lives until the completion or abandonment of the associated project. Upon reaching the end of the relevant project, we will either amortize the acquired IPR&D over its estimated useful life or expense the acquired IPR&D should the project be unsuccessful with no future alternative use.

Significant judgment is required related to the forecasting of future operating results within our discounted cash flow valuation models to determine the valuation of intangible assets. Key assumptions include the anticipated useful lives of acquired intangibles, the projected cash flows associated with each intangible asset, the estimated probability of success for acquired IPR&D projects, and projected growth rates and discount rates. It is possible that significant changes in plans or assumptions may affect the recoverability of these assets and could potentially result in impairment. Our valuation of intangible assets is a "critical accounting estimate" because changes in the assumptions used to develop these estimates could materially affect key financial measures, including operating income, EBITDA, net income, and intangible assets, net.

Goodwill

Our goodwill represents the excess of cost over fair value of net assets acquired from business combinations. The determination of the value of goodwill and intangible assets arising from business combinations requires extensive use of accounting estimates and judgments to allocate the purchase price to the fair value of the net tangible and intangible assets acquired.

We test goodwill at least annually for impairment, and between annual tests if indicators of potential impairment exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. Assessing goodwill impairment involves a high degree of judgment due to the estimates and assumptions used. We believe the estimates and assumptions involved in the impairment assessment to be critical because significant changes in such estimates and assumptions could materially affect key financial measures, including operating income, EBITDA, and net income.

In connection with our change in reporting segments, which occurred during the first quarter of 2019, we performed a quantitative assessment of goodwill immediately prior to and subsequently following the change in reporting segments. The analysis did not result in an impairment. In addition, the net carrying value of goodwill that was previously reported under the prior reporting segments of (i) Bone Growth Therapies, (ii) Spinal Implants, and (iii) Biologics was consolidated and is now included within the Global Spine reporting segment.

In the fourth quarters of 2019 and 2018, we performed a qualitative assessments for our annual goodwill impairment analysis, which did not result in any impairment charge. This qualitative analysis considered all relevant factors specific to the reporting units, including macroeconomic conditions, industry and market considerations, overall financial performance and relevant entity-specific events.

Fair Value Measurements

Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The two most significant items that are or were recorded at fair value include (i) contingent consideration attributable to the Spinal Kinetics acquisition and (ii) our eNeura debt security (prior to its restructuring and settlement in 2019).

The contingent consideration consists of potential future milestone payments of up to $60.0 million in cash associated with the Spinal Kinetics acquisition, which must be achieved within five years of the acquisition date to be paid. The milestone payments include (i) up to $15.0 million for meeting the FDA Milestone and (ii) revenue-based milestone payments of up to $45.0 million in connection with future sales of the M6-C artificial cervical disc and the M6-L artificial lumbar disc. The FDA milestone was achieved and paid in February of 2019.

Prior to its attainment in 2019, we estimated the fair value of the FDA Milestone using a probability-weighted discounted cash flow model. This fair value was based on significant inputs not observable in the market, with key assumptions including our estimation of the probability of FDA approval for the M6-C artificial cervical disc, the timing of approval, and the discount rate applied. Significant changes in these assumptions could have resulted in a significantly higher or lower fair value prior to obtaining FDA approval.

We estimate the fair value of the potential future revenue-based milestone payments using a Monte Carlo simulation. This fair value measurement is based on significant inputs that are unobservable in the market, with key assumptions including the our forecasted future revenues for Spinal Kinetics, the discount rate applied, and assumptions for potential volatility of the forecasted revenue. Significant changes in these assumptions could result in a significantly higher or lower fair value. Holding other inputs constant, an increase in our forecasted future revenues by 5% would have resulted in an increase in the fair value of the contingent consideration of $0.3 million, whereas a decrease in our forecasted future revenues by 5% would have resulted in a decrease in the fair value of the contingent consideration by $0.4 million.

Prior to its restructuring and settlement in 2019 for $4.0 million, the fair value of the eNeura debt security was based upon significant unobservable inputs, including the use of a discounted cash flows model, requiring us to develop our own assumptions. Some of the more significant unobservable inputs used in the fair value measurement of the eNeura debt security were our estimates related to the timing and likelihood of conversion as a result of a change in control event, the timing and likelihood of repayment, and the applicable discount rate.

Further, we were required to determine whether any decline in the fair value of the debt security below its basis was other-than-temporary. In making this determination, we considered our intentions to hold or sell the security, whether it more likely than not that we would be required to sell the security before the recovery of its amortized cost basis, and our best estimate of the amount that we ultimately expected to collect from the security. The estimated amount we expected to collect was based upon significant unobservable inputs, requiring us to develop our own assumptions.

Our fair value measurements are a “critical accounting estimate” because changes in the assumptions used to develop the estimate could materially affect key financial measures, including operating income, EBITDA, and net income.

Litigation and Contingent Liabilities

From time to time, we are parties to or targets of lawsuits, investigations and proceedings, including product liability, personal injury, patent and intellectual property, health and safety and employment and healthcare regulatory matters, which are handled and defended in the ordinary course of business. These lawsuits, investigations or proceedings could involve a substantial number of claims and could also have an adverse impact on our reputation and customer base. Although we maintain various liability insurance programs for liabilities that could result from such lawsuits, investigations or proceedings, we are self-insured for a significant portion of such liabilities.

We accrue for such claims when it is probable that a liability has been incurred and the amount can be reasonably estimated. The assessments of whether a loss is probable or a reasonable possibility, and whether the loss or range of loss is reasonably estimable, often involve a series of complex judgments about future events. Among the factors that we consider in this assessment are the nature of existing legal proceedings, investigations and claims, the asserted or possible damages or loss contingency (if reasonably estimable), the progress of the matter, existing law and precedent, the opinions or views of legal counsel and other advisers, the involvement of the U.S. Government and its agencies in such proceedings, our experience in similar matters and the experience of other companies, the facts available to us at the time of assessment, and how we intend to respond, or have responded, to the proceeding, investigation or claim. Our assessment of these factors may change over time as individual proceedings, investigations or claims progress. For matters where we are not currently able to reasonably estimate the range of reasonably possible loss, the factors that have contributed to this determination include the following: (i) the damages sought are indeterminate, or an investigation has not manifested itself in a filed civil or criminal complaint, (ii) the matters are in the early stages, (iii) the matters involve novel or unsettled legal theories or a large or uncertain number of actual or potential cases or parties, and/or (iv) discussions with the government or other parties in matters that may be expected ultimately to be resolved through negotiation and settlement

have not reached the point where we believe a reasonable estimate of loss, or range of loss, can be made. In such instances, we believe that there is considerable uncertainty regarding the timing or ultimate resolution of such matters, including a possible eventual loss, fine, penalty or business impact, if any.

Changes in the facts and circumstances associated with a claim could have a material impact on our results of operations and cash flows in the period that reserve estimates are recorded or revised. We believe our insurance coverage and reserves are sufficient to cover currently estimated exposures, but we cannot give any assurance that we will not incur liabilities in excess of recorded reserves or our present insurance coverage. Litigation and contingent liabilities are "critical accounting estimates" because changes in the assumptions used to develop the estimates could materially affect key financial measures, including operating income, EBITDA, and net income.

Tax Matters

We and each of our subsidiaries are taxed at the rates applicable within each of their respective jurisdictions. Our income tax expense, effective tax rate, deferred tax assets and deferred tax liabilities will vary according to the jurisdiction in which profits arise. Further, certain of our subsidiaries sell products directly to our other subsidiaries or provide administrative, marketing and support services to our other subsidiaries. These intercompany sales and support services involve subsidiaries operating in jurisdictions with differing tax rates. The tax authorities in such jurisdictions may challenge our treatments under residency criteria, transfer pricing provisions, or other aspects of their respective tax laws, which could affect our composite tax rate and provisions.

We sometimes engage in transactions in which tax consequences may be subject to uncertainty. We account for these uncertain tax positions in accordance with applicable accounting guidance, which requires significant judgment in assessing the estimated tax consequences of a transaction. We evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. We measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. We re-evaluate our income tax positions periodically to consider factors such as changes in facts or circumstances, changes in or interpretations of tax law, effectively settled issues under audit and new audit activity. Such a change in recognition or measurement would result in recognition of a tax benefit or an additional charge to the tax provision, which could have a material impact to the financial statements.

We establish a valuation allowance when measuring deferred tax assets if it is more likely than not that certain deferred tax assets will not be realized in the foreseeable future. This process requires significant judgment as we must project the current tax liability and estimate the deferred tax assets and liabilities into future periods, including net operating loss and tax credit carry forwards. In assessing the need for a valuation allowance, we consider recent operating results, availability of taxable income in carryback years, future reversals of taxable temporary differences, future taxable income projections (exclusive of reversing temporary differences) and all prudent and feasible tax planning strategies.

Tax matters are "critical accounting estimates" because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net income.

Share-based compensation

Determining the appropriate fair value model and calculating the fair value of employee stock awards requires estimates and judgments. Our share-based compensation is a "critical accounting estimate" because changes in the assumptions used to develop estimates of fair value or the requisite service period could materially affect key financial measures, including gross profit, operating income, EBITDA, and net income.

We use the Black-Scholes valuation model to calculate the fair value of service-based stock options. The value is recognized as expense over the service period net of actual forfeitures. The expected term of options granted is estimated based on a number of factors, including the vesting and expiration terms of the award, historical employee exercise behavior for both options that are currently outstanding and options that have been exercised or are expired, the historical volatility of our common stock and an employee's average length of service. The risk-free interest rate is determined based upon a constant U.S. Treasury security rate with a contractual life that approximates the expected term of the option award. We estimate expected volatility based on the historical volatility of our stock.

We use the Monte Carlo valuation methodology to calculate the fair value of market-based stock options and stock units. The value is recognized as expense over the requisite service period and adjusted for forfeitures as they occur. The Monte Carlo methodology that we use to estimate the fair value of market-based options incorporates the possibility that the market condition may not be satisfied.

The fair value of performance-based restricted stock awards and stock units is calculated based upon the closing stock price at the date of grant. The value is recognized as expense over the derived requisite service period beginning in the period in which they are deemed probable to vest. Vesting probability is assessed based upon forecasted earnings and financial results and requires significant judgment.

Non-GAAP Financial Measures

We believe that providing non-GAAP financial measures that exclude certain items provides investors with greater transparency to the information used by senior management in its financial and operational decision-making. We believe it is important to provide investors with the same non-GAAP metrics that senior management uses to supplement information regarding the performance and underlying trends of our business operations in order to facilitate comparisons to historical operating results and internally evaluate the effectiveness of our operating strategies. Disclosure of these non-GAAP financial measures also facilitates comparisons of our underlying operating performance with other companies in the industry that also supplement their GAAP results with non-GAAP financial measures.

The non-GAAP financial measures used in this Annual Report may have limitations as analytical tools and should not be considered in isolation or as a replacement for GAAP financial measures. Some of the limitations associated with the use of these non-GAAP financial measures are that they exclude items that reflect an economic cost that can have a material effect on cash flows. Similarly, certain non-cash expenses, such as equity compensation expense, do not directly impact cash flows, but are part of total compensation costs accounted for under GAAP.

Constant Currency

Constant currency is a non-GAAP measure, which is calculated by using foreign currency rates from the comparable, prior-year period, to present net sales at comparable rates. Constant currency can be presented for numerous GAAP measures, but is most commonly used by management to analyze net sales without the impact of changes in foreign currency rates.

EBITDA

EBITDA is defined as earnings before interest income (expense), net, income taxes, depreciation and amortization. EBITDA is the primary metric used by our Chief Operating Decision Maker in managing the business.

Free Cash Flow

Free cash flow is a non-GAAP financial measure, which is calculated by subtracting capital expenditures from net cash from operating activities. Free cash flow is an important indicator of how much cash is generated or used by our normal business operations, including capital expenditures. Management uses free cash flow as a measure of progress on its capital efficiency and cash flow initiatives.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to certain market risks as part of our ongoing business operations. Primary exposures include changes in interest rates and foreign currency fluctuations. These exposures can impact sales, cost of sales, costs of operations and the cost of financing and yields on cash and short-term investments. We may use derivative financial instruments, where appropriate, to manage these risks. However, our risk management policy does not allow us to hedge positions we do not hold nor do we enter into derivative or other financial investments for trading or speculative purposes.

We are exposed to interest rate risk in connection with our Revolving Credit Facility, which bears interest at floating rates based on LIBOR, or possibly an alternative reference rate to be used in place of LIBOR upon the occurrence of a benchmark transition event, plus an applicable borrowing margin or at a base rate (as defined in the Amended Credit Agreement) plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and

cash flows, assuming other factors are held constant. As we do not have any balance outstanding associated with the Amended Credit Agreement as of December 31, 2019, this risk is currently minimal.

We believe that a concentration of credit risk related to our trade accounts receivable is limited because our customers are geographically dispersed and the end users are diversified across several industries. It is reasonably possible that changes in global economic conditions and/or local operating and economic conditions in the regions these customers operate, or other factors, could affect the future realization of these accounts receivable balances.

Our foreign currency exposure results from fluctuating currency exchange rates, primarily the U.S. Dollar against the Euro, Brazilian Real, or British Pound. We are subject to cost of sales currency exposure when we produce products in foreign currencies such as the Euro, Brazilian Real, or British Pound and sell those products in U.S. Dollars. We are subject to transactional currency exposures when our subsidiaries (or the Company itself) enter into transactions denominated in a currency other than their functional currency. For the year ended December 31, 2019, we recorded a foreign currency loss of $1.4 million on the statement of operations and comprehensive income (loss) resulting from gains and losses in foreign currency transactions.

We also are subject to currency exposure from translating the results of our global operations into the U.S. Dollar at exchange rates that fluctuate during the period. The U.S. Dollar equivalent of international sales denominated in foreign currencies was unfavorably impacted during the years ended December 31, 2019 and December 31, 2018 by monthly foreign currency exchange rate fluctuations of the U.S. dollar against all of the foreign functional currencies for our international operations. As we continue to distribute and manufacture our products in selected foreign countries, we expect that future sales and costs associated with our activities in these markets will continue to be denominated in the applicable foreign currencies, which could cause currency fluctuations to materially impact our operating results. An analysis was performed to determine the sensitivity of our current year net sales and operating income to changes in foreign currency exchange rates. We determined that if the U.S. Dollar decreased in value by 10% relative to all foreign currencies of our international operations it would result in an increase in net sales of $8.6 million and an increase in operating income of $0.8 million. If the U.S. Dollar increased in value by 10% relative to all foreign currencies of our international operations it would result in a decrease in net sales of $8.6 million and a decrease in operating income of $0.8 million.

Item 8. Financial Statements and Supplementary Data

See “Index to Consolidated Financial Statements” on page F-1 of this Annual Report.

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

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

At the end of the period covered by this Annual Report, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Chief Financial Officer, we performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures. Based upon that evaluation, our President and Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this Annual Report, our disclosure controls and procedures were effective.

Management’s Report on Internal Control over Financial Reporting

The Company’s management is responsible for establishing and maintaining adequate internal control over financial reporting (as such term is defined in the Exchange Act Rule 13a-15(f)). The Company’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and (iii) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of the Company’s assets that could have a material effect on the financial statements.

Internal control over financial reporting is designed to provide reasonable assurance to the Company's management and board of directors regarding the preparation of reliable financial statements for external purposes in accordance with U.S. GAAP. Because of the inherent limitations in any internal control, no matter how well designed, misstatements may occur and not be prevented or detected. Accordingly, even effective internal control over financial reporting can provide only reasonable assurance with respect to financial statement preparation. Further, the evaluation of the effectiveness of internal control over financial reporting was made as of a specific date, and continued effectiveness in future periods is subject to the risks that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies and procedures may decline.

In connection with the preparation and filing of this Annual Report, the Company's management, including our President and Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2019, based on the framework set forth in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on its evaluation, the Company's management concluded that, as of December 31, 2019, the Company's internal control over financial reporting is effective based on the specified criteria.

Ernst & Young has issued an audit report on the effectiveness of our internal control over financial reporting, which follows this report.

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fourth quarter of 2019 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Orthofix Medical Inc.

Opinion on Internal Control over Financial Reporting

We have audited Orthofix Medical Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Orthofix Medical Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive income (loss), changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes and our report dated February 24, 2020 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Dallas, Texas
February 24, 2020

Item 9B. Other Information

Not applicable.

PART III

Information required by Items 10, 11, 12, 13 and 14 of Form 10-K is omitted from this Annual Report and will be filed in a definitive proxy statement or by an amendment to this Annual Report not later than 120 days after the end of the fiscal year covered by this Annual Report.

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 others 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 our securities by certain beneficial owners and our directors and executive officers, as well as information with respect to our equity compensation plans, 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 captions “Security Ownership of Certain Beneficial Owners and Management and Related Stockholders” and “Equity Compensation Plan Information,” 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 “Director Independence” 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 accountant 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, Financial Statement Schedules

(a) Documents filed as part of report on Form 10-K

The following documents are filed as part of this Annual Report on Form 10-K:

1. Financial Statements

   See "Index to Consolidated Financial Statements" on page F-1 of this Form 10-K.

2. Financial Statement Schedules

   No schedules are required because either the required information is not present or is not present in amounts sufficient to require submission of the schedule, or because the information required is included in the consolidated financial statements or the notes thereto.

3. Exhibits

Exhibit Number	Description
2.1	Agreement and Plan of Merger, entered into March 15, 2018, by and among Blackstone Medical, Inc., Summit Development, Inc., and Spinal Kinetics, Inc. (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 and incorporated herein by reference).
3.1	Orthofix Medical Inc. Certificate of Incorporation (filed as an exhibit to the Company's Current Report on Form 8-K dated August 1, 2018 and incorporated herein by reference).
3.2	Orthofix Medical Inc. Bylaws (filed as an exhibit to the Company's Current Report on Form 8-K dated August 1, 2018 and incorporated herein by reference).
4.1	Form of Stock Certificate (filed as an exhibit to the Company's Current Report on Form 8-K dated August 1, 2018 and incorporated herein by reference).
4.2*	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934.
10.1	Second Amended and Restated Credit Agreement, dated October 25, 2019, among Orthofix Medical Inc., Orthofix Inc., Orthofix Spinal Implants Inc., Orthofix International B.V., Orthofix III B.V., and certain subsidiaries of Orthofix Medical Inc. as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company's Current Report on Form 8-K filed on November 1, 2019 and incorporated herein by reference).
10.2†	Matrix Commercialization Collaboration Agreement, entered into July 24, 2008, by and between Orthofix Holdings, Inc. and Musculoskeletal Transplant Foundation (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
10.3	Amendment No. 1 to Matrix Commercialization Collaboration Agreement, dated as of December 15, 2010, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.4†	Amendment No. 2 to Matrix Commercialization Collaboration Agreement, dated as of January 9, 2012, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to amendment no. 1 to the Company's Annual Report on Form 10-K/A for the year ended December 31, 2011 and incorporated herein by reference).
10.5†	Amendment No. 3 to Matrix Commercialization Collaboration Agreement, entered into on July 1, 2013 and effective as of June 25, 2013, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2013 and incorporated herein by reference).
10.6	Amendment No. 4 to Matrix Commercialization Collaboration Agreement, entered into on April 1, 2014, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed April 7, 2014 and incorporated herein by reference).

Exhibit Number	Description
10.7†	Amendment No. 5 to Matrix Commercialization Collaboration Agreement, entered into on March 10, 2016, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed March 14, 2016 and incorporated herein by reference).
10.8†	Amendment No. 6 to Matrix Commercialization Collaboration Agreement, entered into on December 29, 2017, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Annual Report on Form 10-K filed February 26, 2018 and incorporated herein by reference).
10.9	Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as Amended (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and incorporated herein by reference).
10.10	Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and incorporated herein by reference).
10.11*	Form of Employee Performance Stock Unit Agreement under the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan.
10.12*	Employee Time-Based Vesting Restricted Stock Unit Grant Agreement for Bradley R. Mason under the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan.
10.13*	Form of Time-Based Vesting Employee Restricted Stock Unit Grant Agreement (2019 Executive Retention Grants) under the Orthofix Medical Inc. Amended and Restated 202 Long-Term Incentive Plan.
10.14	Form of Time-Based Vesting Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.15	Form of Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014-June 2016 (Time-Based Vesting) (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).
10.16	Form of Time-Based Vesting Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.17	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – July 2014-June 2016 (Time-Based Vesting) (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and incorporated herein by reference).
10.18	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (pre-2014 grants) (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.19	Form of Non-Employee Director Restricted Stock Unit Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Form 10-Q filed on August 7, 2017 and incorporated herein by reference).
10.20	Form of Time-Based Vesting Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (*initial grant*) (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.21	Form of Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix International N.V. 2012 Long Term Incentive Plan. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2012 and incorporated herein by reference).
10.22	Employee Inducement Restricted Stock Unit Agreement for Jon Serbousek (filed as an exhibit to the Company's Form S-8 filed on August 5, 2019 and incorporated herein by reference).

Exhibit Number	Description
10.23	Employee Inducement Non-Qualified Stock Option Agreement for Jon Serbousek (filed as an exhibit to the Company's Form S-8 filed on August 5, 2019 and incorporated herein by reference).
10.24	Employee Inducement Restricted Stock Unit Agreement for Beth Stevenson (filed as an exhibit to the Company's Form S-8 filed on February 2, 2019 and incorporated herein by reference).
10.25	Employee Inducement Restricted Stock Unit Agreement for Beth Stevenson (filed as an exhibit to the Company's Form S-8 filed on February 2, 2019 and incorporated herein by reference).
10.26	Inducement Plan for Spinal Kinetics Employees (filed as an exhibit to the Company's Form S-8 filed on April 30, 2018 and incorporated herein by reference).
10.27	Form of Inducement Grant Non-Qualified Stock Option Agreement (filed as an exhibit to the Company's Form S-8 filed on April 30, 2018 and incorporated herein by reference).
10.28	Form of Inducement Grant Restricted Stock Agreement (filed as an exhibit to the Company's Form S-8 filed on April 30, 2018 and incorporated herein by reference).
10.29	Inducement Grant Non-Qualified Stock Option Agreement, dated March 13, 2013, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's Current Report on Form 8-K filed March 13, 2013 and incorporated herein by reference).
10.30	Amended and Restated 2004 Long Term Incentive Plan (filed as an exhibit to the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2009 and incorporated herein by reference).
10.31	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan (post-2008 grants made under the 2004 Long Term Incentive Plan prior to the adoption of the 2012 Long Term Incentive Plan) (filed as an exhibit to the Company's Current Report on Form 8-K filed July 7, 2009 and incorporated herein by reference).
10.32	Form of Indemnification Agreement between Orthofix Medical Inc. and its directors and officers (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-4 (Registration No. 333-224407) filed April 23, 2018).
10.33	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Bradley R. Mason (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.34	Transition and Retirement Agreement, dated February 25, 2019, between Bradley R. Mason and Orthofix Medical Inc. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and incorporated herein by reference).
10.35	Consulting Agreement, dated November 1, 2019, between Orthofix Medical Inc. and Bradley R. Mason (filed as an Exhibit to the Company's Current Report on Form 8-K filed November 1, 2019 and incorporated herein by reference).
10.36	Change in Control and Severance Agreement, dated November 1, 2019, between Orthofix Medical Inc. and Jon Serbousek (filed as an Exhibit to the Company's Current Report on Form 8-K filed November 1, 2019 and incorporated herein by reference).
10.37*	Letter agreement, dated December 4, 2019, between the Company and Kevin Kenny.
10.38*	Change in Control and Severance Agreement, dated November 1, 2019, between Orthofix Medical Inc. and Kevin Kenny.
10.39	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Doug Rice (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.40	Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Kimberley Elting (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).

Exhibit Number	Description
10.41	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Michael M. Finegan (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.42	Change in Control and Severance Agreement, dated September 7, 2016, between Orthofix International N.V. and Davide Bianchi (filed as an exhibit to the Company's Current Report on Form 8-K filed September 9, 2016 and incorporated herein by reference).
10.43	Amended and Restated Employment Contract, dated July 31, 2018 between Orthofix AG and Davide Bianchi (filed as an exhibit to the Company's Current Report on Form 8-K filed August 6, 2018 and incorporated herein by reference).
10.44	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Bradley V. Niemann (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
21.1*	List of Subsidiaries.
23.1*	Consent of Independent Registered Public Accounting Firm.
31.1*	Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer.
31.2*	Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer.
32.1*	Section 1350 Certification of Chief Executive Officer and Certification of Chief Financial Officer.
101	The following financial statements from Orthofix Medical Inc. on Form 10-K for the year ended December 31, 2019 filed on February 24, 2020, formatted in Inline XBRL (Inline Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Consolidated Statements of Changes in Shareholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements.
104	The cover page from Orthofix Medical Inc.'s Annual Report on Form 10-K for the year ended December 31, 2019, formatted in Inline XBRL and contained in Exhibit 101.

* Filed with this Form 10-K.

† Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. This exhibit has been filed separately with the Secretary of the Commission without redactions pursuant to our Application Requesting Confidential Treatment under the Securities Exchange Act of 1934.

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.

ORTHOFIX MEDICAL INC.

Dated: February 24, 2020

By: /s/ JON SERBOUSEK
Name: **Jon Serbousek**
Title: **President and Chief Executive Officer, Director**

Dated: February 24, 2020

By: /s/ DOUG RICE
Name: **Doug Rice**
Title: **Chief Financial Officer**

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

Name	Title	Date
/s/ JON SERBOUSEK **Jon Serbousek**	President and Chief Executive Officer, Director (Principal Executive Officer)	February 24, 2020
/s/ DOUG RICE **Doug Rice**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 24, 2020
/s/ RONALD A. MATRICARIA **Ronald A. Matricaria**	Chairman of the Board of Directors	February 24, 2020
/s/ JAMES HINRICHS **James Hinrichs**	Director	February 24, 2020
/s/ ALEXIS V. LUKIANOV **Alexis V. Lukianov**	Director	February 24, 2020
/s/ LILLY MARKS **Lilly Marks**	Director	February 24, 2020
/s/ MICHAEL E. PAOLUCCI **Michael E. Paolucci**	Director	February 24, 2020
/s/ MARIA SAINZ **Maria Sainz**	Director	February 24, 2020
/s/ JOHN SICARD **John Sicard**	Director	February 24, 2020

ORTHOFIX MEDICAL INC.

Statement of Management's Responsibility for Financial Statements

To the Shareholders of Orthofix Medical Inc.:

Management is responsible for the preparation of the consolidated financial statements and related information that are presented in this Annual Report. The consolidated financial statements, which include amounts based on management's estimates and judgments, have been prepared in conformity with accounting principles generally accepted in the United States. Other financial information in the report to shareholders is consistent with that in the consolidated financial statements.

The Company maintains accounting and internal control systems to provide reasonable assurance at a reasonable cost that assets are safeguarded against loss from unauthorized use or disposition, and that the financial records are reliable for preparing financial statements and maintaining accountability for assets. These systems are augmented by written policies, an organizational structure providing division of responsibilities and careful selection and training of qualified personnel.

The Company engaged Ernst & Young LLP, independent registered public accountants, to audit and render an opinion on the consolidated financial statements in accordance with auditing standards of the Public Company Accounting Oversight Board (United States). These standards include an assessment of the systems of internal controls and test of transactions to the extent considered necessary by them to support their opinion.

The Board of Directors, through its Audit Committee consisting solely of outside directors of the Company, meets periodically with management and our independent registered public accountants to ensure that each is meeting its responsibilities and to discuss matters concerning internal controls and financial reporting. Ernst & Young LLP has full and free access to the Audit Committee.

James Hinrichs
Chairman of the Audit Committee

Jon Serbousek
President and Chief Executive Officer, Director

Doug Rice
Chief Financial Officer

ORTHOFIX MEDICAL INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Orthofix Medical Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Orthofix Medical Inc. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive income (loss), changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 24, 2020 expressed an unqualified opinion thereon.

Adoption of New Accounting Standards

As discussed in Notes 2, 8 and 14 to the consolidated financial statements, the Company changed its methods of accounting for 1) leases in 2019 due to the adoption of ASU No. 2016-02, *Leases (Topic 842)*, 2) recognition of revenue from contracts with customers in 2018 due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers*, and 3) measurement of equity investments at fair value and the recognition of any changes in fair value in 2018 due to the adoption of ASU No. 2016-01, *Financial Instruments* and ASU 2018-03, *Technical Connections and Improvements to Financial Instruments*.

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 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 of material misstatement, whether due to error or fraud. 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Contingent Consideration – Spinal Kinetics

Description of the Matter

As described in Note 11 to the consolidated financial statements, the Company's contingent consideration at the acquisition date of Spinal Kinetics, Inc. consisted of potential milestone payments of $15.0 million for achieving FDA approval and up to $45 million in connection with certain future product sales. At December 31, 2019, the fair value of contingent consideration was $42.7 million.

Auditing the Company's accounting for the fair value of its contingent consideration involved a high degree of subjectivity in evaluating management's estimates and the fair value is sensitive to changes in unobservable inputs, such as the forecasted future revenues for the Spinal Kinetics, Inc. products, discount rate applied, and assumptions for potential volatility in the forecasted revenues.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls that address the risks of material misstatement relating to the measurement and valuation of the contingent consideration liability. For example, we tested controls over the Company's process to estimate the fair value of the contingent consideration, management's review of the significant estimation assumptions and methods used to develop the fair value estimate, the accuracy of the calculations included within the fair value model, and the underlying data used in the model.

To test the fair value of the contingent consideration liability, we performed audit procedures that included, among others, assessing the terms of the arrangement, including the criteria required to achieve the contingent consideration, and evaluating the significant assumptions and underlying data used by the Company in the valuation model. In addition, we involved a valuation specialist to assist in evaluating the appropriateness of the valuation model, certain of the valuation model's assumptions, and to test the model's computational accuracy. We also tested the completeness and accuracy of the underlying data used in the model.

Inventory Excess and Obsolescence Reserves

Description of the Matter

At December 31, 2019, the Company's inventory balance is $82.4 million, which is net of management's estimate of inventory excess and obsolescence reserves. As described in Note 4 to the consolidated financial statements, management adjusts the value of its inventory to net realizable value to the extent it determines inventory cost cannot be recovered due to obsolescence or other factors. In order to make these determinations, management estimates future demand and sales prices to determine the appropriate inventory reserves and to make corresponding adjustments to the carrying value of these inventories to reflect the lower of cost or net realizable value.

Auditing management's estimate of the inventory excess and obsolescence reserves involved a high degree of subjectivity because the estimate was sensitive to changes in assumptions, including forecasted product demand, length of product life cycles, and the period required to evaluate the level of market acceptance for new products. These assumptions have a significant effect on the measurement of inventory excess and obsolescence reserves.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls that address the risks of material misstatement relating to the measurement and valuation of inventory excess and obsolescence reserves. For example, we tested controls over the Company's processes to estimate the inventory excess and obsolescence reserves, management's review and approval of the model used to estimate the inventory excess and obsolescence reserve, including the data inputs and outputs of such model and management's qualitative adjustments to the model.

To test the inventory excess and obsolescence reserve balance, we performed audit procedures that included, among others, evaluating the significant assumptions and qualitative adjustments described above and the underlying data used by the Company in its analysis. Our audit procedures included testing the completeness

and accuracy of the underlying data used in the model and evaluating whether such data was representative of current circumstances. We assessed the historical accuracy of management's estimates and performed sensitivity analyses of significant assumptions to evaluate the changes in the inventory excess and obsolescence reserves that would result from changes in the assumptions.

Revenue Recognition (ASC 606) - Risk of Side Agreements with Distributors

Description of the Matter

As described in Note 14 to the consolidated financial statements, the Company recognizes revenue from stocking distributors ("distributor revenue") upon shipment and receipt of a confirming purchase order, which is when the distributor obtains control of the promised goods. Those revenues are based on the Company's historical collection experience, which considers the potential for, among other things, the return of previously sold products.

Auditing the Company's measurement of any potential variable consideration under the distributor contracts is especially challenging due to the potential of side agreements that may allow for the return of previously sold products.

How We Addressed the Matter in Our Audit

We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's process to (i) review and approve new distributor agreements; (ii) review and approve all changes made to existing arrangements; (iii) review and approve product returns; and (iv) identify and report potential distributor side agreements by inspecting source documentation used during management's review.

Our audit procedures included, among others, confirmation of the terms and conditions of material distributor agreements. In addition, we evaluated whether the Company's actual returns of product from distributors were appropriately approved and considered in management's application of its revenue recognition policy for distributor revenue.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2002.

Dallas, Texas
February 24, 2020

ORTHOFIX MEDICAL INC.

Consolidated Balance Sheets as of December 31, 2019 and 2018

(U.S. Dollars, in thousands except share and per share data)	2019	2018
Assets		
Current assets		
Cash and cash equivalents	$ 69,719	$ 69,623
Restricted cash	684	2,566
Trade accounts receivable, net of allowances of $3,987 and $7,463, respectively	86,805	77,747
Inventories	82,397	76,847
Prepaid expenses and other current assets	20,948	17,856
Total current assets	260,553	244,639
Property, plant and equipment, net	62,727	42,835
Intangible assets, net	54,139	51,897
Goodwill	71,177	72,401
Deferred income taxes	35,117	33,228
Other long-term assets	11,907	21,641
Total assets	**$ 495,620**	**$ 466,641**
Liabilities and shareholders' equity		
Current liabilities		
Trade accounts payable	$ 19,886	$ 17,989
Current portion of finance lease liability	323	—
Other current liabilities	64,674	67,919
Total current liabilities	84,883	85,908
Long-term portion of finance lease liability	20,648	—
Other long-term liabilities	62,458	45,336
Total liabilities	167,989	131,244
Contingencies (Note 12)		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 19,022,619 and 18,579,688 issued and outstanding as of December 31, 2019 and 2018, respectively	1,902	1,858
Additional paid-in capital	271,019	243,165
Retained earnings	57,749	87,078
Accumulated other comprehensive income (loss)	(3,039)	3,296
Total shareholders' equity	327,631	335,397
Total liabilities and shareholders' equity	**$ 495,620**	**$ 466,641**

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

ORTHOFIX MEDICAL INC.

Consolidated Statements of Operations and Comprehensive Income (Loss)
For the years ended December 31, 2019, 2018, and 2017

(U.S. Dollars, in thousands, except share and per share data)	2019	2018	2017
Net sales	$ 459,955	$ 453,042	$ 433,823
Cost of sales	100,607	96,628	93,037
Gross profit	359,348	356,414	340,786
Sales and marketing	223,676	205,527	198,370
General and administrative	85,607	83,251	71,905
Research and development	34,637	33,218	29,700
Acquisition-related amortization and remeasurement	34,212	4,324	—
Operating income (loss)	(18,784)	30,094	40,811
Interest expense, net	(122)	(828)	(416)
Other expense, net	(8,143)	(6,381)	(4,004)
Income (loss) before income taxes	(27,049)	22,885	36,391
Income tax expense	(1,413)	(9,074)	(29,100)
Net income (loss) from continuing operations	(28,462)	13,811	7,291
Discontinued operations (Note 12)			
Loss from discontinued operations	—	—	(1,759)
Income tax benefit	—	—	691
Net loss from discontinued operations	—	—	(1,068)
Net income (loss)	**$ (28,462)**	**$ 13,811**	**$ 6,223**
Net income (loss) per common share—basic			
Net income (loss) from continuing operations	$ (1.51)	$ 0.73	$ 0.40
Net loss from discontinued operations	—	—	(0.06)
Net income (loss) per common share—basic	**$ (1.51)**	**$ 0.73**	**$ 0.34**
Net income (loss) per common share—diluted			
Net income (loss) from continuing operations	$ (1.51)	$ 0.72	$ 0.39
Net loss from discontinued operations	—	—	(0.05)
Net income (loss) per common share—diluted	**$ (1.51)**	**$ 0.72**	**$ 0.34**
Weighted average number of common shares:			
Basic	18,903,289	18,494,002	18,117,405
Diluted	18,903,289	18,911,610	18,498,745
Other comprehensive income (loss), before tax			
Unrealized gain (loss) on debt security	(2,593)	1,770	3,830
Reclassification adjustment for amortization of historical unrealized gains on debt security	(1,034)	—	—
Reclassification adjustment for loss on debt security in net income	(5,193)	—	5,585
Currency translation adjustment	(653)	(1,823)	4,552
Other comprehensive income (loss), before tax	(9,473)	(53)	13,967
Income tax benefit (expense) related to items of other comprehensive income (loss)	2,201	(438)	(3,600)
Other comprehensive income (loss), net of tax	(7,272)	(491)	10,367
Comprehensive income (loss)	$ (35,734)	$ 13,320	$ 16,590

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

ORTHOFIX MEDICAL INC.

Consolidated Statements of Changes in Shareholders' Equity
For the years ended December 31, 2019, 2018, and 2017

(U.S. Dollars, in thousands, except share data)	Number of Common Shares Outstanding	Common Shares	Additional Paid-in Capital	Retained Earnings	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
At December 31, 2016	17,828,155	$ 1,783	$ 204,095	$ 64,179	$ (6,580)	$ 263,477
Net income	—	—	—	6,223	—	6,223
Other comprehensive income, net of tax	—	—	—	—	10,367	10,367
Share-based compensation	—	—	12,557	—	—	12,557
Common shares issued	450,678	45	3,939	—	—	3,984
At December 31, 2017	**18,278,833**	**$ 1,828**	**$ 220,591**	**$ 70,402**	**$ 3,787**	**$ 296,608**
Cumulative effect adjustment from adoption of ASU 2014-09	—	—	—	4,761	—	4,761
Cumulative effect adjustment from adoption of ASU 2016-16	—	—	—	(1,896)	—	(1,896)
Net income	—	—	—	13,811	—	13,811
Other comprehensive loss, net of tax	—	—	—	—	(491)	(491)
Share-based compensation	—	—	18,930	—	—	18,930
Common shares issued	300,855	30	3,644	—	—	3,674
At December 31, 2018	**18,579,688**	**$ 1,858**	**$ 243,165**	**$ 87,078**	**$ 3,296**	**$ 335,397**
Cumulative effect adjustment from adoption of ASU 2016-02	—	—	—	70	—	70
Cumulative effect adjustment from adoption of ASU 2018-02	—	—	—	(937)	937	—
Net loss	—	—	—	(28,462)	—	(28,462)
Other comprehensive loss, net of tax	—	—	—	—	(7,272)	(7,272)
Share-based compensation	—	—	21,540	—	—	21,540
Common shares issued	442,931	44	6,314	—	—	6,358
At December 31, 2019	**19,022,619**	**$ 1,902**	**$ 271,019**	**$ 57,749**	**$ (3,039)**	**$ 327,631**

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

ORTHOFIX MEDICAL INC.

Consolidated Statements of Cash Flows
For the years ended December 31, 2019, 2018, and 2017

(U.S. Dollars, in thousands)	2019	2018	2017
Cash flows from operating activities			
Net income (loss)	$ (28,462)	$ 13,811	$ 6,223
Adjustments to reconcile net income to net cash from operating activities			
Depreciation and amortization	24,699	18,659	20,124
Amortization of debt costs and other assets	3,778	1,024	1,712
Provision for doubtful accounts	1,891	(599)	1,639
Deferred income taxes	1,393	(2,661)	21,286
Share-based compensation	21,540	18,930	12,557
Interest and loss on the valuation of investment securities	5,000	3,050	5,585
Change in fair value of contingent consideration	29,140	3,069	—
Other	2,433	1,633	1,398
Changes in operating assets and liabilities, net of effects of acquisitions			
Trade accounts receivable	(11,037)	(3,706)	(6,562)
Inventories	(5,712)	9,698	(15,645)
Prepaid expenses and other current assets	(3,698)	(1,127)	(6,352)
Trade accounts payable	2,138	(170)	2,324
Other current liabilities	(7,716)	(7,563)	(11,412)
Contingent consideration milestone payment	(1,340)	—	—
Other long-term assets and liabilities	(2,014)	(4,130)	6,095
Net cash from operating activities	**32,033**	**49,918**	**38,972**
Cash flows from investing activities			
Acquisition of business, net of cash acquired	—	(44,294)	—
Capital expenditures for property, plant and equipment	(18,997)	(13,592)	(14,665)
Capital expenditures for intangible assets	(1,527)	(1,664)	(2,283)
Asset acquisitions and other investments	(2,400)	(1,448)	474
Net cash from investing activities	**(22,924)**	**(60,998)**	**(16,474)**
Cash flows from financing activities			
Proceeds from issuance of common shares	11,551	7,100	7,783
Payments related to withholdings for share-based compensation	(5,193)	(3,425)	(3,800)
Contingent consideration milestone payment	(13,660)	—	—
Payments related to finance lease obligation	(365)	—	—
Payment of debt issuance costs and other financing activities	(3,021)	(682)	(445)
Net cash from financing activities	**(10,688)**	**2,993**	**3,538**
Effect of exchange rate changes on cash and restricted cash	(207)	(881)	1,180
Net change in cash, cash equivalents, and restricted cash	(1,786)	(8,968)	27,216
Cash, cash equivalents, and restricted cash at the beginning of the year	72,189	81,157	53,941
Cash, cash equivalents, and restricted cash at the end of the year	**$ 70,403**	**$ 72,189**	**$ 81,157**
Components of cash, cash equivalents, and restricted cash at the end of the year			
Cash and cash equivalents	$ 69,719	$ 69,623	$ 81,157
Restricted cash	684	2,566	—
Cash, cash equivalents, and restricted cash at the end of the year	**$ 70,403**	**$ 72,189**	**$ 81,157**
Supplemental disclosure of cash flow information:			
Noncash investing activities:			
Intangible assets acquired in asset acquisitions	$ 1,600	$ 2,015	$ —
Contingent consideration recognized at acquisition date	—	25,491	—

The accompanying notes form an integral part of these consolidated financial statements

ORTHOFIX MEDICAL INC.

Notes to the Consolidated Financial Statements

Business and basis of consolidation

Orthofix Medical Inc. (previously Orthofix International N.V.) and its subsidiaries (the "Company") is a global medical device company focused on musculoskeletal products and therapies. The Company's mission is to improve patients' lives by providing superior reconstruction and regenerative musculoskeletal solutions to physicians worldwide. Headquartered in Lewisville, Texas, the Company has two reporting segments: Global Spine and Global Extremities. Orthofix products are widely distributed via the Company's sales representatives and distributors.

In 2018, the Company completed a change in its jurisdiction of organization from Curaçao to the State of Delaware (the "Domestication") in accordance with the conversion procedures of Articles 304 and 305 of Book 2 of the Curaçao Civil Code and the domestication procedures of Section 388 of Delaware General Corporation Law. Upon the effectiveness of the Domestication, each common share of Orthofix International N.V. was automatically converted into one share of common stock of Orthofix Medical Inc. This transaction was accounted for as a transfer of assets and liabilities between entities under common control, similar to a pooling of interest. As a result, the assets and liabilities were carried forward at their historical carrying amounts. The Company's common stock continues to be traded on the Nasdaq Global Select Market under the symbol "OFIX."

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions are eliminated in consolidation.

1. Significant accounting policies

The preparation of financial statements in conformity with United States generally accepted accounting principles ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, we evaluate these estimates, including those related to contractual allowances, doubtful accounts, inventories, goodwill, fair value measurements, litigation and contingent liabilities, income taxes, and share-based compensation. We base our estimates on historical experience, future expectations, and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Information on our accounting policies and methods used in the preparation of our consolidated financial statements are included, where applicable, in the respective footnotes that follow.

Footnote	Footnote Reference
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Acquisitions	3
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Property, plant and equipment	5
Intangible assets	6
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Footnote	Footnote Reference
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The following is a discussion of accounting policies and methods used in our consolidated financial statements that are not presented within other footnotes.

Prior period reclassifications

Certain amortization expense related to intangible assets previously reported in general and administrative expenses has been reclassified to acquisition-related amortization and remeasurement based on use of the underlying intangible asset. This reclassification resulted in a decrease to general and administrative expense of $1.3 million for the year ended December 31, 2018.

Market risk

In the ordinary course of business, the Company is exposed to the impact of changes in interest rates and foreign currency fluctuations. The Company's objective is to limit the impact of such movements on earnings and cash flows. In order to achieve this objective, the Company seeks to balance its non-U.S. Dollar denominated income and expenditures.

The financial statements for operations outside the United States are generally maintained in their local currency. All foreign currency denominated balance sheet accounts, except shareholders' equity, are translated to U.S. Dollars at year end exchange rates and revenue and expense items are translated at average rates of exchange prevailing during the year. Gains and losses resulting from the translation of foreign currency are recorded in the accumulated other comprehensive income (loss) component of shareholders' equity. Transactional foreign currency gains and losses, including those generated from intercompany operations, are included in other expense, net and were a loss of $1.4 million, loss of $3.3 million, and a gain of $1.9 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Financial instruments and concentration of credit risk

Financial instruments that could subject the Company to a concentration of credit risk consist primarily of cash, cash equivalents, restricted cash, and accounts receivable. Generally, cash is held at large financial institutions and cash equivalents consist of highly liquid money market funds. The Company performs ongoing credit evaluations of customers, generally does not require collateral, and maintains a reserve for potential credit losses. The Company believes that a concentration of credit risk related to the accounts receivable is limited because customers are geographically dispersed and end users are diversified across several industries.

Net sales to our customers based in Europe were approximately $69 million in 2019, which represents a substantial portion of our trade accounts receivable balance as of December 31, 2019. It is at least reasonably possible that changes in global economic conditions and/or local operating and economic conditions in the regions, or other factors, could affect the future realization of these accounts receivable balances.

Cash, cash equivalents and restricted cash

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

Restricted cash as of December 31, 2018 related to a court order affecting the Company's local bank accounts for its office in São Paulo, Brazil, as part of an investigation of more than 30 companies, which resulted in the freezing of approximately $2.6 million of the Company's cash. On April 3, 2019, the Company's appeal regarding the freezing of its local bank accounts was heard by the Brazil Federal Court of Appeals of Rio de Janeiro, in which the Court ordered the unfreezing of the Company's cash. The cash was then returned without any restrictions in April 2019. As such, this balance was reclassified to cash and cash equivalents during the second quarter of 2019.

In September 2019, approximately $0.7 million of the Company's cash in Brazil was frozen upon request to satisfy a judgment related to an ongoing legal dispute with a former Brazilian distributor. Although the Company is appealing this judgment, this cash has been reclassified to restricted cash. Refer to Note 12 for further discussion of this matter.

Advertising costs

Advertising costs are expensed as incurred. Advertising costs are included within sales and marketing expense and totaled $0.8 million, $0.6 million, and $0.7 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Research and development costs, including in-process research and development ("IPR&D") costs

Expenditures for research and development are expensed as incurred. Expenditures related to the collaborative arrangement with MTF Biologics ("MTF") are expensed based on the terms of the related agreement. No research and development expenditures were incurred for the years ended December 31, 2019 or 2018 under the collaborative arrangement with MTF. Research and development expenditures totaled $0.9 million for the year ended December 31, 2017 under the arrangement with MTF.

In connection with the Spinal Kinetics Inc. acquisition in 2018, the Company recognized $26.8 million of IPR&D costs within patents and other intangible assets, net and recorded additional research and development costs to further develop this acquired IPR&D. See Note 6 for further details.

Acquired IPR&D represents the fair value assigned to acquired research and development assets that have not reached technological feasibility. The fair value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenues from the projects, and discounting the net cash flows to present value. The revenue and cost projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success of developing the asset. Additionally, estimated revenues consider the relevant market sizes and growth factors, expected trends in technology, and the nature and expected timing of new product introductions by the Company and its competitors. The rates utilized to discount the net cash flows to their present value are commensurate with the stage of development of the project and uncertainties in the economic estimates used in the projections. Any future costs to further develop the IPR&D subsequent to acquisition are recorded to research and development expense as incurred. See Note 6 for additional policy discussion related to amortization and impairment testing for IPR&D.

2. Recently adopted accounting standards and recently issued accounting pronouncements

Adoption of Accounting Standards Update ("ASU") 2016-02, Leases (Topic 842)

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, which changes how lessees account for leases. For most leases, the standard requires a liability to be recorded on the balance sheet based on the present value of future lease obligations with a corresponding right-of-use asset. For leases classified as operating leases, the Company is now required to recognize lease costs on a straight-line basis based on the combined amortization of the lease obligation and the right-of-use asset. Other leases are will be accounted for as finance leases, similar to capital leases under the previous accounting standard. Effective January 1, 2019, the Company adopted ASU 2016-02 using a modified retrospective approach. Upon adoption, the Company elected a package of practical expedients permitted within the new standard. The elected practical expedients allow the Company to carry forward its historical lease classification and to not separate and allocate the consideration paid between lease and non-lease components included within a contract. The Company also elected an optional transition method that waives the requirement to apply the ASU to the comparative periods presented within the financial statements in the year of adoption. Therefore, results for reporting periods beginning after January 1, 2019 are presented under Topic 842, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting policies under Topic 840. See Note 8 for additional discussion of the Company's adoption of Topic 842 and its lease accounting policies.

Adoption of ASU 2018-02, Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

In February 2018, the FASB issued ASU 2018-02, which allows entities to reclassify stranded tax effects resulting from the Tax Cuts and Jobs Act (the "Tax Act") from accumulated other comprehensive income (loss) to retained earnings. The Company adopted this guidance effective January 1, 2019, using a modified retrospective approach, which resulted in an increase to accumulated other comprehensive income (loss) and a decrease in retained earnings of $0.9 million.

Adoption of ASU 2014-09, Revenue from Contracts with Customers (Topic 606)

In May 2014, the FASB issued ASU 2014-09. Topic 606 supersedes the revenue recognition requirements in Topic 605, *Revenue Recognition*, and requires entities to recognize revenue when control of the promised goods or services is transferred to customers at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The Company adopted Accounting Standards Codification ("ASC") 606 as of January 1, 2018 using the modified retrospective transition method, which was applied to all contracts. Results for prior period amounts were not adjusted and continue to be reported in accordance with the Company's historic accounting under the previous revenue recognition standard, Topic 605. See Note 14 for further discussion of the Company's revenue recognition policies.

Adoption of ASU 2016-01, Financial Instruments – Overall (Subtopic 825-10), and ASU 2018-03, Technical Corrections and Improvements to Financial Instruments – Overall (Subtopic 825-10)

In January 2016, the FASB issued ASU 2016-01, which was then further clarified in ASU 2018-03, in February 2018. This guidance required entities to measure equity investments at fair value and recognize any changes in fair value in net income. However, for certain equity investments that do not have readily determinable fair values, the new guidance allows companies to measure the investments using a new measurement alternative, which values the investments at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. The Company prospectively adopted both ASU 2016-01 and ASU 2018-03 as of January 1, 2018, and now uses the new measurement alternative for the Company's equity investments in Bone Biologics, Inc. ("Bone Biologics"), which historically had been measured at cost. See Note 11 for further discussion related to our investment in Bone Biologics.

Recently issued accounting pronouncements

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Financial Instruments - Credit Losses (ASU 2016-13), and subsequent amendments	Requires that credit losses for certain types of financial instruments, including trade accounts receivable, be estimated based on expected losses and also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. Applied using a modified retrospective approach, with early adoption permitted.	January 1, 2020	The Company formed an implementation team to evaluate the impact this ASU will have on its consolidated financial statements. Based on its preliminary evaluation, the Company expects to record an increase in its allowance for doubtful accounts of approximately $1.1 million, an increase in deferred income taxes of approximately $0.2 million, and a decrease in retained earnings of approximately $0.9 million. The Company does not expect material impacts to its consolidated statements of operations and comprehensive income (loss) or to its consolidated statements of cash flows.
Goodwill (ASU 2017-04)	Eliminates Step 2 of the current goodwill impairment test, which requires a hypothetical purchase price allocation to measure goodwill impairment. A goodwill impairment loss will instead be measured at the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the recorded amount of goodwill. Applied on a prospective basis, with early adoption permitted.	January 1, 2020	The Company does not expect this ASU to have a significant impact on its financial statements or disclosures.

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Fair value measurement (ASU 2018-13)	Eliminates such disclosures as the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy and adds new disclosure requirements for Level 3 measurements. Certain of the provisions are to be applied retrospectively with other provisions applied prospectively.	January 1, 2020	The Company does not expect the ASU to have a significant impact on its financial statements, but the ASU may have a significant impact on disclosures for any level 3 assets or liabilities.
Implementation costs in a cloud computing arrangement that is a service contract (ASU 2018-15)	Aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this update. Applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption.	January 1, 2020	The Company plans to adopt this ASU prospectively on January 1, 2020. However, the Company does not expect this ASU to have a material impact to its consolidated financial statements.
Simplifying the accounting for income taxes (ASU 2019-12)	Reduces the complexity of accounting for income taxes by eliminating certain exceptions to the general principles in ASC 740, *Income Taxes.* Additionally, the ASU simplifies GAAP by amending the requirements related to the accounting for "hybrid" tax regimes and also adding the requirement to evaluate when a step up in the tax basis of goodwill should be considered part of the business combination and when it should be considered a separate transaction. Certain of the provisions are to be applied retrospectively with other provisions applied prospectively.	January 1, 2021	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

3. Acquisitions

On April 30, 2018, the Company completed the acquisition of Spinal Kinetics Inc. (“Spinal Kinetics”), a privately held developer and manufacturer of artificial cervical and lumbar discs for $45.0 million in net cash, subject to certain adjustments, plus potential milestone payments of up to $60.0 million in cash. The results of operations for Spinal Kinetics have been included in the Company’s financial results since the acquisition date, April 30, 2018.

The fair value of the consideration transferred was $76.6 million, which consisted of the following:

(U.S. Dollars, in thousands)		
Fair value of consideration transferred		
Cash paid	$	51,109
Contingent consideration		25,491
Total fair value of consideration transferred	$	76,600

The contingent consideration consists of potential future milestone payments of up to $60.0 million in cash. The milestone payments include (i) up to $15.0 million if the U.S. Food and Drug Administration (the "FDA") grants approval of Spinal Kinetics' M6-C artificial cervical disc (the "FDA Milestone") and (ii) revenue-based milestone payments of up to $45.0 million in connection with future sales of the M6-C artificial cervical disc and the M6-L artificial lumbar disc. Milestones must be achieved within five years of the Acquisition Date to trigger applicable payments. Refer to Note 11 for further discussion of the valuation of the contingent milestone payments.

The following table summarizes the fair values of assets acquired and liabilities assumed at the acquisition date:

(U.S. Dollars, in thousands)	Preliminary Acquisition Date Fair Value as Previously Reported	Adjustments	Final Acquisition Date Fair Value	Assigned Useful Life
Assets acquired				
Cash and cash equivalents	$ 6,785	$ —	$ 6,785	
Restricted cash	30	—	30	
Trade accounts receivable	1,705	—	1,705	
Inventories	8,175	—	8,175	
Prepaid expenses and other current assets	315	—	315	
Property, plant and equipment	2,285	—	2,285	
Other long-term assets	320	—	320	
Developed technology	12,400	—	12,400	10 years
In-process research and development ("IPR&D")	26,800	—	26,800	Indefinite
Tradename	100	—	100	2 years
Deferred income taxes	2,374	1,220	3,594	
Total identifiable assets acquired	$ 61,289	$ 1,220	$ 62,509	
Liabilities assumed				
Trade accounts payable	$ 351	$ —	$ 351	
Other current liabilities	2,873	(4)	2,869	
Other long-term liabilities	301	—	301	
Total liabilities assumed	3,525	(4)	3,521	
Goodwill	18,836	(1,224)	17,612	
Total fair value of consideration transferred	$ 76,600	$ —	$ 76,600	

The $17.6 million of goodwill recognized was assigned to the Global Spine reporting segment.

On February 6, 2019, the Company obtained FDA approval of the M6-C artificial cervical disc for patients suffering from cervical disease degeneration. Following FDA approval, the Company transferred $26.8 million from IPR&D to developed technology, and began amortization over 10 years.

The Company did not recognize any acquisition related costs during the year ended December 31, 2019 and recorded $3.3 million and $0.8 million of acquisition related costs during the years ended December 31, 2018 and December 31, 2017, respectively, within general and administrative expenses. The Company's results of operations included net sales of $12.4 million and $8.7 million related to Spinal Kinetics for the years ended December 31, 2019 and 2018, respectively. Additionally, the Company's results of operations included net losses of $9.3 million and $5.8 million related to Spinal Kinetics for the years ended December 31, 2019 and 2018, respectively.

Options Medical, LLC Asset Acquisition

On January 31, 2019, the Company acquired certain assets of Options Medical, LLC ("Options Medical"), a medical device distributor based in Florida. Under the terms of the acquisition, the parties agreed to terminate an existing exclusive sales representative agreement, employees of Options Medical became employees of the Company, and the Company acquired all customer lists and customer information related to the sale of the Company's products. As consideration for the assets acquired, the Company paid $6.4 million. The following table summarizes the fair values of assets acquired and liabilities assumed at the acquisition date:

(U.S. Dollars, in thousands)		Fair Value	Balance Sheet Classification	Assigned Useful Life
Assets acquired				
Operating lease assets	$	175	Other long-term assets	
Customer relationships		5,832	Intangible assets, net	10 years
Assembled workforce		568	Intangible assets, net	5 years
Total identifiable assets acquired	$	6,575		
Liabilities assumed				
Operating lease liability - short-term	$	69	Other current liabilities	
Operating lease liability - long-term		106	Other long-term liabilities	
Total liabilities assumed		175		
Total fair value of consideration transferred	$	6,400		

4. Inventories

Inventories are valued at the lower of cost or estimated net realizable value, after provision for excess, obsolete or impaired items, which is reviewed and updated on a periodic basis by management. For inventory procured or produced, whether internally or through contract manufacturing arrangements, at our manufacturing facility in Italy, cost is determined on a weighted-average basis, which approximates the first-in, first-out ("FIFO") method. For inventory procured or produced, whether internally or through contract manufacturing arrangements, at our manufacturing facilities in Texas and California, standard costs, which approximates actual cost on the FIFO method, is used to value inventory. Standard costs are reviewed annually by management, or more often in the event circumstances indicate a change in cost has occurred.

Work-in-process, finished products, and field/consignment inventory include material, labor and production overhead costs. Field/consignment inventory represents immediately saleable finished products inventory that is in the possession of the Company's independent sales representatives or located at third party customers, such as distributors and hospitals.

	December 31,	
(U.S. Dollars, in thousands)	2019	2018
Raw materials	$ 9,587	$ 8,463
Work-in-process	14,027	13,478
Finished products	20,712	18,244
Field/consignment	38,071	36,662
Inventories	$ 82,397	$ 76,847

The Company adjusts the value of its inventory to the extent management determines that the cost cannot be recovered due to obsolescence or other factors. In order to make these determinations, management uses estimates of future demand and sales prices for each product to determine the appropriate inventory reserves and to make corresponding adjustments to the carrying value of these inventories to reflect the lower of cost or market value.

5. Property, plant and equipment

Property, plant and equipment is stated at cost less accumulated depreciation, or when acquired as part of a business combination, at estimated fair value. Costs include all expenditures necessary to place the asset in service, generally including freight and sales and use taxes. Property, plant and equipment includes instrumentation held by customers, which is generally used to facilitate the implantation of the Company's products.

The useful lives of these assets are generally as follows:

	Years
Buildings	25 to 33
Plant and equipment	1 to 10
Instrumentation	3 to 4
Computer software	3 to 7
Furniture and fixtures	4 to 8

The Company evaluates the useful lives of these assets on an annual basis. Depreciation is computed on a straight-line basis over the useful lives of the assets. Depreciation of leasehold improvements is computed over the shorter of the lease term or the useful life of the asset. Total depreciation expense was $17.7 million, $15.9 million and $18.3 million for the years ended December 31, 2019, 2018 and 2017, respectively.

Expenditures for maintenance and repairs and minor renewals and improvements, which do not extend the lives of the respective assets, are expensed as incurred. All other expenditures for renewals and improvements are capitalized. The assets and related accumulated depreciation are adjusted for property retirements and disposals, with the resulting gain or loss included in earnings. Fully depreciated assets remain in the accounts until retired from service.

	December 31,	
(U.S. Dollars, in thousands)	**2019**	**2018**
Cost		
Buildings	$ 3,731	$ 3,746
Plant and equipment	46,470	45,744
Instrumentation	82,327	75,542
Computer software	49,696	47,322
Furniture and fixtures	7,328	6,599
Construction in progress	2,201	2,909
Finance lease assets	21,179	—
Property, plant, and equipment, gross	212,932	181,862
Accumulated depreciation	(150,205)	(139,027)
Property, plant, and equipment, net	$ 62,727	$ 42,835

The Company capitalizes system development costs related to internal-use software during the application development stage. Costs related to preliminary project activities and post-implementation activities are expensed as incurred. Internal-use software is amortized on a straight-line basis over its estimated useful life, generally three to seven years.

During the first quarter of 2019, the Company entered into an amendment for its corporate headquarters lease. As a result, the classification of this lease changed from an operating lease to a finance lease. This resulted in an increase to both the lease liability and lease asset of approximately $8.0 million, when compared to the original operating lease assets and liabilities recorded upon the adoption of ASU 2016-02.

Long-lived assets are evaluated for impairment whenever events or changes in circumstances have occurred that would indicate impairment. For purposes of the evaluation, the Company groups its long-lived assets with other assets and liabilities at the lowest level of identifiable cash flows if the asset does not generate cash flows independent of other assets and liabilities. If the carrying value of the asset or asset group exceeds the undiscounted cash flows expected to result from the use and eventual disposition of the asset group, the Company will write the carrying value down to the fair value in the period identified.

The Company generally determines fair value of long-lived assets as the present value of estimated future cash flows. In determining the estimated future cash flows associated with the assets, the Company uses estimates and assumptions about future revenue contributions, cost structures and remaining useful lives of the asset group. The use of alternative assumptions, including estimated cash flows, discount rates, and alternative estimated remaining useful lives could result in different calculations of impairment.

6. Intangible assets

Intangible assets are recorded at cost, or when acquired as a part of a business combination, at estimated fair value. These assets are amortized on a straight-line basis over the useful lives of the assets.

(U.S. Dollars, in thousands)	Weighted Average Amortization Period	December 31, 2019	December 31, 2018
Cost			
Patents	10 years	$ 42,034	$ 39,085
Developed technology	10 years	39,200	12,400
IPR&D	Indefinite	—	26,800
Customer relationships	9 years	7,430	—
License and other	7 years	15,960	14,654
Trademarks—finite lived	10 years	942	840
	9 years	105,566	93,779
Accumulated amortization			
Patents		$ (38,246)	$ (35,016)
Developed technology		(4,523)	(827)
Customer relationships		(535)	—
License and other		(7,701)	(5,744)
Trademarks—finite lived		(422)	(295)
		(51,427)	(41,882)
Patents and other intangible assets, net		$ 54,139	$ 51,897

Intangible assets related to IPR&D projects are considered to be indefinite-lived until the completion or abandonment of the associated research and development efforts. During the period the assets are considered indefinite-lived, they are not amortized but tested for impairment. Impairment testing is performed at least annually or when a triggering event occurs that could indicate a potential impairment. If and when development is complete, which generally occurs when regulatory approval to market a product is obtained, the associated assets are deemed finite-lived and are amortized over a period that best reflects the economic benefits provided by these assets. On February 6, 2019, the Company obtained FDA approval of the M6-C artificial cervical disc for patients suffering from cervical disease degeneration. Following FDA approval, the Company transferred $26.8 million from IPR&D to developed technology, and began amortization over 10 years.

Amortization expense for intangible assets was $7.0 million, $2.7 million and $1.8 million for the years ended December 31, 2019, December 31, 2018 and 2017, respectively. Future amortization expense for intangible assets is estimated as follows:

(U.S. Dollars, in thousands)	Amortization
2020	$ 7,420
2021	7,317
2022	7,337
2023	6,668
2024	5,799
Thereafter	19,598
Total	$ 54,139

7. Goodwill

The Company tests goodwill at least annually for impairment. The Company tests more frequently if indicators are present or changes in circumstances suggest that impairment may exist. These indicators include, among others, declines in sales, earnings or cash flows, or the development of a material adverse change in the business climate. The Company assesses goodwill for impairment at the reporting unit level, which is defined as an operating segment or one level below an operating segment.

As part of the change in reporting segments, which occurred during the first quarter of 2019, the Company performed a quantitative assessment of goodwill immediately prior to and subsequently following the change in reporting segments. The analysis did not result in an impairment. In addition, the net carrying value of goodwill that was previously reported under the prior reporting segments of (i) Bone Growth Therapies, (ii) Spinal Implants, and (iii) Biologics has been consolidated and is now included within the Global Spine reporting segment.

At the beginning of the fourth quarters of 2019 and 2018, the Company performed a qualitative assessment for its annual goodwill impairment analysis, which did not result in impairment. This qualitative analysis considers all relevant factors specific to the reporting units, including macroeconomic conditions, industry and market considerations, overall financial performance, and relevant entity-specific events.

The following table presents the net carrying value of goodwill, and a rollforward of such balances from December 31, 2018, by reportable segment:

(U.S. Dollars, in thousands)	December 31, 2018	Adjustments	December 31, 2019
Global Spine	$ 72,401	$ (1,224)	$ 71,177
Global Extremities	—	—	—
Goodwill	$ 72,401	$ (1,224)	$ 71,177

8. Leases

As discussed in Note 2, the Company adopted ASU No. 2016-02—*Leases* (Topic 842), as of January 1, 2019, using the modified retrospective approach. Adoption of the new standard resulted in the recognition of operating lease assets and lease liabilities of $20.2 million and $20.5 million, respectively, as of January 1, 2019. The difference between the lease assets and lease liabilities, net of the deferred tax impact, and the elimination of historical prepaid or deferred rent, was recorded as an adjustment to retained earnings. The net impact of adoption to the Company's balance sheet as of January 1, 2019 is presented in the table below. The standard did not have a material impact to the Company's consolidated statements of operations and comprehensive income (loss) or cash flows.

(U.S. Dollars, in thousands)	December 31, 2018	Impact of Adoption of ASC 842	January 1, 2019
Assets			
Current assets			
Cash, cash equivalents, and restricted cash	$ 72,189	$ —	$ 72,189
Accounts receivable, net	77,747	—	77,747
Inventories	76,847	—	76,847
Prepaid expenses and other current assets	17,856	(15)	17,841
Total current assets	244,639	(15)	244,624
Property, plant, and equipment, net	42,835	—	42,835
Intangible assets, net and goodwill	124,298	—	124,298
Deferred income taxes	33,228	71	33,299
Other long-term assets	21,641	20,209	41,850
Total assets	**$ 466,641**	**$ 20,265**	**$ 486,906**
Liabilities and shareholders' equity			
Current liabilities			
Accounts payable	$ 17,989	$ —	$ 17,989
Other current liabilities	67,919	2,166	70,085
Total current liabilities	85,908	2,166	88,074
Other long-term liabilities	45,336	18,028	63,364
Total liabilities	$ 131,244	$ 20,194	$ 151,438
Shareholders' equity			
Common shares	1,858	—	1,858
Additional paid-in capital	243,165	—	243,165
Retained earnings	87,078	71	87,149
Accumulated other comprehensive income	3,296	—	3,296
Total shareholders' equity	335,397	71	335,468
Total liabilities and shareholders' equity	**$ 466,641**	**$ 20,265**	**$ 486,906**

The Company determines if an arrangement is a lease at inception. The Company's leases primarily relate to facilities, vehicles, and equipment. Lease assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Lease assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company's incremental borrowing rate is used as a discount rate, based on the information available at the commencement date, in determining the present value of lease payments. Lease assets also include the impact of any prepayments made and are reduced by impact of any lease incentives.

The Company has made an accounting policy election for short-term leases, in that the Company does not recognize a lease liability or lease asset on the balance sheet for leases with a lease term of twelve months or less as of the commencement date. Rather, any short-term lease payments are recognized as an expense on a straight-line basis over the lease term. The current period short-term lease expense reasonably reflects our short-term lease commitments.

The Company has made a policy election for all classifications of leases to combine lease and nonlease components and to account for them as a single lease component. Variable lease payments are excluded from the lease liability and recognized in the period in which the obligation is incurred. Additionally, lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option.

During the first quarter of 2019, the Company entered into an amendment for its corporate headquarters lease. As a result, the classification of this lease changed from an operating lease to a finance lease, resulting in an increase to both the lease liability and lease asset of approximately $8.0 million.

A summary of the Company's lease portfolio as of December 31, 2019 is presented in the table below:

(U.S. Dollars, in thousands, except lease term and discount rate)	Classification	December 31, 2019
Assets		
Operating leases	Other long-term assets	$ 5,798
Finance leases	Property, plant and equipment, net	20,207
Total lease assets		$ 26,005
Liabilities		
Current		
Operating leases	Other current liabilities	$ 1,875
Finance leases	Current portion of finance lease liability	323
Long-term		
Operating leases	Other long-term liabilities	4,084
Finance leases	Long-term portion of finance lease liability	20,648
Total lease liabilities		$ 26,930
Weighted Average Remaining Lease Term		
Operating leases		4.2 years
Finance leases		20.7 years
Weighted Average Discount Rate		
Operating leases		2.33%
Finance leases		4.38%

The components of lease costs were as follows:

(U.S. Dollars, in thousands)	For the Year Ended December 31, 2019
Finance lease costs:	
Amortization of right-of-use assets	$ 972
Interest on finance lease liabilities	919
Operating lease costs	2,161
Short-term lease costs	255
Variable lease costs	749
Total lease costs	$ 5,056

Supplemental cash flow information related to leases was as follows:

(U.S. Dollars, in thousands)	For the Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities	
Operating cash flows from operating leases	$ 4,075
Operating cash flows from finance leases	919
Financing cash flows from finance leases	365
Right-of-use assets obtained in exchange for lease obligations	
Operating leases	878
Finance leases	21,179

A summary of the Company's remaining lease liabilities as of December 31, 2019 is included below:

(U.S. Dollars, in thousands)	Operating Leases	Finance Leases
2020	$ 1,979	$ 1,013
2021	1,758	1,414
2022	1,409	1,442
2023	259	1,471
2024	143	1,501
Thereafter	686	25,706
Total undiscounted value of lease liabilities	6,234	32,547
Less: Interest	(275)	(11,576)
Present value of lease liabilities	$ 5,959	$ 20,971
Current portion of lease liabilities	$ 1,875	$ 323
Long-term portion of lease liabilities	4,084	20,648
Total lease liabilities	$ 5,959	$ 20,971

9. Other current liabilities

	December 31,	
(U.S. Dollars, in thousands)	2019	2018
Accrued expenses	$ 5,571	$ 6,206
Salaries, bonuses, commissions and related taxes payable	14,008	21,608
Accrued distributor commissions	12,286	10,073
Accrued legal and settlement expenses	9,227	4,196
Contingent consideration liability	14,700	13,600
Short-term operating lease liability	1,875	—
Non-income taxes payable	4,021	3,638
Other payables	2,986	8,598
Other current liabilities	$ 64,674	$ 67,919

In December 2019, the Company approved and initiated a targeted restructuring plan in the U.S. to streamline costs and to better align talent with the Company's strategic initiatives. The plan consists primarily of the realignment of certain personnel, representing an extremely limited number of positions, which will require severance payments. As of December 31, 2019, the Company recorded a liability of $3.2 million in connection with this activity, all of which was recognized in 2019 within general and administrative expenses.

10. Long-term debt

On October 25, 2019, the Company, and certain of its wholly-owned subsidiaries (collectively with the Company, the "Borrowers"), as borrowers, and certain material subsidiaries of the Company as guarantors, entered into a Second Amended and Restated Credit Agreement (the "Amended Credit Agreement") with JPMorgan Chase Bank, N.A. ("JPMorgan"), as Administrative Agent, and certain lender parties thereto. The Amended Credit Agreement provides for a $300 million secured revolving credit facility (the "Facility") amending and restating the $125 million secured revolving credit facility that previously existed with such lenders. The Credit Agreement has a maturity date of October 25, 2024. As of December 31, 2019, the Company has no borrowings outstanding under the Credit Agreement.

Borrowings under the Amended Credit Agreement may be used for, among other things, working capital and other general corporate purposes of the Company and its subsidiaries (including permitted acquisitions and permitted payments of dividends and other distributions). The Facility is available in U.S. Dollars with up to $150 million of the Facility available to be borrowed in Euros and British Pounds (the "Agreed Currencies"). The Facility further permits up to $50 million of the Facility to be utilized for the issuance of letters of credit in the Agreed Currencies. The Borrowers have the ability to increase the amount of the Facility, which increases may take the form of increases to the revolving credit commitments or the issuance of new term A loans, by an aggregate amount of up to the greater of $150 million or an incremental amount such that the total amount of the Facility does not exceed 350% of consolidated EBITDA of the Company (as determined for the four fiscal quarter period most recently ended for which financial statements are available), upon satisfaction of customary conditions precedent for such increases or incremental loans and receipt of additional commitments by one or more existing or new lenders.

Borrowings under the Facility bear interest at a floating rate, which is, at the Borrowers' option, either LIBOR, or possibly an alternative reference rate to be used in place of LIBOR upon the occurrence of a benchmark transition event, plus an applicable margin ranging from 1.25% to 2.25% or a base rate plus an applicable margin ranging from 0.25% to 1.25% (in each case subject to adjustment based on the Company's total leverage ratio). An unused fee ranging from 0.15% to 0.25% (subject to adjustment based on the Company's total leverage ratio) is payable quarterly in arrears based on the daily amount of the undrawn portion of each lender's revolving credit commitment under the Facility. Fees are payable on outstanding letters of credit at a rate equal to the applicable margin for LIBOR loans, plus certain customary fees payable solely to the issuer of the letter of credit.

Certain of the Company's existing and future material subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of the Borrowers' obligations under the Amended Credit Agreement. The obligations of the Borrowers and each of the Guarantors with respect to the Amended Credit Agreement are secured by a pledge of substantially all of the personal property assets of the Borrowers and each of the Guarantors, including accounts receivables, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their respective subsidiaries.

The Amended Credit Agreement contains customary affirmative and negative covenants, including limitations on the Company's and its subsidiaries ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness and enter into affiliate transactions. In addition, the Amended Credit Agreement contains financial covenants requiring the Company on a consolidated basis to maintain, as of the last day of any fiscal quarter, a total net leverage ratio of not more than 3.5 to 1.0 (which ratio can be permitted to increase to 4.0 to 1.0 for no more than 4 fiscal quarters following a material acquisition) and an interest coverage ratio of at least 3.0 to 1.0. The Amended Credit Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Facility may be accelerated and/or the lenders' commitments terminated. The Credit Agreement also includes events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Facility may be accelerated and/or the lenders' commitments terminated. The Company is in compliance with all required financial covenants as of December 31, 2019.

In conjunction with obtaining the Facility, the Company has paid $1.5 million in debt issuance costs and has capitalized a total of $1.8 million associated with the Facility. These costs are being amortized over the life of the Facility. The debt issuance costs are included in other long-term assets, net of accumulated amortization. As of December 31, 2019 and December 31, 2018, debt issuance costs, net of accumulated amortization, were $1.7 million and $0.6 million, respectively. Debt issuance costs amortized or expensed totaled $0.4 million, $0.4 million, and $1.0 million for the years ended December 31, 2019, 2018, and 2017, respectively.

The Company has an unused available line of credit of €5.5 million ($6.2 million and $6.3 million) at December 31, 2019 and 2018, respectively, in its Italian line of credit. This unsecured line of credit provides the Company the option to borrow amounts in Italy at interest rates determined at the time of borrowing.

The Company paid cash related to interest of $0.8 million, $0.8 million, and $0.8 million for the years ended December 31, 2019, 2018, and 2017, respectively.

11. Fair value measurements and investments

Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Non-financial assets and liabilities of the Company measured at fair value include any long-lived assets that are impaired in a currently reported period or equity securities measured at observable prices in orderly transactions. The authoritative guidance also describes three levels of inputs that may be used to measure fair value:

Level 1: quoted prices in active markets for identical assets and liabilities

Level 2: observable inputs other than quoted prices in active markets for identical assets and liabilities

Level 3: unobservable inputs in which there is little or no market data available, which require the reporting entity to develop its own assumptions

The Company's financial instruments include cash equivalents, restricted cash, collective trust funds, treasury securities, trade accounts receivable, accounts payable, long-term secured debt, equity warrants, equity securities, available for sale debt securities, contingent consideration and deferred compensation plan liabilities. The carrying value of cash equivalents, restricted cash, trade accounts receivable, and accounts payable approximate fair value due to the short-term maturities of these instruments. The Company's credit facilities carry a floating rate of interest, and therefore, the carrying value of long-term debt is considered to approximate the fair value.

The Company's collective trust funds, treasury securities, equity warrants, equity securities, debt security, contingent consideration, and deferred compensation plan liabilities are the only financial instruments recorded at fair value on a recurring basis as follows:

(U.S. Dollars, in thousands)	Balance December 31, 2019	Level 1	Level 2	Level 3
Assets				
Equity securities	$ 219	$ —	$ 219	$ —
Total	$ 219	$ —	$ 219	$ —
Liabilities				
Contingent consideration	$ (42,700)	$ —	$ —	$ (42,700)
Deferred compensation plan	(1,255)	—	(1,255)	—
Total	$ (43,955)	$ —	$ (1,255)	$ (42,700)

(U.S. Dollars, in thousands)	Balance December 31, 2018	Level 1	Level 2	Level 3
Assets				
Treasury securities	$ 490	$ 490	$ —	$ —
Equity securities	219	—	219	—
Debt security	17,820	—	—	17,820
Total	$ 18,529	$ 490	$ 219	$ 17,820
Liabilities				
Contingent consideration	(28,560)	—	—	(28,560)
Deferred compensation plan	$ (1,275)	$ —	$ (1,275)	$ —
Total	$ (29,835)	$ —	$ (1,275)	$ (28,560)

The fair value of treasury securities was determined based on quoted prices in active markets for identical assets, therefore, the Company categorized these instruments as Level 1 financial instruments.

The fair value of the Company's collective trust funds, equity warrants, equity securities, and deferred compensation plan liabilities are determined based on inputs that are readily available in public markets or can be derived from information available in publicly quoted markets; therefore, the Company has categorized these instruments as Level 2 financial instruments.

Equity Warrants and Securities

The Company holds investments in common stock and warrants to purchase shares of common stock of Bone Biologics. The Company's common stock investments are recorded within other long-term assets although the fair value of the warrants was reduced to zero in 2018. The equity securities are considered investments that do not have readily determinable fair values. As such, the Company measures these investments at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. In 2018, Bone Biologics completed a series of equity financing activities, which provided a new observable price change in an orderly transaction. As a result, the Company determined its investment was impaired and recorded a charge of $4.4 million in other expense, net.

As of December 31, 2019, the Company holds common stock of Bone Biologics and warrants to purchase approximately 13 thousand shares at a weighted average exercise price of $10.00 per share (after adjusting the shares and exercise price for a reverse stock split executed by Bone Biologics in 2018). Under the terms of the warrant purchase agreements, the warrants to purchase common stock in Bone Biologics are exercisable over a seven year period, which expires in 2020, and are transferable by the holder to other parties.

The changes in valuation of these securities for the years ended December 31, 2019, 2018, and 2017 are shown below:

(U.S. Dollars, in thousands)	2019	2018	2017
Equity securities and warrants at January 1	$ 219	$ 2,768	$ 2,768
Impact of adoption of ASU 2016-01 recognized in other income	—	1,629	—
Purchase of additional common stock	—	500	—
Fair value adjustments, expirations, and impairments recognized in other expense	—	(4,678)	—
Equity securities and warrants at December 31	$ 219	$ 219	$ 2,768

Debt Security

Until October of 2019, the Company held a debt security of eNeura, Inc. ("eNeura"), a privately held medical technology company that is developing devices for the treatment of migraines. The principal amount of the debt security was $15.0 million and accrued interest at 8.0%, with payment due at maturity. The debt security was originally set to mature on March 4, 2019. On March 1, 2019, the Company entered into an Amended and Restated Senior Secured Promissory Note with eNeura (the "Restructured Debt Security") to restructure the debt security, which extended the maturity date to the earlier of (i) March 4, 2022, (ii) the effective date of a change in control, or (iii) the effective date of an initial public offering by eNeura, and which also eliminated the conversion feature included within the original note. As consideration for the extension, eNeura issued to the Company a Warrant to Purchase Common Stock (the "Warrant"), exercisable at $0.01 per share over a ten year contractual term, for a number of shares equal to 10% of the sum of the outstanding principal and accrued interest on the Amended and Restated Debt Security as of March 1, 2019, divided by $1.00 (subject to certain anti-dilution provisions).

Prior to the restructuring, the debt security was accounted for as an available for sale debt security at fair value and included within other long-term assets. The fair value was based upon significant unobservable inputs, including the use of a discounted cash flow model and assumptions regarding the expected payback period for the debt security, requiring the Company to develop its own assumptions; therefore, the Company had categorized this asset as a Level 3 financial asset. The Company evaluated any declines in fair value, if any, each quarter to determine if impairments are other-than-temporary. The debt security had an amortized cost basis of $9.0 million at the time of the restructuring and as of December 31, 2018.

Subsequent to the restructuring, the debt security was no longer classified as an available for sale debt security, but rather as a held to maturity debt security. The debt security was reclassified from an available for sale debt security to a held to maturity debt security at its fair value on the date of the restructuring. As a result, the unrealized gains included in accumulated other comprehensive income (loss) related to the debt security were to be subsequently amortized to interest income over the remaining term of the Restructured Debt Security.

The Warrant was recorded at fair value and included in other long-term assets. The fair value of the Warrant was based on significant unobservable inputs, including the use of a discounted cash flow model and an option-pricing model, requiring the Company to develop its own assumptions; therefore, the Company categorized this asset as a Level 3 financial asset. The Warrant was considered an investment that does not have a readily determinable fair value. As such, the Company measured the Warrant at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer.

During the quarter ended September 30, 2019, the Company engaged in negotiations with eNeura to settle the Restructured Debt Security and on October 25, 2019, the Company and eNeura settled the Restructured Debt Security for a $4.0 million cash payment and agreed to transfer the Warrant to eNeura. As such, the Company determined the Restructured Debt Security and Warrant were impaired and adjusted the carrying value of the Restructured Debt Security to $4.0 million, its settlement value, by recording a net other-than-temporary impairment of $6.5 million in other expense, net, which included a reclassification of the related unrealized gains included in accumulated other comprehensive income (loss) of $5.2 million.

The following table provides a reconciliation of the beginning and ending balances for debt securities measured at fair value using significant unobservable inputs (Level 3):

(U.S. Dollars, in thousands)	2019	2018	2017
Balance at January 1	$ 17,820	$ 16,050	$ 12,220
Gains (losses) recorded for the period			
Recognized in other expense, net	—	—	(5,585)
Recognized in other comprehensive income (loss)	(2,593)	1,770	9,415
Change in classification of debt security to held to maturity	(15,227)	—	—
Issuance of Warrant as consideration for extension	491	—	—
Impairment of Warrant	(491)	—	—
Balance at December 31	$ —	$ 17,820	$ 16,050

Contingent Consideration

Contingent consideration consists of potential future milestone payments of up to $60.0 million in cash associated with the Spinal Kinetics acquisition. The milestone payments include (i) up to $15.0 million upon FDA approval of the M6-C artificial cervical disc (the "FDA Milestone") and (ii) revenue-based milestone payments of up to $45.0 million in connection with future sales of the acquired artificial discs (the "Revenue Milestones"). Milestones must be achieved within five years of April 30, 2018 to trigger applicable payments.

On February 6, 2019, the Company obtained FDA approval of the M6-C artificial cervical disc. This approval triggered the Company's payment obligation of $15.0 million for the achievement of the FDA Milestone, which was paid on February 14, 2019. Prior to its payment, the Company estimated the fair value of the FDA Milestone using a probability-weighted discounted cash flow model. The fair value was based on significant unobservable inputs and thus represented a Level 3 measurement. The key assumptions affecting the fair value of the milestone payment included the Company's estimation of the timing and probability of FDA approval.

The Company estimates the fair value of the Revenue Milestones using a Monte Carlo simulation. This fair value measurement is based on significant unobservable inputs and thus represents a Level 3 measurement. The key assumptions in applying the Monte Carlo valuation model include the Company's forecasted future revenues for Spinal Kinetics products, the discount rates applied, and assumptions for potential volatility of forecasted revenue. Significant changes in these assumptions could result in a significantly higher or lower fair value. As of December 31, 2019, the estimated fair value of the remaining Revenue Milestones was $42.7 million; however, the actual amount ultimately paid could be higher or lower than this amount. As of December 31, 2019, the Company has classified $14.7 million of the liability within other current liabilities, as the Company expects to pay one of the Revenue Milestones in the next twelve months, and the remaining $28.0 million within other long-term liabilities.

Any changes in fair value related to contingent consideration are recorded as an operating expense and included within acquisition-related amortization and remeasurement. The following table provides a reconciliation of the beginning and ending balances for the contingent consideration measured at fair value using significant unobservable inputs (Level 3):

(U.S. Dollars, in thousands)	2019	2018
Contingent consideration at January 1	$ 28,560	$ —
Acquisition date fair value	—	25,491
Increase in fair value recognized in acquisition-related amortization and remeasurement	29,140	3,069
Payment made	(15,000)	—
Contingent consideration at December 31	$ 42,700	$ 28,560

The $29.1 million increase in fair value in 2019 is primarily attributable to a change in management's forecast of future net sales of the artificial discs, including an acceleration of the expected timing of such future sales, subsequent to the Company's launch of the product in the U.S. market upon receiving FDA approval.

12. Commitments and Contingencies

Contingencies policy

The Company records accruals for certain outstanding legal proceedings, investigations or claims when it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. The Company evaluates, on a quarterly basis, developments in legal proceedings, investigations and claims that could affect the amount of any accrual, as well as any developments that would make a loss contingency both probable and reasonably estimable. When a loss contingency is not both probable and reasonably estimable, the Company does not accrue the loss. However, if the loss (or an additional loss in excess of the accrual) is at least a reasonable possibility and material, then the Company discloses a reasonable estimate of the possible loss or range of loss, if such reasonable estimate can be made. If the Company cannot make a reasonable estimate of the possible loss, or range of loss, then that is disclosed. In addition, legal fees and other directly related costs are expensed as incurred.

In addition to the matters described in the paragraphs below, in the normal course of its business, the Company is involved in various lawsuits from time to time and may be subject to certain other contingencies. The Company believes any losses related to these matters are individually and collectively immaterial as to a possible loss and range of loss.

January 2017 SEC Settlements

In January 2017, the SEC approved the Company's offers of settlement in connection with the SEC's investigations of accounting matters leading to the Company's prior restatement of financial statements and the Company's review of improper payments with respect to its subsidiary in Brazil. The settlements approved by the SEC resolved these two matters, and included payments totaling $14.4 million to the SEC of amounts previously accrued and funded into escrow during 2016. In addition, in 2017, the Company received a favorable insurance settlement of approximately $6 million associated with prior costs incurred related to these matters, which was recognized within general and administrative expenses.

Discontinued Operations – Matters Related to Breg and Indemnification Obligations

On May 24, 2012, the Company sold Breg, Inc. ("Breg"), a former subsidiary, to an affiliate of Water Street Healthcare Partners II, L.P. ("Water Street"). Under the terms of the agreement, the Company indemnified Water Street and Breg with respect to certain specified matters. In May 2018, Breg settled and resolved a post-close cold therapy claim in California state court. Pursuant to the Company's indemnification obligation, the Company made a final payment to its insurer in the amount of $1.7 million to help fund the Breg settlement. Charges incurred as a result of this indemnification were reflected as discontinued operations in our consolidated statements of operations and comprehensive income (loss). The Company does not expect any additional charges related to this discontinued operation.

Italian Medical Device Payback ("IMDP")

In 2015, the Italian Parliament introduced rules for entities that supply goods and services to the Italian National Healthcare System. The healthcare law is expected to impact the business and financial reporting of companies operating in the medical technology sector that sell medical devices in Italy. A key provision of the law is a 'payback' measure, requiring companies selling medical devices in Italy to make payments to the Italian government if medical device expenditures exceed regional maximum ceilings. Companies are required to make payments equal to a percentage of expenditures exceeding maximum regional caps. There is considerable uncertainty about how the law will operate and what the exact timeline is for finalization. The Company's current assessment of the IMDP involves significant judgment regarding the expected scope and actual implementation terms of the measure as the latter have not been clarified to date by Italian authorities. The Company accounts for the estimated cost of the IMDP as sales and marketing expense and recorded expense of $1.3 million, $1.0 million, and $0.9 million for the years ended December 31, 2019, 2018, and 2017, respectively. As of December 31, 2019, the Company has accrued $4.9 million related to the IMDP, which it has classified within other long-term liabilities; however, the actual liability could be higher or lower than the amount accrued once the law has been clarified by the Italian authorities.

Brazil

In July 2018, the Federal Prosecution Service in Rio de Janeiro and representatives from the Brazilian antitrust authority inspected the offices of more than 30 companies, including the Company's office in São Paulo, as part of an investigation into tender irregularities in the medical device industry. Before doing so, the authorities obtained a court order affecting the Company's (and other companies') local bank accounts resulting in the freezing of approximately $2.5 million of the Company's cash, which the Company reclassified to restricted cash. On April 3, 2019, the Company's appeal regarding the freezing of its local bank accounts was heard by the Brazil Federal Court of Appeals of Rio de Janeiro, in which the Court ordered the unfreezing of the Company's cash. The cash was then returned without any restriction in April 2019. As such, this balance was reclassified to cash and cash equivalents in 2019.

In September 2019, approximately $0.7 million of the Company's cash in Brazil was frozen upon request to satisfy a judgment related to an ongoing legal dispute with a former Brazilian distributor. Although the Company is appealing the judgment, this cash has been reclassified to restricted cash. As of December 31, 2019, the Company has accrued $1.7 million related to this matter.

13. Shareholders' equity

Dividends

The Company has not paid dividends to holders of its common stock in the past. Certain subsidiaries of the Company have restrictions on their ability to pay dividends in certain circumstances pursuant to the Amended Credit Agreement. In the event that the Company decides to pay a dividend to holders of its common stock in the future with dividends received from its subsidiaries, the Company may, based on prevailing rates of taxation, be required to pay additional withholding and income tax on such amounts received from its subsidiaries.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) is comprised of foreign currency translation adjustments and the unrealized gains (losses) on the Company's debt security, which was settled in 2019. The components of and changes in accumulated other comprehensive income (loss) are as follows:

(U.S. Dollars, in thousands)	Currency Translation Adjustments	Debt Security	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2017	$ (563)	$ 4,350	$ 3,787
Other comprehensive income (loss)	(1,823)	1,770	(53)
Income taxes	—	(438)	(438)
Balance at December 31, 2018	$ (2,386)	$ 5,682	$ 3,296
Cumulative effect adjustment from adoption of ASU 2018-02	—	937	937
Other comprehensive loss	(653)	(2,593)	(3,246)
Income taxes	—	642	642
Reclassification adjustment to:			
Interest income (expense), net	—	(1,034)	(1,034)
Other expense, net	—	(5,193)	(5,193)
Income taxes	—	1,559	1,559
Balance at December 31, 2019	$ (3,039)	$ —	$ (3,039)

14. Revenue recognition and accounts receivable

Revenue Recognition

The Company accounts for a contract when there is approval and commitment from both parties, the rights of the parties are identified, payment terms are identified, the contract has commercial substance, and collectability of consideration is probable. The Company's contracts may contain one or more performance obligations. If a contract contains more than one performance obligation, the Company allocates the total transaction price to each of the performance obligations based upon the observable standalone selling price of the promised goods or services underlying each performance obligation. The Company recognizes revenue when control of the promised goods or services is transferred to the customer, which typically occurs at a point in time

upon shipment, delivery, or utilization, in an amount that reflects the consideration which the Company expects to be entitled in exchange for the promised goods or services. The amount the Company expects to be entitled to in exchange for the goods or services reflects any fixed amount stated per the contract and estimates for any variable consideration, such as discounts, to the extent that is it probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved.

The following sections discuss the Company's revenue recognition policies by significant product category:

Bone Growth Therapies

Bone Growth Therapies revenue is largely attributable to the U.S. and is comprised of third-party payor transactions and wholesale revenue.

The largest portion of Bone Growth Therapies revenue is derived from third-party payors. This includes commercial insurance carriers, health maintenance organizations, preferred provider organizations, and governmental payors, such as Medicare. Revenue is recognized when the product is fitted to and accepted by the patient and all applicable documents required by the third-party payor have been obtained. Amounts paid by third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

Wholesale revenue is related to the sale of the Company's bone growth stimulators directly to durable medical equipment suppliers. Wholesale revenues are typically recognized upon shipment and receipt of a confirming purchase order, which is when the customer obtains control of the promised goods.

Biologics

Biologics revenue is largely attributable to the U.S. and is primarily related to a collaborative arrangement with MTF, which extends through July 28, 2027. Under this arrangement, the Company markets tissue for bone repair and reconstruction under the brand names Trinity Evolution and Trinity ELITE. Per the terms of the agreement, MTF sources the tissue, processes it to create the bone growth matrix, packages, and delivers the tissue to the customer in accordance with orders received from the Company. The Company has exclusive global marketing rights for the Trinity Evolution and Trinity ELITE tissues, as well as non-exclusive marketing rights for other products, and receives marketing fees from MTF based on total sales. MTF is considered the primary obligor in these arrangements; therefore, the Company recognizes marketing service fees on a net basis within net sales upon shipment of the product to the customer.

Spinal Implants and Global Extremities

Spinal Implants and Global Extremities products are distributed world-wide, with U.S. sales largely comprised of commercial sales and international sales derived from both commercial sales and through stocking distributor arrangements.

Commercial revenue is largely related to the sale of the Company's Spinal Implants and Global Extremities products to hospital customers. The customer obtains control and revenues are recognized when these products have been utilized and a confirming purchase order has been received from the hospital.

Other revenues within the Spinal Implants and Global Extremities product categories are derived from stocking distributors, who purchase the Company's products and then re-sell them directly to customers, such as hospitals. For revenue from stocking distributor arrangements, subsequent to the adoption of Topic 606 effective January 1, 2018, the Company recognizes revenue upon shipment and receipt of a confirming purchase order, which is when the distributor obtains control of the promised goods. The transaction price with stocking distributors is estimated based upon the Company's historical collection experience with the stocking distributor. To derive this estimate, the Company analyzes twelve months of historical invoices by stocking distributor and the subsequent collections on those invoices for a period of up to 24 months subsequent to the invoice date. The historical collection percentage, which is specific to each stocking distributor, is then used to calculate the transaction price. Cost of sales is also recorded upon transfer of control of the product to the customer subsequent to the adoption of Topic 606.

Prior to the adoption of Topic 606, or for all periods presented prior to January 1, 2018, the Company recognized revenue from stocking distributor arrangements once the product was delivered to the end customer (the "sell-through method"). Because the Company did not have reliable information about when its distributors sold the product through to end customers, the Company used cash collection from distributors as a basis for revenue recognition under the sell-through method. Although in many cases the

Company was legally entitled to the accounts receivable at the time of shipment, the Company did not recognize accounts receivables or any corresponding deferred revenues at the time of shipment associated with stocking distributor transactions for which revenue was recognized on the sell-through method. The Company also considered whether to match the related cost of sales with revenue or to recognize cost of sales upon shipment. In making this assessment, the Company considered the financial viability of its stocking distributors, based on their creditworthiness, to determine if collectability of amounts sufficient to realize the costs of the products shipped was reasonably assured at the time of shipment. In instances where the stocking distributor was determined to be financially viable, the Company deferred the costs of sales until revenue was recognized.

Product Sales and Marketing Service Fees

The table below presents net sales, which includes product sales and marketing service fees, for each of the years ended December 31, 2019, 2018, and 2017.

	For the year ended December 31,		
(U.S. Dollars, in thousands)	**2019**	**2018**	**2017**
Product sales	$ 397,064	$ 395,589	$ 373,538
Marketing service fees	62,891	57,453	60,285
Net sales	$ 459,955	$ 453,042	$ 433,823

Product sales primarily consists of the sale of Bone Growth Therapies, Spinal Implants, and Global Extremities products. Marketing service fees are received from MTF based on total sales of biologics tissues and relates solely to the Biologics product category within the Global Spine reporting segment. Marketing service fees received from MTF were $62.9 million, or approximately 96% of total Biologics revenues, for the year ended December 31, 2019. As MTF is the Company's single supplier for the Trinity Evolution and Trinity ELITE tissue forms, which are derived from human cadaveric donors, any event or circumstance that would impact MTF's continued access to donated human cadaveric tissue or the Company's ability to market these tissues may adversely impact the Company's financial results.

Revenues exclude any value added or other local taxes, intercompany sales and trade discounts. Shipping and handling costs for products shipped to customers are included in cost of sales, and were $2.8 million, $2.7 million and $3.0 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Trade Accounts Receivable and Allowances

Payment terms vary by the type and location of the Company's customers and the products or services offered. The term between invoicing and when payment is due is not significant. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for doubtful accounts and contractual allowances. Revisions in allowances for doubtful accounts estimates are recorded as an adjustment to bad debt expense within sales and marketing expenses. Revisions to contractual allowances are recorded as an adjustment to net sales. The Company's estimates are periodically tested against actual collection experience.

The Company will generally sell receivables from certain Italian hospitals each year to accelerate cash collections. During 2019, 2018, and 2017 the Company sold €9.8 million, €9.8 million, and €9.8 million ($10.9 million, $11.5 million, and $11.2 million) of receivables, respectively. The estimated related fees for 2019, 2018, and 2017 were $0.3 million, $0.3 million and $0.3 million, respectively, which is recorded as interest expense. Trade accounts receivables sold without recourse are removed from the balance sheet at the time of sale.

Puerto Rico Settlement

In June 2019, the Company received a payment of $1.4 million from the Administration of Medical Services of Puerto Rico, a government-owned corporation, in settlement of approximately $2.5 million of outstanding accounts receivable. This $2.5 million of outstanding accounts receivable had previously been fully reserved between the Company's allowances for doubtful accounts and contractual allowances. As a result of this settlement, and in accordance with the Company's policy, the Company recorded the resulting adjustment to contractual allowances of $0.4 million within net sales and the recovery of the allowance for doubtful accounts as a credit to bad debt expense of $1.0 million.

Other Contract Assets

The Company's contract assets, excluding trade accounts receivable ("other contract assets"), largely consist of payments made to certain distributors to obtain contracts, gain access to customers in certain territories, and to provide the benefit of the exclusive

distribution of the Company's products. Other contract assets are included in other long-term assets and were $3.7 million and $1.9 million as of December 31, 2019 and 2018, respectively.

Other contract assets are amortized on a straight-line basis over the term of the related contract. No impairments were incurred for other contract assets in 2019 or 2018. Further, the Company has applied the practical expedient allowed within Topic 606 to expense sales commissions when incurred, as the applicable amortization period would be for one year or less.

15. Business segment information

The Company changed its reportable business segments, beginning with the first quarter of 2019, to align with changes in how the Company manages its business, reviews operating performance and allocates resources. The Company now reports results under two reportable segments: Global Spine and Global Extremities. These reporting segments represent the operating segments for which the Chief Executive Officer, who is also Chief Operating Decision Maker (the "CODM"), reviews financial information and makes resource allocation decisions among businesses. The primary metric used by the CODM in managing the Company is earnings before interest, tax, depreciation, and amortization ("EBITDA"). The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. Accordingly, the reporting segment information has been prepared based on these two reporting segments. Prior periods have been recast to present the change in reporting segments.

Global Spine

The Global Spine reporting segment offers three primary product categories: Bone Growth Therapies, Spinal Implants, and Biologics.

The Bone Growth Therapies product category manufactures, distributes, and provides support services of market leading bone growth stimulator devices that enhance bone fusion. These Class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in the cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). This product category uses distributors and sales representatives to sell its devices to hospitals, healthcare providers, and patients, primarily in the U.S.

The Spinal Implants product category designs, develops, and markets a broad portfolio of motion preservation and fixation implant products used in surgical procedures of the spine. Spinal Implants distributes its products through a network of distributors and sales representatives to sell spine products to hospitals and healthcare providers, globally.

The Biologics product category provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This product category specializes in the marketing of the Company's exclusive regeneration tissue forms and distributes its tissues to hospitals and healthcare providers, primarily in the U.S., through a network of independent distributors and sales representatives. The partnership with MTF allows the Company to exclusively market the Trinity Evolution and Trinity ELITE tissue forms for musculoskeletal defects to enhance bony fusion.

Global Extremities

The Global Extremities reporting segment offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions unrelated to the spine. This reporting segment specializes in the design, development, and marketing of the Company's orthopedic products used in fracture repair, deformity correction and bone reconstruction procedures. Global Extremities distributes its products through a network of distributors and sales representatives to sell orthopedic products to hospitals, and healthcare providers, globally.

Corporate

Corporate activities are comprised of the operating expenses and activities of the Company not necessarily identifiable within the two reporting segments.

The table below presents net sales by major product category by reporting segment:

	Year Ended December 31,					
	2019		2018		2017	
(U.S. Dollars, in thousands)	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Bone Growth Therapies	$ 197,181	42.9%	$ 195,252	43.1%	$ 185,900	42.9%
Spinal Implants	94,544	20.6%	91,658	20.2%	81,957	18.9%
Biologics	65,496	14.2%	59,684	13.2%	62,724	14.4%
Global Spine	357,221	77.7%	346,594	76.5%	330,581	76.2%
Global Extremities	102,734	22.3%	106,448	23.5%	103,242	23.8%
Net sales	$ 459,955	100.0%	$ 453,042	100.0%	$ 433,823	100.0%

The following table presents EBITDA, the primary metric used in managing the Company, by reporting segment:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
Global Spine	$ 39,528	$ 76,545	$ 84,034
Global Extremities	7,496	9,453	7,143
Corporate	(49,252)	(43,626)	(34,246)
Total EBITDA	(2,228)	42,372	56,931
Depreciation and amortization	(24,699)	(18,659)	(20,124)
Interest expense, net	(122)	(828)	(416)
Income (loss) before income taxes	$ (27,049)	$ 22,885	$ 36,391

The following table presents depreciation and amortization by reporting segment:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
Global Spine	$ 14,329	$ 9,512	$ 9,834
Global Extremities	5,575	5,342	6,040
Corporate	4,795	3,805	4,250
Total	$ 24,699	$ 18,659	$ 20,124

Geographical information

The following data includes net sales by geographic destination:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
U.S.	$ 361,939	$ 355,353	$ 345,145
Italy	19,560	19,331	17,059
Germany	12,688	11,606	7,063
United Kingdom	10,090	8,731	8,725
Brazil	7,685	7,120	10,356
Others	47,993	50,901	45,475
Net sales	$ 459,955	$ 453,042	$ 433,823

The table below presents net sales by geographic destination for each reporting segment and for the consolidated Company:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
Global Spine			
U.S.	$ 335,410	$ 326,994	$ 318,227
International	21,811	19,600	12,354
Total Global Spine	357,221	346,594	330,581
Global Extremities			
U.S.	26,529	28,359	26,918
International	76,205	78,089	76,324
Total Global Extremities	102,734	106,448	103,242
Consolidated			
U.S.	361,939	355,353	345,145
International	98,016	97,689	88,678
Net sales	$ 459,955	$ 453,042	$ 433,823

The following data includes property, plant and equipment by geographic area:

(U.S. Dollars, in thousands)	2019	2018
U.S.	$ 51,278	$ 31,344
Italy	7,937	7,732
Germany	849	861
United Kingdom	1,082	896
Brazil	141	191
Others	1,440	1,811
Total	$ 62,727	$ 42,835

16. Acquisition-related amortization and remeasurement

Acquisition-related amortization and remeasurement consists of amortization related to intangible assets acquired through business combinations or asset acquisitions and the remeasurement of any related contingent consideration arrangement. Components of acquisition-related amortization and remeasurement for the twelve months ended December 31, 2019, 2018, and 2017, respectively, are as follows:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
Changes in fair value of contingent consideration	$ 29,140	$ 3,069	$ —
Amortization of acquired intangibles	5,072	1,255	—
Total	$ 34,212	$ 4,324	$ —

17. Share-based compensation

At December 31, 2019, and 2018, the Company had stock option and award plans, and a stock purchase plan.

2012 Long Term Incentive Plan

The Board of Directors adopted the Amended and Restated 2012 Long-Term Incentive Plan (the "2012 LTIP") on April 13, 2012, which was subsequently provided by shareholder ratification. The 2012 LTIP provides for the grant of options to purchase shares of the Company's common stock, stock awards (including restricted stock, unrestricted stock, and stock units), stock appreciation rights,

performance-based awards and other equity-based awards. All of the Company's employees and the employees of the Company's subsidiaries and affiliates are eligible and may receive awards under the 2012 LTIP. In addition, the Company's non-employee directors, consultants, and advisors who perform services for the Company and its subsidiaries and affiliates may receive awards under the 2012 LTIP. Incentive share options; however, are only available to the Company's employees. Awards granted under the 2012 LTIP expire no later than ten years after the date of grant. At December 31, 2019, the Company reserves a total of 4,750,000 shares of common stock for issuance pursuant to the 2012 LTIP, subject to certain adjustments set forth in the 2012 LTIP. At December 31, 2019, there were 1,067,947 options outstanding under the 2012 LTIP, of which 714,180 were exercisable. In addition, there were 119,217 shares of unvested restricted stock outstanding and 560,844 restricted stock units outstanding, some of which contain market-based vesting conditions, under the 2012 LTIP as of December 31, 2019.

2004 Long Term Incentive Plan

The 2004 Long Term Incentive Plan (the "2004 LTIP") reserved 3.1 million shares for issuance, subject to certain adjustments set forth in the 2004 LTIP. At December 31, 2019, there were 25,500 options outstanding under the 2004 LTIP, all of which were exercisable.

Inducement Plans

The Inducement Plan for Spinal Kinetics Employees (the "Spinal Kinetics Inducement Plan") reserved 51,705 shares for issuance to employees of Spinal Kinetics as an inducement to continue employment with the Company. At December 31, 2019, there were 7,156 options outstanding under the Spinal Kinetics Inducement Plan, all of which were exercisable, and 5,608 shares of unvested restricted stock outstanding.

In conjunction with the Options Medical acquisition, an inducement grant of 25,478 restricted stock units, with a fair value of $1.4 million, was awarded to the Options Medical founder. The award vests in one-third annual increments beginning on the first anniversary of the grant date and is contingent upon continued employment. As of December 31, 2019, there were 25,478 shares of unvested restricted stock outstanding relating to this inducement.

In August 2019, the Company appointed a new President of Global Spine, who was then subsequently promoted to President and Chief Executive Officer. As an inducement to accept employment with the Company, the individual was awarded a grant of stock options to acquire up to 50,711 shares of common stock and an award of 14,743 restricted stock units. Both awards will vest in one-fourth annual increments beginning on the first anniversary of the grant date. As of December 31, 2019, there were 50,711 options outstanding under this inducement, none of which were exercisable, and 14,743 shares of unvested restricted stock outstanding.

Stock Purchase Plan

The Second Amended and Restated Stock Purchase Plan, as Amended (the "Stock Purchase Plan") provides for the issuance of shares of the Company's common stock to eligible employees and directors of the Company and its subsidiaries that elect to participate in the plan and acquire shares of common stock through payroll deductions (including executive officers).

During each purchase period, eligible employees may designate between 1% and 25% of their compensation to be deducted for the purchase of common stock under the plan (or such other percentage in order to comply with regulations applicable to Employees domiciled in or resident of a member state of the European Union). For eligible directors, the designated percentage will be applied to an amount equal to his or her director compensation paid in cash for the current plan period. The purchase price of the shares under the plan is equal to 85% of the fair market value on the first day of the plan period or, if lower, on the last day of the plan period.

Due to the compensatory nature of such plan, the Company records the related share-based compensation in the consolidated statement of operations. Compensation expense is estimated using the Black-Scholes valuation model, with such value recognized as expense over the plan period. As of December 31, 2019, the aggregate number of shares reserved for issuance under the Stock Purchase Plan is 2,350,000. As of December 31, 2019, 1,827,147 shares had been issued.

Share-Based Compensation Expense

Share-based compensation expense is recorded in the same line of the consolidated statements of operations as the employee's cash compensation. The following tables present the detail of share-based compensation by line item in the consolidated statements of income as well as by award type, for the years ended December 31, 2019, 2018, and 2017:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
Cost of sales	$ 715	$ 522	$ 486
Sales and marketing	2,512	1,802	1,471
General and administrative	16,872	15,197	9,671
Research and development	1,441	1,409	929
Total	$ 21,540	$ 18,930	$ 12,557

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
Stock options	$ 4,054	$ 3,061	$ 2,388
Time-based restricted stock awards and stock units	11,084	7,265	5,540
Performance-based restricted stock awards and stock units	—	1,998	462
Market-based restricted stock units	4,733	5,256	2,904
Stock purchase plan	1,669	1,350	1,263
Total	$ 21,540	$ 18,930	$ 12,557

The income tax benefit related to this expense was $3.5 million, $3.2 million, and $3.4 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Stock Options

The fair value of time-based stock options is determined using the Black-Scholes valuation model, with such value recognized as expense over the service period, which is typically four years, net of actual forfeitures. The fair value of market-based stock options is determined at the date of the grant using the Monte Carlo valuation methodology, with such value recognized as expense over the requisite service period adjusted for forfeitures as they occur. The Monte Carlo methodology incorporates into the valuation the possibility that the market condition may not be satisfied.

A summary of the Company's assumptions used in determining the fair value of the stock options granted during the year is shown in the following table.

	Year Ended December 31,		
	2019	2018	2017
Assumptions:			
Expected term (in years)	5.0	4.5	4.5
Expected volatility	29.7% – 31.0%	28.7% – 30.1%	31.2%
Risk free interest rate	1.38% – 2.31%	2.55% – 2.79%	1.93%
Dividend yield	—	—	—
Weighted average grant date fair value	$ 14.64	$ 16.28	$ 13.32

The expected term of the options granted is estimated based on a number of factors, including the vesting and expiration terms of the award, historical employee exercise behavior for both options that are currently outstanding and options that have been exercised or are expired, and an employee's average length of service. Expected volatility is based on the historical volatility of the Company's common stock. The risk-free interest rate is determined based upon a constant U.S. Treasury security rate with a contractual life that approximates the expected term of the option.

Summaries of the status of the Company's stock option plans as of December 31, 2019 and 2018 and changes during the year ended December 31, 2019 are presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at December 31, 2018	1,175,887	$ 41.87	
Granted	279,248	$ 49.17	
Exercised	(74,729)	$ 37.20	
Forfeited or expired	(79,092)	$ 54.84	
Outstanding at December 31, 2019	1,301,314	$ 42.92	5.69
Vested and expected to vest at December 31, 2019	1,301,314	$ 42.92	5.69
Exercisable at December 31, 2019	896,836	$ 39.97	4.24

As of December 31, 2019, the unamortized compensation expense relating to options granted and expected to be recognized was $3.7 million. This amount is expected to be recognized through December 2023 over a weighted average period of approximately 1.7 years. The total intrinsic value of options exercised was $1.4 million, $3.2 million and $2.2 million for the years ended December 31, 2019, 2018, and 2017, respectively. For the year ended December 31, 2019 we received $2.8 million in cash from stock option exercises, with the tax benefit realized for the tax deductions from these exercises of $0.3 million. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2019 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for options that had exercise prices lower than $46.18, the closing price of the Company's stock on December 31, 2019. The aggregate intrinsic value of options outstanding was $7.3 million, $13.6 million, and $18.7 million for the years ended December 31, 2019, 2018, and 2017, respectively. The aggregate intrinsic value of options exercisable was $6.7 million, $11.0 million, and $12.4 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Time-based Restricted Stock Awards and Stock Units

During the year ended December 31, 2019, the Company granted to employees and non-employee directors 319,189 shares of time-based restricted stock awards or stock units, which vest at various dates through December 2023. The compensation expense, which represents the fair value of the stock measured at the market price at the date of grant, is recognized on a straight-line basis over the vesting period, which is typically four years, net of actual forfeitures.

Since 2017, the annual grant to non-employee directors has been made in the form of one-year vesting restricted stock units with deferred delivery ("DSUs"), whereby shares are not settled until after the director ceases service as a director. As of December 31, 2019, there were 47,077 DSUs outstanding that are vested but not settled.

The aggregate fair value of time-based restricted stock awards and stock units that vested during the years ended December 31, 2019, 2018 and 2017 was $9.5 million, $8.0 million and $7.3 million, respectively. Unamortized compensation expense related to time-based restricted stock awards and stock units amounted to $15.3 million at December 31, 2019, and is expected to be recognized over a weighted average period of approximately 2.5 years. The aggregate intrinsic value of time-based restricted stock awards and stock units outstanding was $21.6 million, $18.8 million and $17.8 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Performance-based Restricted Stock Awards and Stock Units

The Company's performance-based restricted stock awards and stock units contain performance-based vesting conditions.

The fair value of performance-based restricted stock awards and stock units is calculated based upon the closing stock price at the date of grant. Such value is recognized as expense over the derived requisite service period beginning in the period in which they are deemed probable to vest, net of actual forfeitures. Vesting probability is assessed based upon forecasted earnings and financial results. The Company did not grant any performance-based restricted stock awards or stock units to employees during the years ended December 31, 2019, 2018, or 2017.

During the year ended December 31, 2015, the Company granted to employees 110,660 shares of performance-based restricted stock awards, which vested based upon the achievement of certain earnings or return on invested capital targets. No compensation expense was recorded for these awards in 2019 as the performance targets were obtained in prior years. Approximately $0.4 million and $0.5 million of compensation expense was recorded for the years ended December 31, 2018 and 2017, respectively, associated with these performance-based restricted stock awards. The fair value of performance-based restricted stock awards that vested during the years ended December 31, 2019, 2018, and 2017, were $3.2 million, $0.0 million, and $4.9 million, respectively. No unamortized compensation expense related to performance-based restricted stock awards remains as of December 31, 2019. The aggregate intrinsic value of performance-based restricted stock awards outstanding was $0.0 million, $2.9 million and $3.0 million for the years ended December 31, 2019, 2018, and 2017, respectively.

During the year ended December 31, 2015, the Company also granted 55,330 shares of performance-based restricted stock units to employees, which vested based upon the achievement of certain earnings or return on invested capital targets for the year ended December 31, 2018. The Company recognized compensation expense of $0.0 million, $1.6 million, and $0.0 million associated with these 2015 performance-based restricted stock units for the years ended December 31, 2019, 2018, and 2017, respectively. The fair value of performance-based restricted stock units that vested during the years ended December 31, 2019, 2018, and 2017, were $2.7 million, $0.0 million, and $0.0 million, respectively. No unamortized compensation expense remains as of December 31, 2019 related to these 2015 performance-based restricted stock units. The aggregate intrinsic value of performance-based restricted stock units outstanding was $0.0 million, $2.5 million, and $3.0 million for the years ended December 31, 2019, 2018, and 2017, respectively.

Market-based Restricted Stock Units

The Company's market-based restricted stock units contain market-based vesting conditions.

The fair value of market-based restricted stock units is determined at the date of the grant using the Monte Carlo valuation methodology, with any discounts for post-vesting restrictions estimated using the Chaffe Model. The Monte Carlo methodology incorporates into the valuation the possibility that the market condition may not be satisfied. Such value is recognized on a straight-line basis over the vesting period, net of actual forfeitures. The awards, if the market conditions are achieved, will be settled in shares of common stock, with one share of common stock issued per restricted stock unit if targets are achieved at the 100% level. Awards may be achieved at a minimum level of 50% and a maximum of 200%. The market conditions for the awards are based on the Company's stock achieving certain total shareholder return targets relative to specified index companies during a 3-year performance period beginning on each respective grant date. The Company recorded $4.7 million $5.3 million, and $2.9 million in compensation expense for the years ended December 31, 2019, 2018, and 2017, respectively, related to market-based restricted stock units. Unamortized compensation expense for market-based restricted stock units amounted to $3.8 million at December 31, 2019, and is expected to be recognized over a weighted average period of approximately 1.2 years. The aggregate intrinsic value of market-based restricted stock units outstanding was $11.9 million, $14.2 million, and $10.2 million for the years ended December 31, 2019, 2018, and 2017, respectively.

A summary of the status of our time-based, performance-based and market-based restricted stock awards and stock units as of December 31, 2019 and 2018 and changes during the year ended December 31, 2019 are presented below:

	Time-based Restricted Stock Awards and Stock Units		Performance-based Restricted Stock Awards and Stock Units		Market-based Restricted Stock Units	
	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2018	357,592	$ 49.77	102,155	$ 33.12	271,295	$ 57.44
Granted	319,189	$ 52.48	—	$ —	60,722	$ 65.27
Vested and settled	(157,053)	$ 46.82	(102,155)	$ 33.12	—	$ —
Cancelled	(51,000)	$ 52.85	—	$ —	(74,855)	$ 15.92
Outstanding at December 31, 2019	468,728	$ 51.96	—	$ —	257,162	$ 60.08

Retirement of the Company's President and Chief Executive Officer

On February 25, 2019, the Company entered into a Transition and Retirement Agreement (the "Retirement Agreement") with the Company's President and Chief Executive Officer, Brad Mason. Under the Retirement Agreement, the parties agreed that Mr. Mason would continue to serve in his role until his successor was appointed by the Board and commenced employment, which occurred on October 31, 2019 (the "Retirement Date"). The parties agreed that Mr. Mason would provide ongoing transition assistance to the Company pursuant to a consulting arrangement during the 12 months following the Retirement Date, and that Mr. Mason will be paid $40,000 per month for such transition consulting services.

As part of the Retirement Agreement, certain time-based stock options and restricted stock awards were modified to vest on the Retirement Date. In addition, stock options were modified to extend the post-termination exercise period from 18 months under a standard qualified retirement to up to four years, dependent upon the remaining contractual terms of the options. For fiscal year 2019, in lieu of Mr. Mason's normal annual incentive awards under the 2012 LTIP, and in recognition of the ongoing transition assistance that he agreed to provide, Mr. Mason was granted an award of RSUs on April 1, 2019, with a grant date fair market value of $2.0 million that will vest on the first anniversary of the date of grant, subject to him continuing to provide transition consulting services through his Retirement Date. The full fair value of the award was recorded as expense in 2019. The Company recognized approximately $6.5 million in share-based compensation expense during the year ended December 31, 2019 related to the Retirement Agreement, which was charged to general and administrative expense in the consolidated statements of operations and comprehensive income (loss).

18. Defined contribution plans and deferred compensation

Defined Contribution Plans

Orthofix Inc. sponsors a defined contribution plan (the "401(k) Plan") covering substantially all full time U.S. employees. The 401(k) Plan allows participants to contribute up to 80% of their pre-tax compensation, subject to certain limitations, with the Company matching 100% of the first 2% of the employee's base compensation and 50% of the next 4% of the employee's base compensation if contributed to the 401(k) Plan. During the years ended December 31, 2019, 2018, and 2017, expenses incurred relating to the 401(k) Plan, including matching contributions, were approximately $2.7 million, $2.3 million, and $2.0 million, respectively.

The Company also operates defined contribution plans for its international employees meeting minimum service requirements. The Company's expenses for such contributions during each of the years ended December 31, 2019, 2018, and 2017 were $1.0 million, $1.1 million and $1.1 million, respectively.

Deferred Compensation Plans

Under Italian Law, our Italian subsidiary accrues, on behalf of its employees, deferred compensation, which is paid on termination of employment. The accrual for deferred compensation is based on a percentage of the employee's current annual remuneration plus an annual charge. Deferred compensation is also accrued for the leaving indemnity payable to agents in case of dismissal, which is regulated by a national contract and is equal to approximately 3.8% of total commissions earned from the Company. The Company's relations with its Italian employees, who represent 18.6% of total employees at December 31, 2019, are governed by the provisions of a National Collective Labor Agreement setting forth mandatory minimum standards for labor relations in the metal mechanic workers industry. The Company is not a party to any other collective bargaining agreement. The balance in other long-term liabilities as of December 31, 2019 and 2018 was $1.3 million, and represents the amount which would be payable if all the employees and agents had terminated employment at that date.

19. Income taxes

Income (loss) from continuing operations before provision for income taxes consisted of the following:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
U.S.	$ (24,890)	$ 28,642	$ 27,774
Non-U.S.	(2,159)	(5,757)	8,617
Income (loss) before income taxes	$ (27,049)	$ 22,885	$ 36,391

The provision for income taxes on continuing operations consists of the following:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2019	2018	2017
U.S.			
Current	$ (1,911)	$ 9,480	$ 3,620
Deferred	2,008	(3,430)	20,222
	97	6,050	23,842
Non-U.S.			
Current	1,931	2,255	4,062
Deferred	(615)	769	1,196
	1,316	3,024	5,258
Income tax expense	$ 1,413	$ 9,074	$ 29,100

The differences between the income tax provision at the U.S. federal statutory tax rate and the Company's effective tax rate for the years ended December 31, 2019, 2018, and 2017 consist of the following:

	2019		2018		2017[1]	
(U.S. Dollars, in thousands, except percentages)	Amount	Percent	Amount	Percent	Amount	Percent
Statutory U.S. federal income tax rate	$ (5,680)	21.0%	$ 4,806	21.0%	$ 12,737	35.0%
State taxes, net of U.S. federal benefit	1,043	(3.9)	1,038	4.5	1,598	4.4
Foreign rate differential, including withholding taxes	131	(0.5)	784	3.4	(3,849)	(10.6)
Valuation allowances, net	(165)	0.6	4,116	18.0	3,548	9.7
Research credits	(829)	3.1	(710)	(3.1)	(397)	(1.1)
Italian subsidiary intangible asset	—	—	(230)	(1.0)	(381)	(1.0)
Domestic manufacturing deduction	—	—	—	—	(818)	(2.2)
Unrecognized tax benefits, net of settlements	(2,745)	10.1	81	0.4	6,002	16.5
Impact of the Tax Act	—	—	(560)	(2.4)	8,347	22.9
Equity compensation	626	(2.3)	(1,646)	(7.2)	272	0.7
Executive compensation	1,504	(5.6)	606	2.6	123	0.3
Contingent consideration	5,678	(21.0)	528	2.3	—	—
Other, net	1,850	(6.7)	261	1.2	1,918	5.4
Income tax expense/effective rate	$ 1,413	(5.2)%	$ 9,074	39.7%	$ 29,100	80.0%

[1] The rate reconciliation for 2017 is based on the U.S. federal income tax rate, rather than the Company's country of domicile rate at that time. The Company believes, given the large proportion of taxable income earned in the U.S., this presentation is more meaningful.

Certain items within the tables of this footnote have been recast for previous years to conform to current year presentation.

On December 22, 2017, the Tax Act was signed into law making significant changes to the Internal Revenue Code. Changes include, but are not limited to, a U.S. corporate rate decrease from 35% to 21% effective for tax years beginning after December 31, 2017, the transition of U.S. international taxation from a worldwide tax system to a territorial system, and a one-time transition tax on the mandatory deemed repatriation of cumulative foreign earnings as of December 31, 2017. The Company calculated its best estimate of the impact of the Tax Act in the 2017 income tax provision in accordance with its understanding of the Tax Act and guidance available as of the date of this filing. As a result, the Company recorded $8.3 million of additional income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted. The provisional amount related to the remeasurement of certain deferred tax assets and liabilities, based on the rates at which they are expected to reverse in the future was $8.6 million. The provisional amount related to the one-time transition tax on the mandatory deemed repatriation of foreign earnings was zero. The Company also recorded a benefit of $0.3 million related to an income tax liability recorded in 2016 related to repatriation of earnings from our subsidiary in Puerto Rico.

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, we

determined that the $8.6 million of the deferred tax expense recorded in connection with the remeasurement of certain deferred tax assets and liabilities and the zero transition tax on the mandatory deemed repatriation of foreign earnings was a provisional amount and a reasonable estimate at December 31, 2017. A more detailed analysis of the Company's deferred tax assets and liabilities and its historical foreign earnings as well as potential correlative adjustments was completed in 2018, which resulted in an additional benefit of $0.6 million in the first quarter of 2018 and minimal adjustments in the fourth quarter of 2018. As of December 31, 2018, the Company has completed its accounting for the tax effects of enactment of the Tax Act.

The Company paid cash relating to taxes totaling $8.1 million, $15.6 million, and $3.3 million for the years ended December 31, 2019, 2018, and 2017, respectively.

The Company's deferred tax assets and liabilities are as follows:

	December 31,	
(U.S. Dollars, in thousands)	2019	2018
Intangible assets and goodwill	$ 1,390	$ 1,682
Inventories and related reserves	13,216	12,151
Deferred revenue and cost of goods sold	4,652	4,652
Other accruals and reserves	4,337	2,799
Accrued compensation	9,221	8,317
Allowance for doubtful accounts	971	2,346
Net operating loss and tax credit carryforwards	44,230	52,664
Lease liabilities	6,268	—
Other, net	1,567	2,200
	85,852	86,811
Valuation allowance	(38,741)	(49,014)
Deferred tax asset	$ 47,111	$ 37,797
Withholding taxes	(40)	—
Property, plant and equipment	(5,881)	(4,569)
Right-of-use lease assets	(6,073)	—
Deferred tax liability	(11,994)	(4,569)
Net deferred tax assets	$ 35,117	$ 33,228

The Company accounts for income taxes using the asset and liability method, under which deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and income tax basis of assets and liabilities, and for operating losses and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the years in which those items are expected to be realized. Tax law and rate changes are recorded in the period such changes are enacted. The Company establishes a valuation allowance when it is more likely than not that certain deferred tax assets will not be realized in the foreseeable future.

The valuation allowance is primarily attributable to net operating loss carryforwards and temporary differences in certain foreign jurisdictions. The net decrease in the valuation allowance of $10.3 million during the year principally relates to the decrease of valuation allowances on net operating loss carryforwards in foreign jurisdictions due to expiration, statutory rate changes, and changes regarding the realizability of net deferred tax assets. It is reasonably possible that the valuation allowance will decrease in 2020 related to expiration of foreign net operating losses.

The Company has federal net operating loss carryforwards of $25.5 million and research and development credits of $1.6 million as a result of the acquisition of Spinal Kinetics. These carryforwards are subject to limitation under the provisions of Section 382 and will begin to expire in 2026. The Company has state net operating loss carryforwards of approximately $35.5 million, of which $22.0 million relates to Spinal Kinetics and begins to expire in 2020. Additionally, the Company has net operating loss carryforwards in various foreign jurisdictions of approximately $145.3 million that begin to expire in 2020, the majority of which relate to the Company's Netherlands and Brazil operations.

Prior to the Domestication, as an entity incorporated in Curaçao, "foreign earnings" referred to both U.S. and non-U.S. earnings. As a result of the Domestication, only income sourced outside of the U.S. is considered unremitted foreign earnings. Unremitted foreign earnings decreased from $50.4 million at December 31, 2018 to $49.2 million at December 31, 2019. The decrease is due to the impact of currency translation. As a result of the 2017 Tax Act, current year earnings have been deemed to be repatriated. Those foreign subsidiary earnings that are subject to U.S. taxation as a component of Global Intangible Low Taxed Income (GILTI) under the Tax Act are included as a component of current tax expense. The Company's investment in foreign subsidiaries continues to be indefinite in nature; however, the Company may periodically repatriate a portion of these earnings to the extent that it does not incur significant additional tax liability.

The Company records a benefit for uncertain tax positions when the weight of available evidence indicates that it is more likely than not, based on an evaluation of the technical merits, that the tax position will be sustained on audit. The tax benefit is measured as the largest amount that is more than 50% likely to be realized upon settlement. The Company re-evaluates income tax positions periodically to consider changes in facts or circumstances such as changes in or interpretations of tax law, effectively settled issues under audit, and new audit activity. The Company includes interest and any applicable penalties related to income tax issues as part of income tax expense in its consolidated financial statements.

The Company's unrecognized tax benefit was $16.9 million and $21.4 million for the years ended December 31, 2019 and 2018, respectively. The Company recorded net interest and penalties expense (benefit) on unrecognized tax benefits of $(0.1) million, $1.4 million, and $2.3 million for the years ended December 31, 2019, 2018, and 2017, respectively, and had approximately $6.6 million and $6.7 million accrued for payment of interest and penalties as of December 31, 2019 and 2018, respectively. The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company's effective tax rate if recognized. The Company believes it is reasonably possible that, in the next 12 months, the amount of unrecognized tax benefits, exclusive of interest and penalties, related to the resolution of federal, state and foreign matters could be reduced by $13.0 million to $13.5 million as audits close and statutes expire.

A reconciliation of the gross unrecognized tax benefits (excluding interest and penalties) for the years ended December 31, 2019, 2018, and 2017 follows:

(U.S. Dollars, in thousands)	2019	2018
Balance as of January 1,	$ 21,351	$ 23,676
Additions for current year tax positions	309	170
Increases for prior year tax positions	1,711	1,653
Settlements of prior year tax positions	(1,183)	(1,499)
Expiration of statutes	(5,284)	(2,649)
Balance as of December 31,	$ 16,904	$ 21,351

The Company and its subsidiaries file income tax returns in the U.S. federal jurisdiction and in certain state and foreign jurisdictions, including Italy and the United Kingdom. The statute of limitations with respect to federal and state tax filings is closed for years prior to 2014. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to 2015.

During the third quarter of 2015, the Internal Revenue Service commenced an examination of the Company's federal income tax return for 2012. The Company concluded this examination in the first quarter of 2018 with no material impact to the financial statements. In October 2016, the Company was notified of an examination of its federal income tax return for 2013 and in December 2017, the examination for 2013 was concluded with no change. In November 2017, the Company was notified of an examination of its federal income tax return for 2015. In February 2019, the Company reached an agreement and concluded this examination. As a result, the Company recognized a benefit of approximately $1.8 million during 2019. The Company cannot reasonably determine if any state and local or foreign examinations, will have a material impact on its financial statements and cannot predict the timing regarding resolution of these tax examinations.

20. Earnings per share (EPS)

The Company uses the two-class method of computing basic EPS due to the existence of non-vested restricted stock awards with nonforfeitable rights to dividends or dividend equivalents (referred to as participating securities). Basic EPS is computed using the weighted average number of common shares outstanding during each of the respective years. Diluted EPS is computed using the weighted average number of common and common equivalent shares outstanding during each of the respective years using the

more dilutive of either the treasury stock method or two-class method. The difference between basic and diluted shares, if any, largely results from common equivalent shares, which represents the dilutive effect of the assumed exercise of certain outstanding share options, the assumed vesting of restricted stock granted to employees and directors, or the satisfaction of certain necessary conditions for contingently issuable shares (see Note 17).

For each of the three years ended December 31, 2019, 2018, and 2017, no significant adjustments were made to net income for purposes of calculating basic and diluted EPS. The following is a reconciliation of the weighted average shares used in the diluted EPS computations.

	Year Ended December 31,		
	2019	2018	2017
Weighted average common shares-basic	18,903,289	18,494,002	18,117,405
Effect of diluted securities:			
Unexercised stock options and employee stock purchase plan	—	313,648	209,691
Unvested time-based restricted stock awards	—	—	123,592
Unvested performance-based restricted stock awards	—	103,960	48,057
Weighted average common shares-diluted	18,903,289	18,911,610	18,498,745

There were 1,704,708, 349,930 and 418,859 weighted average outstanding options, restricted stock, and performance-based or market-based equity awards not included in the diluted earnings per share computation for the years ended December 31, 2019, 2018, and 2017, respectively, because inclusion of these awards was anti-dilutive or, for performance-based and market-based awards, all necessary conditions have not been satisfied by the end of the respective period.

21. Quarterly financial data (unaudited)

	2019				
(U.S. Dollars, in thousands, except per share data)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
Net sales	$ 109,112	$ 115,850	$ 113,499	$ 121,494	$ 459,955
Cost of sales	23,708	25,812	24,896	26,191	100,607
Gross profit	85,404	90,038	88,603	95,303	359,348
Operating expense	89,852	89,587	107,485	91,208	378,132
Operating income (loss)	(4,448)	451	(18,882)	4,095	(18,784)
Net income (loss) from continuing operations	897	(547)	(40,498)	11,686	(28,462)
Net income (loss)	$ 897	$ (547)	$ (40,498)	$ 11,686	$ (28,462)
Net income (loss) per common share — basic:					
Net income (loss) from continuing operations	$ 0.05	$ (0.03)	$ (2.14)	$ 0.61	$ (1.51)
Net income (loss)	$ 0.05	$ (0.03)	$ (2.14)	$ 0.61	$ (1.51)
Net income (loss) per common share — diluted:					
Net income (loss) from continuing operations	$ 0.05	$ (0.03)	$ (2.14)	$ 0.60	$ (1.51)
Net income (loss)	$ 0.05	$ (0.03)	$ (2.14)	$ 0.60	$ (1.51)

	2018				
(U.S. Dollars, in thousands, except per share data)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
Net sales	$ 108,709	$ 111,547	$ 111,708	$ 121,078	$ 453,042
Cost of sales	24,147	22,835	24,020	25,626	96,628
Gross profit	84,562	88,712	87,688	95,452	356,414
Operating expense[1, 2]	76,692	82,797	83,781	83,050	326,320
Operating income[1, 2]	7,870	5,915	3,907	12,402	30,094
Net income (loss) from continuing operations[2]	5,226	925	(1,211)	8,871	13,811
Net income (loss)	$ 5,226	$ 925	$ (1,211)	$ 8,871	$ 13,811
Net income (loss) per common share — basic:					
Net income (loss) from continuing operations	$ 0.28	$ 0.05	$ (0.07)	$ 0.47	$ 0.73
Net income (loss)	$ 0.28	$ 0.05	$ (0.07)	$ 0.47	$ 0.73
Net income (loss) per common share — diluted:					
Net income (loss) from continuing operations	$ 0.27	$ 0.05	$ (0.07)	$ 0.46	$ 0.72
Net income (loss)	$ 0.27	$ 0.05	$ (0.07)	$ 0.46	$ 0.72

[1] The Company reclassified $1.1 million of previously reported expense during the second quarter of 2018 related to changes in fair value of contingent consideration in the table above to conform to current period presentation.
[2] The Company reclassified less than $10 thousand of previously reported net income (loss) from discontinued operations during the first, second, and third quarters of 2018 to continuing operations to conform to current period presentation.

22. Subsequent events

On February 3, 2020, the Company, through a wholly owned subsidiary, entered into an Asset Purchase Agreement (the "Purchase Agreement") with Wittenstein SE ("Wittenstein"), a privately-held German-based company, to acquire assets associated with the FITBONE intramedullary lengthening system for limb lengthening of the femur and tibia bones. Under the terms of the Purchase Agreement, as consideration for the acquired assets, the Company will pay $18 million in cash consideration and will enter into manufacturing supply contract with Wittenstein.

The acquisition is anticipated to close by the end of the first quarter of 2020, subject to customary closing conditions.

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