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, 2018

or

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

For the transition period from _____ to _____.

Commission File Number: 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	**Nasdaq Global Select Market**
(Title of Class)	**(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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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, 2018, as reported by the Nasdaq Global Select Market, was approximately $1,050.4 million.

As of February 22, 2019, 19,061,192 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. 2019 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, 2018
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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. (previously Orthofix International N.V.) 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 over 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.

On July 31, 2018, the Company completed a change in its jurisdiction of organization from Curaçao to the State of Delaware in accordance with the conversion procedures of the Curaçao Civil Code and the Domestication procedures of Delaware General Corporation Law (the "Domestication"). In connection with the Domestication, we changed our name to "Orthofix Medical Inc." Our shareholders approved and authorized the Domestication at the 2018 Annual General Meeting of Shareholders held on July 17, 2018.

Information regarding shareholder tax consequences of the Domestication and potential tax elections is available on our website under Goverance at www.Orthofix.com. A detailed explanation of the tax consequences of the Domestication is available in the 2018 Proxy Statement, available under Financials & Filings on our website. For additional information, contact us at redomicile@orthofix.com.

YOU SHOULD CONSULT YOUR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF U.S. FEDERAL TAX LAWS TO YOUR PARTICLAR SITUATION, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER THE LAWS OF ANY STATE, LOCAL OR NON-U.S. JURISDICTION.

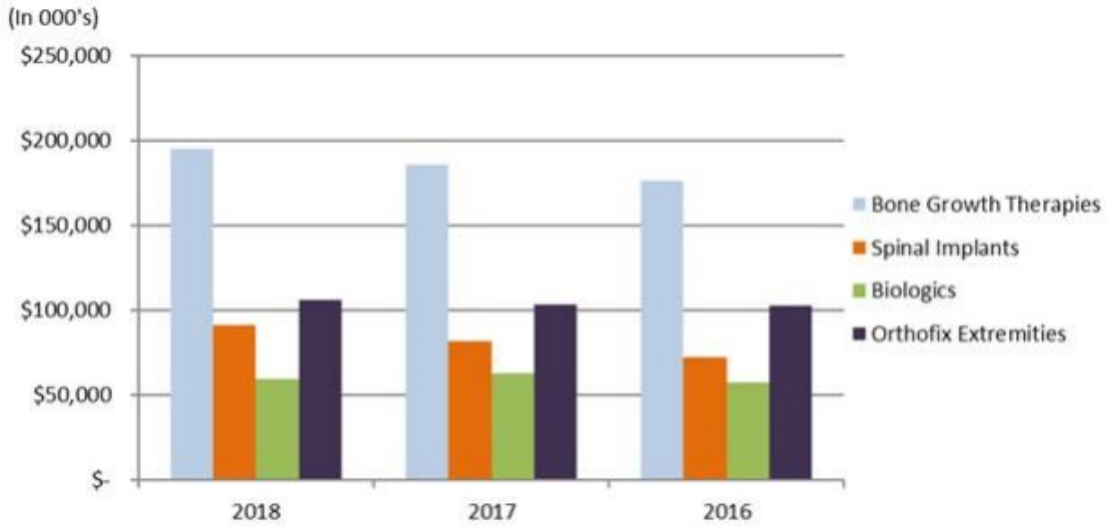
The Company originally was formed in 1987 in Curaçao and is now a corporation operating under the laws of the State of Delaware. Our executive offices are located in Lewisville, Texas.

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 Internet 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 four reporting segments: Bone Growth Therapies (formerly referred to as BioStim), Spinal Implants (formerly referred to as Spine Fixation), Biologics, and Orthofix Extremities (formerly referred to as Extremity Fixation), which accounted for 43%, 20%, 13%, and 24%, respectively, of our total net sales in 2018. 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, 2018, 2017, and 2016.



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 16 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Bone Growth Therapies

The Bone Growth Therapies reporting segment manufactures, distributes, and provides 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. We currently have research and a clinical study underway to identify potential clinical indications for treating rotator cuff tears. We sell this reporting segment's 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 reporting segment 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 segment are:

- 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 late 2016, the North American Spine Society ("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 January 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 how their patients are adhering to prescribed treatment protocols. 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. In the presence of certain risk factors, however, some fractures do not heal or heal slowly, resulting in "nonunions." Traditionally, orthopedists have treated such fracture 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 March 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 how their patients are adhering to prescribed treatment protocols. 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 an efficacy of healing. From these efforts, many studies have been recently 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

The Spinal Implants reporting segment designs, develops and markets a portfolio of motion preservation and 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 reporting segment is to become a first choice for our distributors and surgeons by demonstrating strength in partnership. Our key strategies in this segment are:

- Execute controlled, limited market launch and extensive training curriculum in the U.S. for our M6-C artificial cervical disc
- Continue the strong pace of new product launches
- 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

Product	Primary Application
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
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 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
SAMBA-SCREW System	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

On April 30, 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 historically have been exclusively distributed outside the U.S. On February 6, 2019, we received FDA approval of the M6-C Artificial Cervical Disc to treat patients with cervical disc degeneration. We expect to release the M6-C Artificial Cervical Disc in 2019 in the U.S. through a controlled, limited market launch accompanied by an extensive training and education curriculum for surgeons.

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. This includes the Cetra, 3°, Reliant and Hallmark cervical plates. Additionally, 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 product 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

The Biologics reporting segment provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This reporting segment 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 employed and independent sales representatives. Our partnership with MTF allows us to exclusively market the Trinity Evolution and Trinity ELITE 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 reporting segment 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 segment are:

- Expand sales force coverage in the spine market and continue to expand into other orthopedic procedures
- Continue to leverage the surgeon-preferred Trinity ELITE characteristics and clinical evidence
- 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
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 reporting segment'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.

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 Evolution, Trinity ELITE, 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 Evolution and Trinity ELITE 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.

Orthofix Extremities

The Orthofix 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 theseproducts through a global network of distributors and sales representatives to sell our orthopedic products to hospitals and healthcare providers.

Orthofix Extremities Strategy

Our strategy for the Orthofix 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 TL-Hex
- Continue the strong pace of new product launches
- Acquire or license products, technologies and companies to support these market opportunities.

Orthofix Extremities Products

The following table and discussion identify the principal Orthofix 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

Product	Primary Application
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

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 as well as 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.

Building on the TrueLok brand, the TL-HEX TrueLok Hexapod System was released in 2012 in international markets and in 2015 in the U.S. TL-HEX 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' position is 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 as well as 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 new 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 TL and TL-HEX line, we have also developed a patient app to support the patient in the TL-HEX fixator daily management. 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 TL and TL-HEX line, but specifically developed for younger patients, we created the Edugame, an online app to help patient 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. Adding to the XCaliber bone screw product line are our 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 new 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.

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 2018, 2017 and 2016 we incurred $33.2 million, $29.7 million and $28.8 million, respectively, of research and development expense.

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 key 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 legal compliance 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” (February 2017)), 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 Orthofix 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, 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.

Our Biologics reporting segment markets tissue for bone repair and reconstruction under the brand names Trinity Evolution and Trinity ELITE, 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 reporting segment 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 covered by FDA's "Good Tissues Practices" regulations, which cover all stages of allograft processing. There can be no assurance our suppliers of the Trinity Evolution, Trinity ELITE and allograft products 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 from the market a product 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

In addition, 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 Europe, 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.

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 October 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.

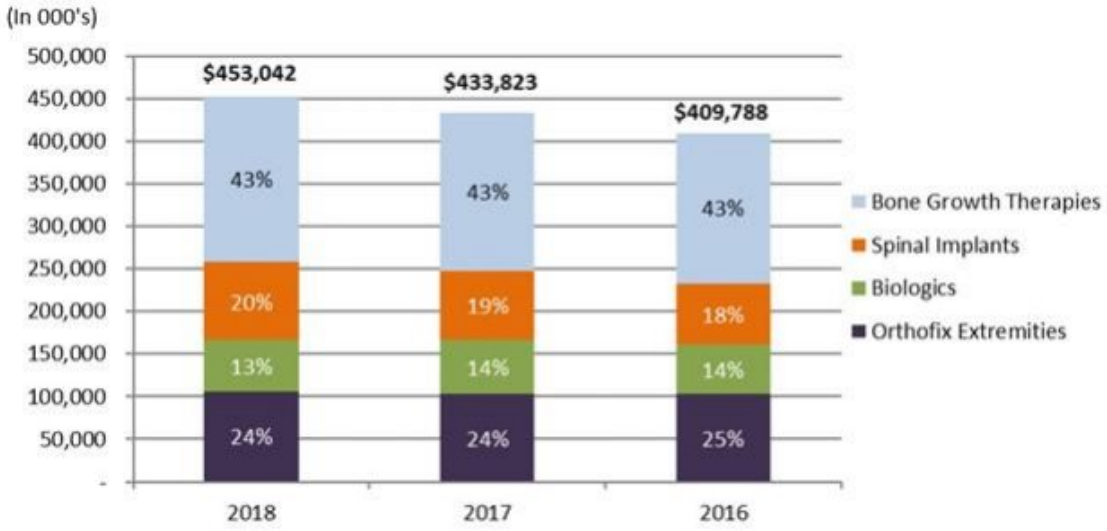
Sales, Marketing and Distribution

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

Our revenues are generated from the sales of products in our four reporting segments: Bone Growth Therapies, Spinal Implants, Biologics, and Orthofix Extremities. See the chart below for the distribution of sales between each of our reporting segments for each of the years ended December 31, 2018, 2017, and 2016.



Sales Network

We have a broad sales network comprised of direct sales representatives 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 over 70 countries.

In our largest market, the U.S., our sales network is generally comprised of four sales forces, each addressing one of our reporting segments, however some independent distributors sell products for more than one of our segments. A hybrid distribution network of direct sales representatives and independent distributors sells products in our Bone Growth Therapies reporting segment, while primarily independent distributors sell products in our Spinal Implants, Biologics, and Orthofix Extremities reporting segments.

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 marketing 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 reporting unit 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 Orthofix 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 on Track mobile app 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 Evolution and Trinity ELITE 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 Evolution and Trinity ELITE 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, 2018, we had 954 employees worldwide. Of these, 686 were employed in the U.S. and 268 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 187 at December 31, 2018, 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.

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 and 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 and 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.

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, was enacted, which 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:

- requires certain medical device manufacturers to pay an excise tax equal to 2.3% of the price for which such manufacturer sells its medical devices; this excise tax was previously suspended until December 31, 2017. On January 22, 2018, the President signed the Extension of Continuing Appropriations Act, 2018, which extended the moratorium on the tax until December 31, 2019.
- 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 have 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. Additional legislative changes to the ACA and changes resulting from current litigation challenging certain aspects of the ACA remains possible. Any such future changes, 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.

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 Bone Growth Therapies, Spinal Implants, Biologics, and Orthofix Extremities 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 or as a 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.

During 2018, we continued to make improvements in revenues related to several new products we introduced to the market over the past several years, including the TL-HEX TrueLok Hexapod System, Galaxy Fixation System, Chimaera Hip Fracture System, Ankle Hind Foot Nailing System, Firebird NXG Spinal Fixation System, FORZA XP Spacer System, SKYHAWK Lateral Interbody Fusion System & Lateral Plate System, CENTURION POCT System, PILLAR SA PTC PEEK Spacer System, JANUS Midline Fixation Screw, and the Cetra Anterior Cervical Plate, among others. In 2019, we will be launching the M6-C artificial certivical disc in the U.S. market. 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, which can depend, among other things, on the product achieving broad clinical acceptance, the level of third-party reimbursement and the introduction of competing technologies. 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. 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. In particular, we recently upgraded our financial reporting system and other information technology systems as part of our infrastructure initiative, Project Bluecore. These and any other 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 (IT) 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. However, 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 Evolution and Trinity ELITE 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 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.

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 and 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 stock units. 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;
- 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 our 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 and other factors, many of which are outside our control.

We have loaned $15 million to an early stage company and may not be able to recoup our investment.

On March 4, 2015, we entered into an option agreement with eNeura, Inc. ("eNeura"), a privately held medical technology company that is developing devices for the treatment of migraines. The option agreement provided us with an exclusive option until September 2016 to acquire eNeura, which we ultimately did not exercise. In consideration for the option, (i) we paid a non-refundable $0.3 million fee to eNeura, and (ii) we loaned eNeura $15 million pursuant to a convertible, secured promissory note that was issued to us, which note matures on March 4, 2019.

eNeura is using the proceeds of our loan to fund product development work related to its business and to fund its ongoing operations and no assurance can be made that eNeura's business will ultimately be successful. Although the promissory note is secured by many of eNeura's assets (including its intellectual property assets), no assurance can be made that eNeura will be able to repay the promissory note when due in the event that the promissory note does not convert to equity. In such an event, we could lose all or a substantial portion of our $15 million loan investment. In addition, if a change in control of eNeura (generally defined as a third-party acquisition of fifty percent or more of eNeura's voting equity or all or substantially all of eNeura's assets) occurs prior to the maturity date on March 4, 2019, the eNeura Note will automatically convert into preferred stock of eNeura, and the value of such preferred stock could be less than the principal amount of the note.

Currently, we do not expect to collect the complete principal and interest on March 4, 2019 and are in negotiations with eNeura to possibly extend and/or modify other terms of the eNeura Note. Any significant changes to the term of the eNeura Note, including extending the due date, could have a material impact on the fair value of the security.

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 2018 have had a favorable impact of $2.3 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 or penalty, which could adversely affect our profitability.

Our subsidiaries, Orthofix Holdings, Inc., Victory Medical Limited, and Orthofix International B.V. maintain a $125 million secured revolving credit facility secured by a pledge of substantially all of our property.

On August 31, 2015, the Company, through its subsidiaries, Orthofix Holdings, Inc. and Victory Medical Limited (collectively the "Borrowers"), entered into a credit agreement (the "Credit Agreement") providing for a five-year secured revolving credit facility of $125 million. On December 8, 2017, the Company amended the Credit Agreement and the primary provision of the Credit Agreement to be amended, among other things, was to add the Company's subsidiary, Orthofix International B.V. as a Borrower, Guarantor, and a loan party. On July 31, 2018, the Company amended and restated the Credit Agreement in connection with the Domestication of the Company from a Curaçao company to a Delaware corporation. 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.

The Company and certain of its existing and future U.S., U.K., and Netherlands domiciled subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of the Borrowers' obligations under the Credit Agreement. The obligations of the Borrowers and each of the Guarantors with respect to the Credit Agreement are secured by a pledge of substantially all of the tangible and intangible personal property of the Borrowers and each of the Guarantors, including accounts receivable, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their subsidiaries.

The 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, repay subordinated indebtedness and enter into affiliate transactions. In addition, the Credit Agreement contains financial covenants requiring us on a consolidated basis to maintain, as of the last day of any fiscal quarter, a total leverage ratio of not more than 3.0 to 1.0 and an interest coverage ratio of at least 3.0 to 1.0. 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.

We believe that we are in compliance with the negative covenants, and there were no events of default, at December 31, 2018 (and in prior periods). However, there can be no assurance that the Company would 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, 2018 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 Spinal Kinetics	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	8,100	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 13 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 22, 2019, we had 361 holders of record of our common stock. The closing price of our common stock on February 22, 2019 was $65.51. 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
2017		
First Quarter	$ 40.37	$ 33.51
Second Quarter	46.86	36.10
Third Quarter	50.40	42.68
Fourth Quarter	56.53	47.27
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

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 cirucmstances 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.

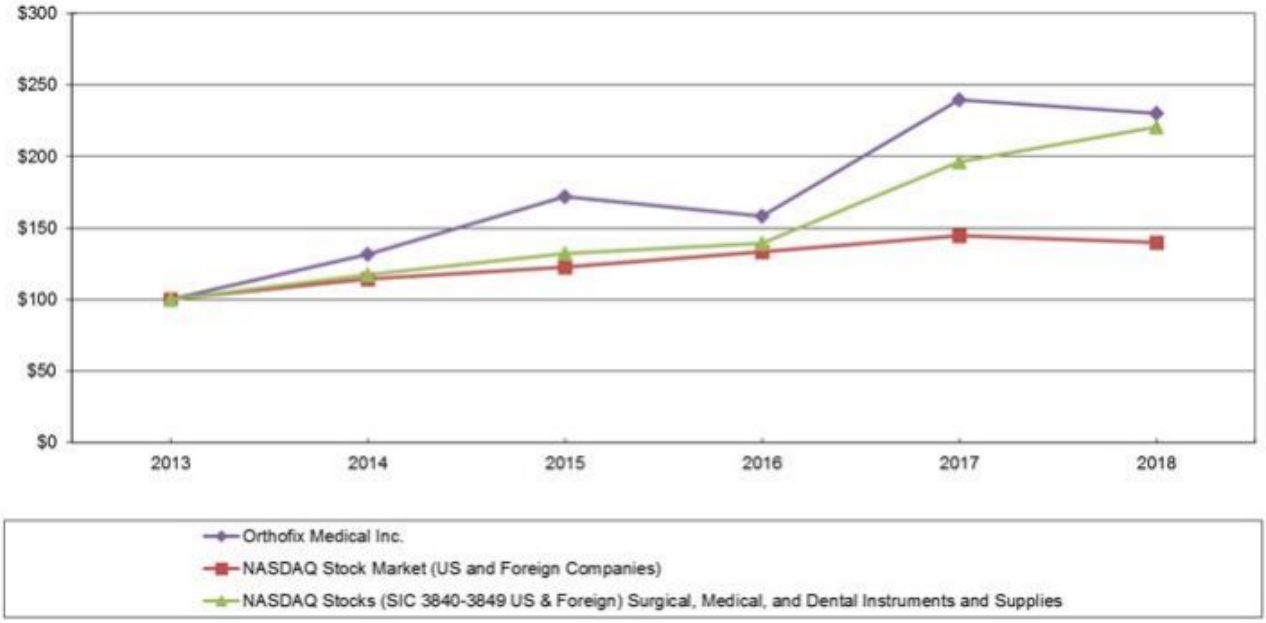
Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of 2018.

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, 2013. 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)	**2018**	**2017**	**2016**	**2015**	**2014**
Consolidated operating results					
Net sales	$ 453,042	$ 433,823	$ 409,788	$ 396,489	$ 402,277
Gross profit	356,414	340,786	321,935	309,964	303,365
Gross margin	79%	79%	79%	78%	75%
Operating income (1)	30,094	40,811	21,067	9,225	17,136
Net income (loss) from continuing operations	13,811	7,291	3,497	(2,342)	(3,744)
Net loss from discontinued operations	—	(1,068)	(441)	(467)	(4,793)
Net income (loss) (2)	$ 13,811	$ 6,223	$ 3,056	$ (2,809)	$ (8,537)
Net income (loss) per common share – basic					
Net income (loss) from continuing operations	$ 0.73	$ 0.40	$ 0.19	$ (0.12)	$ (0.20)
Net loss from discontinued operations	—	(0.06)	(0.02)	(0.03)	(0.26)
Net income (loss)	$ 0.73	$ 0.34	$ 0.17	$ (0.15)	$ (0.46)
Net income (loss) per common share – diluted					
Net income (loss) from continuing operations	$ 0.72	$ 0.39	$ 0.19	$ (0.12)	$ (0.20)
Net loss from discontinued operations	—	(0.05)	(0.02)	(0.03)	(0.26)
Net income (loss)	$ 0.72	$ 0.34	$ 0.17	$ (0.15)	$ (0.46)

(1) Includes the following:

- Legal, accounting, and other professional fees incurred in 2018, 2017, 2016, 2015, and 2014 of $1.1 million, $3.4 million, $2.0 million and $9.1 million, and $15.6 million, respectively, in connection with the accounting review and restatements through March 2015 and legal fees associated with the SEC Investigation, 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)	**2018**	**2017**	**2016**	**2015**	**2014**
Consolidated financial position					
Total assets	$ 466,641	$ 405,354	$ 372,103	$ 400,222	$ 392,956
Long-term debt	—	—	—	—	—
Shareholders' equity	335,397	296,608	263,477	290,311	299,627

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.

Executive Summary

We are a global medical device company focused on musculoskeletal products and therapies. Headquartered in Lewisville, Texas, we have four reporting segments: Bone Growth Therapies (formerly referred to as BioStim), Spinal Implants (formerly referred to as Spine Fixation), Biologics, and Orthofix Extremities (formerly referred to as Extremity Fixation). Our products are distributed by our sales representatives and distributors in over 70 countries.

Notable highlights and accomplishments in 2018 include the following:

- Net sales were $453.0 million, an increase of 4.4% on a reported basis and 3.9% on a constant currency basis.
- Net income from continuing operations was $13.8 million, an increase of 89.4% from the prior year.
- Non-GAAP net margin, an internal metric that we define as gross profit less sales and marketing expense, was $150.9 million, an increase of 5.9% from the prior year.

Results of Operations

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

	Year ended December 31,		
	2018 (%)	2017 (%)	2016 (%)
Net sales	100.0	100.0	100.0
Cost of sales	21.3	21.4	21.4
Gross profit	78.7	78.6	78.6
Sales and marketing	45.4	45.7	44.2
Non-GAAP net margin	33.3	32.8	34.3
General and administrative	18.7	16.6	18.7
Research and development	7.3	6.9	7.0
Changes in fair value of contingent consideration	0.7	—	—
Charges related to U.S. Government resolutions	—	—	3.6
Operating income	6.6	9.4	5.1
Net income from continuing operations	3.0	1.7	0.9
Net loss from discontinued operations	—	(0.3)	(0.2)
Net income	3.0	1.4	0.7

Net Sales by Reporting Segment

The following table presents net sales, which includes product sales and marketing service fees, by reporting segment:

				Percentage Change			
				2018/2017	2018/2017	2017/2016	2017/2016
(U.S. Dollars, in thousands)	2018	2017	2016	Reported	Constant Currency	Reported	Constant Currency
Bone Growth Therapies	$ 195,252	$ 185,900	$ 176,561	5.0%	5.0%	5.3%	5.3%
Spinal Implants	91,658	81,957	72,632	11.8%	11.9%	12.8%	12.7%
Biologics	59,684	62,724	57,912	-4.8%	-4.8%	8.3%	8.3%
Orthofix Extremities	106,448	103,242	102,683	3.1%	0.9%	0.5%	-0.9%
Net sales	$ 453,042	$ 433,823	$ 409,788	4.4%	3.9%	5.9%	5.5%

Bone Growth Therapies

Bone Growth Therapies manufactures, distributes, and provides support services of market leading devices that enhance bone fusion. Bone Growth Therapies uses distributors and sales representatives to sell its devices to hospitals, healthcare providers, and patients.

2018 Compared to 2017

Net sales increased $9.4 million or 5.0%

- Increase primarily driven by the execution of our commercial strategies and the continued leverage of our recently launched next generation products supported by our STIM On Track mobile application

2017 Compared to 2016

Net sales increased $9.3 million or 5.3%

- Increased as we continue to leverage the engagement of our expansive sales force, the positive North American Spine Society ("NASS") coverage recommendation and the launch of our next generation products and Stim on Track

Spinal Implants

Spinal Implants designs, develops and markets a broad portfolio of 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.

2018 Compared to 2017

Net sales increased $9.7 million or 11.8%

- Increase of $8.7 million driven by international sales of M6 Artificial Discs subsequent to our acquisition of Spinal Kinetics, which closed during the second quarter of 2018
- Increase of 3.4% in U.S. sales due to the annualized sales of new distributor partners added during 2017 and from the uptake of recent product introductions
- Decrease in legacy international sales, primarily as a result of disruption to our distribution in our Australian and German subsidiaries

2017 Compared to 2016

Net sales increased $9.3 million or 12.8%

- Increase of 20.6% in U.S. sales due to the addition of new distributor partners in the last several quarters; the uptake of recent product introductions, including our PTC family product lines and Cetra; and improved legacy distributor engagement
- Despite strong performance in certain locations, such as Australia, year-over-year international sales decreased largely due to a decrease in order volumes from international stocking distributors

Biologics

Biologics 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.

2018 Compared to 2017

Net sales decreased $3.0 million or 4.8%

- Decrease of 6.1% primarily driven by the contractual reduction during the first quarter of 2018 in the amount we receive for marketing service fees for Trinity tissues from MTF Biologics ("MTF")
- Volume for Trinity tissues increased by 3.3%, partially offset by low single-digit pricing pressure in the market

2017 Compared to 2016

Net sales increased $4.8 million or 8.3%

- Increase in volume for our Trinity products primarily driven by the addition of new distributors over the prior year
- Benefit from improving performance from our national distribution partner and the reactivation of a national hospital contract

Orthofix Extremities

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

2018 Compared to 2017

Net sales increased $3.2 million or 3.1%

- Increase largely due to the change in foreign currency exchange rates, which had a positive impact on net sales of $2.3 million
- Increase of $1.4 million within the U.S. due to continued distribution expansion and adoption of our TrueLok products
- Increase in international sales of $2.8 million, excluding the impact of changes in foreign currency exchange rates, due to continued expansion of our distributors and growth in European subsidiaries
- Partially offset by an expected decrease of $3.3 million in Brazil as a result of our Orthofix Extremities restructuring during 2017

2017 Compared to 2016

Net sales increased $0.6 million or 0.5%

- Growth in the U.S. and the U.K., largely due to the continued adoption of our TL-HEX product line
- Increase of $1.5 million attributable to a favorable impact from foreign currency translation
- Partially offset by a decrease of $3.6 million related to our Orthofix Extremities restructuring, which consisted of the divestiture of a non-core business in the U.K. and a reduction in sales in Brazil and Puerto Rico as we converted from a direct sales model to the use of stocking distributors
- And additionally offset by a decrease in cash collections from specific international stocking distributors whose revenue is recognized upon cash receipt

Gross Profit and Non-GAAP Net Margin

				Percentage Change	
(U.S. Dollars, in thousands)	**2018**	**2017**	**2016**	**2018/2017**	**2017/2016**
Gross profit	$ 356,414	$ 340,786	$ 321,935	4.6%	5.9%
Sales and marketing	205,527	198,370	181,287	3.6%	9.4%
Non-GAAP net margin	$ 150,887	$ 142,416	$ 140,648	5.9%	1.3%
Gross margin	78.7%	78.6%	78.6%	0.1%	0.0%
Non-GAAP net margin	33.3%	32.8%	34.3%	0.5%	-1.5%

2018 Compared to 2017

Non-GAAP net margin, an internal metric that we define as gross profit less sales and marketing expense, increased $8.5 million

- Gross profit increased $15.6 million
    - Primarily due to the growth in net sales with gross margin improving slightly from 78.6% in 2017 to 78.7% in 2018
    - Partially offset by the addition of Spinal Kinetics acquisition-related inventory fair market value adjustments of $1.4 million within the Spinal Implants reporting segment
- Sales and marketing expense increased $7.2 million
    - Primarily due to the increase in net sales, with sales and marketing expenses as a percentage of net sales improving slightly to 45.4% of net sales in 2018 compared to 45.7% in 2017

2017 Compared to 2016

Non-GAAP net margin increased $1.8 million

- Gross profit increased $18.9 million
    - Largely driven by the increase in net sales for each of our reporting segments, as gross margin remained relatively flat
    - Partially offset by an increase of $0.2 million in expense relating to our Orthofix Extremities and U.S. restructurings
- Sales and marketing expense increased $17.1 million
    - Primarily relating to higher commission expenses in 2017, relating to geographic mix in Orthofix Extremities and higher commission rates from new distributors for Biologics and Spinal Implants, and an increase in other compensation costs as a result of the increase in net sales

The following table presents non-GAAP net margin by reporting segment. The reasons for the changes in non-GAAP net margin by reporting segment are generally consistent with the information provided above for gross profit and sales and marketing expense.

				Percentage Change	
(U.S. Dollars, in thousands)	**2018**	**2017**	**2016**	**2018/2017**	**2017/2016**
Bone Growth Therapies	$ 86,252	$ 77,369	$ 75,469	11.5%	2.5%
Spinal Implants	7,628	8,730	8,650	-12.6%	0.9%
Biologics	26,298	25,692	26,891	2.4%	-4.5%
Orthofix Extremities	31,391	31,071	30,526	1.0%	1.8%
Corporate	(682)	(446)	(888)	52.9%	-49.8%
Non-GAAP net margin	$ 150,887	$ 142,416	$ 140,648	5.9%	1.3%

General and Administrative Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2018**	**2017**	**2016**	**2018/2017**	**2017/2016**
General and administrative	$ 84,506	$ 71,905	$ 76,409	17.5%	-5.9%
As a percentage of net sales	18.7%	16.6%	18.7%	2.1%	-2.1%

2018 Compared to 2017

General and administrative expense increased $12.6 million

- Increase of $6.3 million in expenses associated with strategic investments, such as our due diligence and integration efforts in connection with the Spinal Kinetics acquisition and expenditures related to the Domestication

- Increase in share-based compensation expense of $5.5 million, largely related to increases in expense attributable to our performance-based and market-based awards and a change in the timing of our annual grants to executives and key personnel
- Increase of $1.8 million associated with legal judgments and settlements, including previous SEC and FCPA matters, largely as a result of the receipt of a favorable insurance settlement in 2017 of approximately $6.1 million associated with prior costs incurred
- Increase of $0.9 million relating to the amortization of acquired intangibles associated with the Spinal Kinetics acquisition
- Partially offset by decreases in certain compensation-related costs, including bonus incentives and benefits

2017 Compared to 2016

General and administrative expense decreased $4.5 million

- We received a favorable insurance settlement in 2017 of approximately $6.1 million associated with prior costs incurred related to SEC and FCPA matters
- Decrease of $3.6 million from a reduction in Project Bluecore expenses, as the project was completed in 2016
- Decrease in share-based compensation expense of $3.5 million, largely driven by a net decrease in expense attributable to performance-based and market-based awards
- Core expense reductions through savings in other professional fees of $2.0 million
- Partially offset by an increase in spending of $5.7 million for evaluation of strategic investments
- Further offset by an unfavorable change related to legal settlements of $3.5 million, largely as a result of a favorable commercial litigation settlement received in 2016 of $3.0 million
- Pursuant to our settlement of the SEC Investigation and FCPA matters in Brazil, we agreed to retain an independent compliance consultant for one year to review and test the Company's FCPA compliance program, which began in March 2017 and resulted in an increase in expense of $1.8 million

Research and Development Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2018**	**2017**	**2016**	**2018/2017**	**2017/2016**
Research and development	$ 33,218	$ 29,700	$ 28,803	11.8%	3.1%
As a percentage of net sales	7.3%	6.9%	7.0%	0.4%	-0.1%

2018 Compared to 2017

Research and development expense increased $3.5 million

- Increase in research and development costs largely attributable to the Spinal Kinetics acquisition and the regulatory efforts associated with the U.S. Food and Drug Administration ("FDA") premarket approval of the M6 Artificial Cervical Disc

2017 Compared to 2016

Research and development expense increased $0.9 million

- Increase in costs associated with clinical trials of $0.7 million, primarily due to invested resources to identify potential new indications for our PEMF technology, such as for osteoarthritis of the knee or as an adjunct to rotator cuff repair
- Increase in costs largely attributable to the initiation of the Company's U.S. restructuring plan in 2017, which primarily affected our corporate shared services, and resulted in an increase in expense of $0.5 million

Changes in Fair Value of Contingent Consideration

(U.S. Dollars, in thousands)	2018	2017	2016	Percentage Change 2018/2017	Percentage Change 2017/2016
Changes in fair value of contingent consideration	$ 3,069	$ —	$ —	—	—
As a percentage of net sales	0.7%	0.0%	0.0%	0.7%	0.0%

2018 Compared to 2017

The fair value of contingent consideration increased $3.1 million

- Changes relate to the fair value of the potential future milestone payments of up to $60.0 million in cash associated with the Spinal Kinetics acquisition. For additional information, see Note 3 of the Notes to the Consolidated Financial Statements.

Charges Related to U.S. Government Resolutions

(U.S. Dollars, in thousands)	2018	2017	2016	Percentage Change 2018/2017	Percentage Change 2017/2016
Charges related to U.S. Government resolutions	$ —	$ —	$ 14,369	—	-100.0%
As a percentage of net sales	0.0%	0.0%	3.6%	0.0%	-3.6%

2017 Compared to 2016

We recorded $14.4 million in 2016 for our settlements with the Division of Enforcement of the SEC related to the SEC's investigation of (1) our prior accounting review and restatements of financial statements and (2) allegations of improper payments in Brazil. For additional information, see Note 13 of the Notes to the Consolidated Financial Statements.

Non-operating Income (Expense)

(U.S. Dollars, in thousands)	2018	2017	2016	Percentage Change 2018/2017	Percentage Change 2017/2016
Interest income (expense), net	$ (828)	$ (416)	$ 763	99.0%	-154.5%
Other expense, net	(6,381)	(4,004)	(2,806)	59.4%	42.7%

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 eNeura debt security. Interest income in 2016 was primarily from our eNeura debt security; however, we discontinued recognizing interest income on the debt security in 2017. 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.

2018 Compared to 2017

Other income (expense), net, decreased $2.4 million

- Decrease of $5.3 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement loss of $3.3 million in 2018 compared to a gain of $1.9 million in 2017
- Decrease of $3.1 million from impairments and changes in fair value relating to our equity holdings and warrants in Bone Biologics common stock
- Partially offset by an increase of $5.6 million associated with an other-than-temporary impairment on the eNeura debt security in 2017 that did not recur in 2018

2017 Compared to 2016

Other income (expense), net, decreased $1.2 million

- Decrease of $2.9 million associated with other-than-temporary impairments on the eNeura debt security, as we recorded impairments of $5.6 million and $2.7 million before taxes in 2017 and 2016, respectively

- Partially offset by an increase of $2.0 million associated with changes in foreign currency rates, as we recorded a non-cash remeasurement gain of $1.9 million in 2017 compared to a loss of less than $0.1 million in 2016

Income Taxes

(U.S. Dollars, in thousands)	2018	2017	2016	Percentage Change 2018/2017	Percentage Change 2017/2016
Income tax expense	$ 9,074	$ 29,100	$ 15,527	-68.8%	87.4%
Effective tax rate	39.7%	80.0%	81.6%	-40.3%	-1.6%

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 effective 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

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 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. We calculated our best estimate of the impact of the Tax Act in our 2017 year end income tax provision in accordance with our understanding of the Tax Act and guidance available as of the date of that filing. As a result, we recorded $8.3 million of additional income tax expense in the fourth quarter of 2017, the period in which the legislation was enacted. This provisional amount related to 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. We 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. We have finalized the accounting for the Tax Act, which resulted in an additional benefit of $0.6 million in the first quarter of 2018 and minimal adjustments in the fourth quarter.

2017 Effective Tax Rate

The decrease in the effective tax rate during the year was primarily a result of the increase in income before income taxes, partially offset by the charge related to recording the impact of the Tax Act. The primary factors affecting our effective tax rate for 2017 are as follows:

- The charge related to recognizing the impact of the Tax Act
- Increases in unrecognized tax benefits
- Current period losses in jurisdictons where we do not currently receive a tax benefit

Liquidity and Capital Resources

Cash, cash equivalents, and restricted cash at December 31, 2018 was $72.2 million compared to $81.2 million at December 31, 2017.

(U.S. Dollars, in thousands)	Year Ended December, 31, 2018	2017	Change
Net cash from operating activities	$ 49,918	$ 38,972	$ 10,946
Net cash from investing activities	(60,998)	(16,474)	(44,524)
Net cash from financing activities	2,993	3,538	(545)
Effect of exchange rate changes on cash and restricted cash	(881)	1,180	(2,061)
Net change in cash, cash equivalents, and restricted cash	$ (8,968)	$ 27,216	$ (36,184)

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)	2018	2017	Change
Net cash from operating activities	$ 49,918	$ 38,972	$ 10,946
Capital expenditures	(15,256)	(16,948)	1,692
Free cash flow	$ 34,662	$ 22,024	$ 12,638

Operating Activities

Cash flows from operating activities increased $10.9 million

- Increase in net income of $7.6 million
- Net decrease of $21.2 million for non-cash gains and losses, primarily related to deferred income taxes, share-based compensation expense, an other-than-temporary impairment incurred relating to the eNeura debt security in 2017, and loss on the valuation of our investments in Bone Biologics in 2018
- Net increase of $24.6 million relating to changes in working capital, primarily attributable to changes in inventories, as a result of improved inventory management initiatives put into place in 2017 and 2018

Two of our primary working capital accounts are trade accounts receivable and inventory. Day's sales in receivables were 63 days at December 31, 2018 compared to 53 days at December 31, 2017, with the increase largely attributable to our adoption of Accounting Standards Update ("ASU") 2014-09 in 2018. Inventory turns were 1.3 times as of December 31, 2018 compared to 1.1 times at December 31, 2017, primarily resulting from improved inventory management initatives put into place in 2017 and 2018.

Adoption of ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash

In November 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-18, which reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. We adopted this standard as of January 1, 2018 using a retrospective transition approach. Adoption of this ASU resulted in an increase in net cash from operating activities of $2.5 million for the year ended December 31, 2018 and a decrease in net cash from operating activities of $14.4 million for the year ended December 31, 2017.

Investing Activities

Cash flows from investing activities decreased $44.5 million

- Decrease of $44.3 million associated with cash paid in relation to the Spinal Kinetics acquisition, net of cash acquired, which closed on April 30, 2018
- Decrease of $0.9 million associated with the acquisition of certain intangible assets in transactions with former distributors in 2018
- Decrease of $0.5 million due to our additional investment in Bone Biologics during 2018
- Decrease of $0.5 million due to proceeds received in 2017 upon the maturity of certain time-based deposits
- Partially offset by a reduction in capital expenditures of $1.7 million

Financing Activities

Cash flows from financing activities decreased $0.5 million

- Decrease in net proceeds of $0.3 million from the issuance of common shares
- Decrease of $0.2 million related to the payment of debt issuance costs and other financing activities

Credit Facilities

On August 31, 2015, we entered into a Credit Agreement with JPMorgan Chase Bank, N.A. ("JPMorgan"), the Administrative Agent, and certain lenders party thereto, which provided a five year $125 million secured revolving credit facility.

On December 8, 2017, we amended the Credit Agreement with JPMorgan. The primary provision of the amendment, among other things, was to add our subsidiary, Orthofix International B.V., as a Borrower, Guarantor, and a loan party. In addition, two of our subsidiaries, Orthofix Limited and Orthofix II B.V. were also added as Guarantors and loan parties.

On July 31, 2018, we amended and restated the Credit Agreement with JPMorgan and the lenders party thereto pursuant to a First Amended and Restated Credit Agreement ("Amended Credit Agreement"). The Amended Credit Agreement is substantially the same as the previous Credit Agreement, except for certain amendments to, among other things, (i) effectuate the Domestication of the Company from a Curaçao company to a Delaware corporation, (ii) limit the pledge by the Company and each domestic subsidiary of the Company of equity interests in their respective first tier foreign subsidiaries to 65% of the voting interests in such foreign subsidiaries, (iii) limit the guarantee and joint and several obligations of each subsidiary guarantor that is a foreign subsidiary so that such foreign subsidiary guarantors are only providing guarantees, or are jointly and severally obligated, for obligations of other foreign subsidiaries, and (iv) limit the secured obligations that are secured by collateral provided by subsidiary guarantors that are foreign subsidiaries to secured obligations of foreign subsidiaries.

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, 2018, we have not made any borrowings under the credit facility. 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 €5.8 million ($6.7 million and $7.0 million) at December 31, 2018 and 2017, 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 13 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Spinal Kinetics Acquisition and Contingent Consideration

As consideration for the Spinal Kinetics acquisition, we agreed to pay an aggregate of $45.0 million in cash, subject to certain adjustments, upon closing plus milestone payments in the future of up to $60.0 million in cash. We closed on the acquisition on April 30, 2018 and paid the $45.0 million of cash, adjusted for certain items, due at close with cash on hand. The milestone payments include (i) up to $15.0 million if 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. The fair value of the contingent consideration arrangement as of December 31, 2018 was $28.6 million; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration. Approximately $13.6 million of this liability is included within other current liabilities and $15.0 million is included within other long-term liabilities. For additional discussion of this matter, see Note 3 of the Notes to the Consolidated Financial Statements.

On February 6, 2019, we obtained FDA approval of the M6-C artificial cervical disc for patients suffering from cervical disease degeneration. This approval triggered our payment obligation of $15.0 million of contingent consideration attributable to the Spinal Kinetics purchase price. We had accrued a liability of $13.6 million within other current liabilities as of December 31, 2018 related to this milestone payment and paid the $15.0 million FDA Milestone payment on February 14, 2019 from cash on hand.

Debt Security

In 2015, we loaned $15.0 million to eNeura, a privately held medical technology company that is developing devices for the treatment of migraines, pursuant to a Convertible Promissory Note (the "eNeura Note"). The eNeura Note accrues interest at 8.0% and will mature on March 4, 2019, with interest due when the eNeura Note matures. The security is collateralized by eNeura's intellectual property in the event of default or nonpayment.

Currently, we do not expect to collect the complete principal and interest on March 4, 2019 and are in negotiations with eNeura to possibly extend and/or modify other terms of the eNeura Note. Any significant changes to the term of the eNeura Note, including extending the due date, could have a material impact on the fair value of the security. For additional discussion of this matter, see Note 8 of the Notes to the Consolidated Financial Statements.

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 $335.7 million at December 31, 2017 to $50.4 million at December 31, 2018. The substantial decrease is due to the elimination of US accumulated earnings and other impacts as a result of the Domestication. 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 additional tax liability.

Contractual Obligations

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

		Payments Due by Period			
(U.S. Dollars, in thousands)	**Total**	**2019**	**2020 - 2022**	**2023**	**2024 and thereafter**
Operating leases	$ 24,922	$ 3,330	$ 8,493	$ 1,727	$ 11,372
Inventory purchase commitments (1)	66	66	—	—	—
Total (2)(3)	$ 24,988	$ 3,396	$ 8,493	$ 1,727	$ 11,372

(1) We have inventory purchase commitments with third-party manufacturers. Due to the uncertainty of our future purchasing requirements, obligations under these agreements are included in the preceding table at the amount committed through December 31, 2018, all of which are due in 2019.

(2) As a result of obtaining FDA approval for the M6-C artificial cervical disc on February 6, 2019, we are required to make a $15.0 million payment in 2019 related to the achievement of the FDA milestone, which we paid on February 14, 2019. In addition, we may be required to make additional 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; however, we are unable to reliably estimate the timing of cash settlement, if any, related to the revenue-based milestone payments.

(3) 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 $28.1 million as of December 31, 2018 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, 2018, 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, non-GAAP net margin, operating income, 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.

Orthofix Extremities and Spinal Implants 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 Orthofix 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, 2018 would result in an increase or decrease to sales and marketing expense of $0.7

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, 2018 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, non-GAAP net margin, operating income, 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, 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. 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, non-GAAP net margin, operating income, net income, and inventory. We regularly evaluate our exposure for inventory write-downs. If conditions or assumptions used in determining the market value change, additional inventory adjustments in the future may be necessary.

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 completeion or abandonment of the associated project. Upon reaching the end of the revelant 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.

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 net income.

In the fourth quarters of 2018 and 2017, 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. In the fourth quarter of 2016, we performed a quantitative impairment analysis that did not result in an impairment charge.

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 recorded at fair value are our eNeura debt security and contingent consideration attributable to the Spinal Kinetics acquisition.

The fair value of the eNeura debt security is 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 are the estimated likelihood of conversion to equity and the discount rate. Holding other

inputs constant, a decrease in our assumption for the likelihood of conversion to equity of 10% would result in an increase in fair value of the debt security of $1.9 million.

Further, we are required to determine whether any decline in the fair value below the cost basis of the eNeura debt security is other than temporary. In making this determination, we consider our intentions to hold or sell the security, whether it more likely than not that we will be required to sell the security before the recovery of its amortized cost basis, and our best estimate of the amount that we ultimately expect to collect from the security. The estimated amount we expect to collect is based upon significant unobservable inputs, requiring us to develop our own assumptions, including the probability of holding the security to maturity or converting the security to equity.

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. We estimate the fair value of the contingent consideration attributable to the FDA Milestone using a probability-weighted discounted cash flow model. This fair value is based on significant inputs not observable in the market with key assumptions including our estimation of the probability and timing of obtaining FDA approval for the M6-C artificial cervical disc and the discount rate applied. Significant changes in these assumptions could result in a significantly higher or lower fair value. Holding other inputs constant, an increase in our estimate for probability of FDA approval as of December 31, 2018 by 5% would have resulted in an increase in the fair value of the contingent consideration of $0.7 million, whereas a decrease in our estimate of probability of FDA approval by 5% would have resulted in a decrease in the fair value of the contingent consideration of $0.7 million. On February 6, 2019, we obtained FDA approval, triggering our payment obligation of $15.0 million of contingent consideration attributable to the Spinal Kinetics purchase price.

The Company estimated 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 $1.8 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 $1.7 million.

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.

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 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.

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.

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 recorded $8.6 million of deferred tax expense 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 as a provisional amount and a reasonable estimate at December 31, 2017. Additional work was performed during 2018, including a more detailed analysis of our deferred tax assets and liabilities and our historical foreign earnings as well as potential correlative adjustments. As a result, we recorded $0.6 million of tax benefit in the first quarter of 2018. The U.S. Treasury continues to promulgate proposed, temporary, and final regulations regarding the application the Tax Act. Any future adjustments that result of the application of these tax law changes will be relected in the quarter the guidance is issued.

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, non-GAAP net margin, operating income, 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.

Non-GAAP Net Margin

Non-GAAP net margin is an internal metric that we define as gross profit less sales and marketing expense. Non-GAAP net margin 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 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, 2018, 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, 2018, we recorded a foreign currency loss of $3.3 million on the statement of income and comprehensive income 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 favorably impacted during the years ended December 31, 2018 and 2017 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 $0.4 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 $0.4 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, 2018 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, 2018, the Company's internal control over financial reporting is effective based on the specified criteria. As permitted by the rules of the SEC, the Company's management excluded Spinal Kinetics from its annual assessment of the effectiveness of internal control over financial reporting for the year ended December 31, 2018, the year of acquisition. As of December 31, 2018, Spinal Kinetics' financial statements constituted approximately 17% and 21% of our total assets and net assets, respectively, approximately 2% of our revenues and a net loss of $5.8 million for the year ended December 31, 2018.

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 2018 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, 2018, 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. (formerly Orthofix International N.V.) (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of Spinal Kinetics, Inc., which is included in the 2018 consolidated financial statements of the Company and constituted approximately 17% and 21% of total and net assets, respectively, as of December 31, 2018 and 2% of revenues and a net loss of $5.8 million for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of Spinal Kinetics, Inc.

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, 2018 and 2017, the related consolidated statements of income and comprehensive income, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and our report dated February 25, 2019 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 25, 2019

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).
10.1	Credit Agreement, dated as of August 31, 2015, among Orthofix Holdings, Inc. and Victory Medical Limited as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto 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 September 1, 2015 and incorporated herein by reference).
10.2	First Amendment to Credit Agreement dated as of March 7, 2016 but effective as of February 29, 2016, among Orthofix Holdings, Inc. and Victory Medical Limited as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2016 and incorporated herein by reference).
10.3	Second Amendment to Credit Agreement dated as of December 8, 2017, among Orthofix Holdings, Inc., Victory Medical Limited, and Orthofix International B.V. as borrowers, Orthofix International N.V. and certain subsidiaries of Orthofix International N.V. party thereto 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 Annual Report on Form 10-K for the year ended December 31, 2018 and incorporated herein by reference).
10.4	First Amended and Restated Credit Agreement, dated as of July 31, 2018, among Orthofix Holdings, Inc., Victory Medical Limited, Orthofix International B.V., Orthofix Medical Inc. 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 August 6, 2018 and incorporated herein by reference).
10.5†	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).

Exhibit Number	Description
10.6	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).
10.7†	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).
10.8†	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).
10.9	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).
10.10†	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).
10.11†	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).
10.12*	Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as Amended.
10.13*	Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan.
10.14	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).
10.15	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).
10.16	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 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).
10.18	Form of 2016 Employee Performance Stock Unit 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).
10.19	Form of Employee Performance Vesting Restricted Stock and Performance Share Unit Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan – June 2015 Grants (filed as an exhibit to the Company's Form 10-Q filed on August 4, 2015 and incorporated herein by reference).
10.20	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).
10.21	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).

Exhibit Number	Description
10.22	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).
10.23	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).
10.24	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	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).
10.26	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).
10.27	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).
10.28	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).
10.29	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).
10.30	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).
10.31	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).
10.32	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).
10.33	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).
10.34	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).
10.35	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).
10.36	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).
10.37	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).

Exhibit Number	Description
10.38	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).
10.39*	Transition and Retirement Agreement, dated February 25, 2019, between Bradley R. Mason and Orthofix Medical Inc.
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, 2018 filed on February 25, 2019, formatted in XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Income and Comprehensive Income, (iii) Consolidated Statements of Changes in Shareholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements.

* 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 25, 2019

By: /s/ BRADLEY R. MASON
Name: **Bradley R. Mason**
Title: **President and Chief Executive Officer, Director**

Dated: February 25, 2019

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/ BRADLEY R. MASON **Bradley R. Mason**	President and Chief Executive Officer, Director (Principal Executive Officer)	February 25, 2019
/s/ DOUG RICE **Doug Rice**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2019
/s/ RONALD A. MATRICARIA **Ronald A. Matricaria**	Chairman of the Board of Directors	February 25, 2019
/s/ LUKE FAULSTICK **Luke Faulstick**	Director	February 25, 2019
/s/ JAMES HINRICHS **James Hinrichs**	Director	February 25, 2019
/s/ ALEXIS V. LUKIANOV **Alexis V. Lukianov**	Director	February 25, 2019
/s/ LILLY MARKS **Lilly Marks**	Director	February 25, 2019
/s/ MICHAEL E. PAOLUCCI **Michael E. Paolucci**	Director	February 25, 2019
/s/ MARIA SAINZ **Maria Sainz**	Director	February 25, 2019
/s/ JOHN SICARD **John Sicard**	Director	February 25, 2019

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 F. Hinrichs
Chairman of the Audit Committee

Bradley R. Mason
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. (formerly Orthofix International N.V.) (the Company) as of December 31, 2018 and 2017, the related consolidated statements of income and comprehensive income, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2018, and the related notes (collectively referred to as the “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, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, in conformity with 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, 2018, 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 25, 2019 expressed an unqualified opinion thereon.

Adoption of New Accounting Standards

As discussed in Notes 2 and 15 to the consolidated financial statements, the Company changed its methods of accounting for 1) recognition of revenue from contracts with customers in 2018 due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers*, 2) 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*, 3) intra-entity transfers of assets in 2018 and 2017 due to the adoption of ASU No. 2016-16, *Income Taxes: Intra-Entity Transfers of Assets Other Than Inventory*, and 4) classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows in 2018 and 2017 due to the adoption of ASU No. 2016-18, *Statement of Cash Flows: Restricted Cash*.

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.

/s/ Ernst & Young LLP

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

Dallas, Texas
February 25, 2019

ORTHOFIX MEDICAL INC.

Consolidated Balance Sheets as of December 31, 2018 and 2017

(U.S. Dollars, in thousands except share and per share data)	2018	2017
Assets		
Current assets		
Cash and cash equivalents	$ 69,623	$ 81,157
Restricted cash	2,566	—
Trade accounts receivable, less allowances of $7,463 and $8,405 at December 31, 2018 and 2017, respectively	77,747	63,437
Inventories	76,847	81,330
Prepaid expenses and other current assets	17,856	25,877
Total current assets	244,639	251,801
Property, plant and equipment, net	42,835	45,139
Patents and other intangible assets, net	51,897	10,461
Goodwill	72,401	53,565
Deferred income taxes	33,228	23,315
Other long-term assets	21,641	21,073
Total assets	**$ 466,641**	**$ 405,354**
Liabilities and shareholders' equity		
Current liabilities		
Trade accounts payable	$ 17,989	$ 18,111
Other current liabilities	67,919	61,295
Total current liabilities	85,908	79,406
Other long-term liabilities	45,336	29,340
Total liabilities	131,244	108,746
Contingencies (Note 13)		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 18,579,688 and 18,278,833 issued and outstanding as of December 31, 2018 and 2017, respectively	1,858	1,828
Additional paid-in capital	243,165	220,591
Retained earnings	87,078	70,402
Accumulated other comprehensive income	3,296	3,787
Total shareholders' equity	335,397	296,608
Total liabilities and shareholders' equity	**$ 466,641**	**$ 405,354**

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

ORTHOFIX MEDICAL INC.

Consolidated Statements of Income and Comprehensive Income
For the years ended December 31, 2018, 2017 and 2016

(U.S. Dollars, in thousands, except share and per share data)	2018	2017	2016
Net sales	$ 453,042	$ 433,823	$ 409,788
Cost of sales	96,628	93,037	87,853
Gross profit	356,414	340,786	321,935
Sales and marketing	205,527	198,370	181,287
General and administrative	84,506	71,905	76,409
Research and development	33,218	29,700	28,803
Changes in fair value of contingent consideration	3,069	—	—
Charges related to U.S. Government resolutions (Note 13)	—	—	14,369
Operating income	30,094	40,811	21,067
Interest income (expense), net	(828)	(416)	763
Other expense, net	(6,381)	(4,004)	(2,806)
Income before income taxes	22,885	36,391	19,024
Income tax expense	(9,074)	(29,100)	(15,527)
Net income from continuing operations	13,811	7,291	3,497
Discontinued operations (Note 13)			
Loss from discontinued operations	—	(1,759)	(638)
Income tax benefit	—	691	197
Net loss from discontinued operations	—	(1,068)	(441)
Net income	**$ 13,811**	**$ 6,223**	**$ 3,056**
Net income per common share—basic			
Net income from continuing operations	$ 0.73	$ 0.40	$ 0.19
Net loss from discontinued operations	—	(0.06)	(0.02)
Net income per common share—basic	**$ 0.73**	**$ 0.34**	**$ 0.17**
Net income per common share—diluted			
Net income from continuing operations	$ 0.72	$ 0.39	$ 0.19
Net loss from discontinued operations	—	(0.05)	(0.02)
Net income per common share—diluted	**$ 0.72**	**$ 0.34**	**$ 0.17**
Weighted average number of common shares:			
Basic	18,494,002	18,117,405	18,144,019
Diluted	18,911,610	18,498,745	18,463,161
Other comprehensive income (loss), before tax			
Unrealized gain (loss) on derivative instrument	—	—	(360)
Unrealized gain (loss) on debt security	1,770	3,830	(1,744)
Reclassification adjustment for loss on debt security in net income	—	5,585	2,727
Currency translation adjustment	(1,823)	4,552	(726)
Other comprehensive income (loss) before tax	(53)	13,967	(103)
Income tax expense related to items of other comprehensive income (loss)	(438)	(3,600)	(245)
Other comprehensive income (loss), net of tax	(491)	10,367	(348)
Comprehensive income	$ 13,320	$ 16,590	$ 2,708

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, 2018, 2017 and 2016

(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, 2015	18,659,696	$ 1,866	$ 232,126	$ 62,551	$ (6,232)	$ 290,311
Cumulative effect adjustment from adoption of ASU 2016-09	—	—	2,032	(1,428)	—	604
Net income	—	—	—	3,056	—	3,056
Other comprehensive loss, net of tax	—	—	—	—	(348)	(348)
Share-based compensation	—	—	15,966	—	—	15,966
Common shares issued	713,140	71	17,242	—	—	17,313
Retirement of repurchased common stock	(1,544,681)	(154)	(63,271)	—	—	(63,425)
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**

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, 2018, 2017 and 2016

(U.S. Dollars, in thousands)	2018	2017	2016
Cash flows from operating activities			
Net income	$ 13,811	$ 6,223	$ 3,056
Adjustments to reconcile net income to net cash from operating activities			
Depreciation and amortization	18,659	20,124	20,841
Amortization of debt costs and other assets	1,024	1,712	1,569
Provision for doubtful accounts	(599)	1,639	1,117
Deferred income taxes	(2,661)	21,286	10,460
Share-based compensation	18,930	12,557	15,966
Other-than-temporary impairment on debt securities	—	5,585	2,727
Loss on valuation of equity securities	3,050	—	—
Change in fair value of contingent consideration	3,069	—	—
Other	1,633	1,398	1,061
Changes in operating assets and liabilities, net of effects of acquisitions			
Trade accounts receivable	(3,706)	(6,562)	392
Inventories	9,698	(15,645)	(5,284)
Prepaid expenses and other current assets	(1,127)	(6,352)	701
Trade accounts payable	(170)	2,324	(1,771)
Other current liabilities	(7,563)	(11,412)	6,537
Other long-term assets and liabilities	(4,130)	6,095	1,704
Net cash from operating activities	**49,918**	**38,972**	**59,076**
Cash flows from investing activities			
Acquisition of business, net of cash acquired	(44,294)	—	—
Capital expenditures for property, plant and equipment	(13,592)	(14,665)	(16,432)
Capital expenditures for intangible assets	(1,664)	(2,283)	(1,902)
Asset acquisitions and other investments	(1,448)	—	—
Other investing activities	—	474	(3,613)
Net cash from investing activities	**(60,998)**	**(16,474)**	**(21,947)**
Cash flows from financing activities			
Proceeds from issuance of common shares	7,100	7,783	19,720
Payments related to withholdings for share-based compensation	(3,425)	(3,800)	(2,407)
Payment of debt issuance costs and other financing activities	(682)	(445)	—
Repurchase and retirement of common shares	—	—	(63,425)
Net cash from financing activities	**2,993**	**3,538**	**(46,112)**
Effect of exchange rate changes on cash and restricted cash	(881)	1,180	(739)
Net change in cash, cash equivalents, and restricted cash	(8,968)	27,216	(9,722)
Cash, cash equivalents, and restricted cash at the beginning of the year	81,157	53,941	63,663
Cash, cash equivalents, and restricted cash at the end of the year	**$ 72,189**	**$ 81,157**	**$ 53,941**
Components of cash, cash equivalents, and restricted cash at the end of the year			
Cash and cash equivalents	$ 69,623	$ 81,157	$ 39,572
Restricted cash	2,566	—	14,369
Cash, cash equivalents, and restricted cash at the end of the year	**$ 72,189**	**$ 81,157**	**$ 53,941**
Supplemental disclosure of cash flow information:			
Noncash investing activities:			
Purchase of intangible assets	$ 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 four reporting segments: Bone Growth Therapies (formerly referred to as BioStim), Spinal Implants (formerly referred to as Spine Fixation), Biologics, and Orthofix Extremities (formerly referred to as Extremity Fixation). Orthofix products are widely distributed via the Company's sales representatives and distributors.

On July 31, 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. The Company's shareholders approved and authorized the Domestication at the Company's 2018 Annual General Meeting of Shareholders held on July 17, 2018 (the "Annual General Meeting") by the affirmative vote of shareholders representing an absolute majority of the outstanding common shares of the Company as of the record date for the Annual General Meeting.

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 their respective footnotes that follow.

Significant Accounting Policy	Footnote Reference
Recently adopted accounting standards and recently issued accounting pronouncements	2
Acquisition of Spinal Kinetics, Inc.	3
Inventories	4
Property, plant and equipment	5
Patents and other intangible assets	6
Goodwill	7
Investments	8
Long-term debt	10
Fair value measurements	11
Commitments	12
Contingencies	13
Shareholders' equity	14
Revenue recognition and accounts receivable	15
Business segment information	16
Share-based compensation	17
Defined contribution plans and deferred compensation	18
Income taxes	19
Earnings per share	20

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

Amounts previously reported in the consolidated statements of income and comprehensive income as SEC / FCPA matters and related costs have been reclassified to general and administrative expenses to conform with current period presentation, resulting in a decrease of general and administrative expense of $2.5 million for the year ended December 31, 2017 and an increase in general and administrative expense of $2.0 million for the year ended December 31, 2016.

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 weighted 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 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 $3.3 million, gain of $1.9 million, and loss of less than $0.1 million for the years ended December 31, 2018, 2017 and 2016, 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 2018, which results in a substantial portion of our trade accounts receivable balance as of December 31, 2018. It is at least reasonably possible that changes in global economic conditions and/or local operating and economic conditions in the regions these distributors operate, 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.

In 2018, restricted cash 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. As such, the Company reclassified this cash balance to restricted cash. Refer to Note 13 for further discussion of this matter.

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

Expenditures related to the collaborative arrangement with MTF Biologics ("MTF") are expensed based on the terms of the related agreement. No expenditures were incurred for the year ended December 31, 2018 under the collaborative arrangement with MTF and expenditures totaled $0.9 million and $1.3 million for the years ended December 31, 2017 and 2016, respectively. Expenditures for research and development are expensed as incurred.

As part of 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 costs to further develop this acquired IPR&D . See Note 3 for further details.

Acquired IPR&D represents the fair value assigned to acquired research and development assets that have not reached technological feasibility. The 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 revenues and costs projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success of developing the asset. Additionally, the 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") 2014-09, Revenue from Contracts with Customers (Topic 606)

In May 2014, the Financial Accounting Standards Board ("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. 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 15 for further details.

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 requires entities to generally 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 these 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 during the first quarter of 2018 now uses the new

measurement alternative for the Company's equity investments in Bone Biologics, Inc. ("Bone Biologics"), which have historically been held at cost. This resulted in an increase in the previously recorded value of the Company's equity investments in Bone Biologics, which was recorded within other current assets or other long-term assets and other income, of $1.6 million, or $0.09 per share before taxes, during the three months ended March 31, 2018. During the three months ended September 30, 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 to be impaired and recorded a charge of $4.4 million in other expense, net, during the third quarter of 2018. See Note 11 for further details.

Adoption of ASU 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory

In October 2016, the FASB issued ASU 2016-16, which reduces diversity in practice of accounting for intra-entity transfers of assets, particularly for intra-entity transfers of intellectual property. The new standard states an entity should recognize the income tax consequences of an intra-entity transfer when the transfer occurs, as opposed to historical U.S. GAAP guidance which prohibited the recognition of current and deferred income taxes for an intra-entity asset transfer until the asset had been sold to an outside party. During the third and fourth quarters of 2017, the Company executed two intra-entity asset transfers that resulted in prepaid income taxes of $8.6 million. The Company adopted this new standard using a modified retrospective approach as of January 1, 2018, which resulted in a reduction of prepaid income taxes of $8.6 million and an increase in deferred tax assets of $6.7 million, with these changes offset by an adjustment to the Company's retained earnings of $1.9 million. Adoption of this guidance did not have a material impact to the Company's consolidated statements of income and comprehensive income or to its consolidated statements of cash flows.

Adoption of ASU 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash

In November 2016, the FASB issued ASU 2016-18, which reduces diversity in classification and presentation of restricted cash, including transfers between cash and restricted cash, on the statement of cash flows. The Company adopted this standard as of January 1, 2018 using a retrospective transition approach. Adoption of this ASU resulted in an increase in net cash from operating activities of $2.5 million for the year ended December 31, 2018, a decrease in net cash from operating activities of $14.4 million for the year ended December 31, 2017, and an increase in net cash from operating activities of $14.4 million for the year ended December 31, 2016.

Adoption of ASU 2017-01, Business Combinations (Topic 805)

In January 2017, the FASB issued ASU 2017-01, which clarifies the definition of a business. This amendment states that when substantially all of the fair value of gross assets acquired is concentrated in a single identifiable asset or a group of similar identifiable assets, that the set of assets acquired is not a business, which will likely result in more acquisitions being accounted for as asset acquisitions rather than business combinations. Based upon this guidance, which the Company adopted as of January 1, 2018, the Company accounted for certain transactions during 2018 totaling $3.4 million as asset acquisitions, recognized within patents and other intangible assets, net, rather than business combinations, as the sets of assets acquired did not meet the definition of a business.

Recently issued accounting standards

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Leases (ASU 2016-02 and other related updates)	Requires a lessee to recognize lease assets and lease liabilities for leases classified as operating leases. Applied using a modified retrospective approach. An entity can choose to apply the provisions at the beginning of the earliest comparative period presented in the financial statements or at the beginning of the period of adoption. The Company expects to apply the provisions at the beginning of the period of adoption, January 1, 2019.	January 1, 2019	The Company established a cross-functional implementation team to analyze the impact of the standard on the Company's population of leases and to evaluate the Company's current accounting policies relating to leases. The Company has evaluated the impact of this ASU, which will result in current operating leases being reflected on the consolidated balance sheet. The Company expects to recognize lease assets and lease liabilities of approximately $20 million as of January 1, 2019. The Company does not expect material impacts to its consolidated statements of income and comprehensive income or to the consolidated statements of cash flows. Additionally, this guidance will materially change the Company's disclosures, requiring the Company to provide users more quantitative and qualitative information about the Company's leases, any significant judgments required in applying the ASU, and amounts recognized within the consolidated financial statements related to the Company's leases.
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 is currently evaluating the impact this ASU may have on its consolidated financial statements. However, the Company does not expect this ASU to have a significant impact on its financial statements or disclosures.
Comprehensive income (ASU 2018-02)	Allows entities to reclassify from accumulated other comprehensive income to retained earnings stranded tax effects resulting from the Tax Cuts and Jobs Act (the "Tax Act"). Applied either in the period of adoption or retrospectively to each period (or periods) in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Act is recognized.	January 1, 2019	The Company anticipates adopting this ASU on January 1, 2019. The adoption will result in an increase to accumulated other comprehensive income and a decrease in retained earnings of $0.9 million.
Fair value measurement (ASU 2018-13)	Eliminates certain disclosures, such 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 is currently evaluating the impact this ASU may have on its consolidated financial statements.

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 is currently evaluating the impact this ASU may have on its consolidated financial statements.

3. Acquisition of Spinal Kinetics, Inc.

On March 15, 2018, the Company entered into a definitive merger agreement (the "Merger Agreement") to acquire 100% of the outstanding stock of Spinal Kinetics Inc. ("Spinal Kinetics"), a privately held developer and manufacturer of artificial cervical and lumbar discs, to strengthen the Company's product portfolio and fill a strategic gap in the Spinal Implants business. On April 30, 2018 (the "Acquisition Date"), the Company completed the acquisition and all outstanding shares of Spinal Kinetics' capital stock were converted into the right to receive at the closing an aggregate of $45.0 million in net cash, subject to certain adjustments, plus potential milestone payments of up to $60.0 million in cash. The Company made the closing payments from cash on hand on April 30, 2018.

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

(U.S. Dollars, in thousands)	As of April 30, 2018	Adjustments	As of December 31, 2018
Fair value of consideration transferred			
Cash paid	$ 50,564	$ 545	$ 51,109
Contingent consideration	25,491	—	25,491
Total fair value of consideration transferred	$ 76,055	$ 545	$ 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. The fair value of the contingent consideration arrangement at the Acquisition Date was $25.5 million and increased to $28.6 million as of December 31, 2018; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration. The increase in fair value of $3.1 million was recorded in changes in fair value of contingent consideration. For additional discussion regarding the valuation of the contingent consideration, see Note 11.

The following table summarizes the preliminary estimated fair values of the assets acquired and liabilities assumed. A final determination of the allocation of the purchase price to assets acquired and liabilities assumed has not been made and the following should be considered preliminary. The final determination is subject to completion of the Company's valuation of the acquired deferred income taxes and tax attributes, including net operating loss carryforwards, which is expected to be completed within one year from the Acquisition Date.

(U.S. Dollars, in thousands)	As of April 30, 2018	Adjustments	As of December 31, 2018	Assigned Useful Life
Assets acquired				
Cash and cash equivalents	$ 6,785	$ —	$ 6,785	
Restricted cash	30	—	30	
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	3,483	(1,109)	2,374	
Total identifiable assets acquired	$ 62,398	$ (1,109)	$ 61,289	
Liabilities assumed				
Accounts payable	$ 351	$ —	$ 351	
Other current liabilities	2,873	—	2,873	
Other long-term liabilities	301	—	301	
Total liabilities assumed	3,525	—	3,525	
Goodwill	17,182	1,654	18,836	
Total fair value of consideration transferred	$ 76,055	$ 545	$ 76,600	

The purchase price exceeded the fair value of the net tangible and identifiable intangible assets acquired from Spinal Kinetics. As a result, the Company recorded goodwill in connection with the acquisition. Specifically, the goodwill includes the assembled workforce and synergies associated with the combined entity and is not expected to be deductible for tax purposes. The $18.8 million of goodwill recognized was assigned to the Spinal Implants reporting segment.

The IPR&D intangible asset is considered an indefinite-lived asset until the completion or abandonment of the associated research and development efforts. Accordingly, during the development period after the acquisition, this asset is not amortized but, instead, is subject to impairment review and testing provisions. Upon completion of the IPR&D project, which occurred on February 6, 2019, the Company began to amortize this intangible.

The Company recognized $3.3 million and $0.8 million of acquisition related costs that were expensed during the years ended December 31, 2018 and 2017, respectively. These costs are included in the consolidated statements of income and comprehensive income within general and administrative expenses. The results of operations for Spinal Kinetics have been included in the Company's financial results since the Acquisition Date and included $8.7 million of revenue and a net loss of $5.8 million for the year ended December 31, 2018 in the consolidated statement of income and comprehensive income.

The following table presents the unaudited pro forma results for the years ended December 31, 2018 and 2017, which combines the historical results of operations of the Company and Spinal Kinetics as though the companies had been combined as of January 1, 2017. The unaudited pro forma information is presented for informational purposes only and is not indicative of the results of operations that would have been achieved if the acquisition had taken place at such time.

(U.S. Dollars, in thousands)	2018 (unaudited)	2017 (unaudited)
Net sales	$ 457,960	$ 448,277
Net income (loss) from continuing operations	16,157	(1,492)

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 facility in Texas, 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, field inventory and consignment inventory include material, labor and production overhead costs. Field 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.

Prior to the adoption of ASU 2014-09, or for all periods presented prior to January 1, 2018, deferred cost of sales resulted from certain transactions where the Company had shipped product or performed services for which all revenue recognition criteria had not yet been met. Once all revenue recognition criteria had been met, the revenue and associated cost of sales were recognized. Subsequent to the adoption of ASU 2014-09, the Company no longer has transactions which result in the recognition of deferred cost of sales. See Notes 2 and 15 for further discussion of the Company's adoption of ASU 2014-09.

	December 31,	
(U.S. Dollars, in thousands)	2018	2017
Raw materials	$ 8,463	$ 6,067
Work-in-process	13,478	12,487
Finished products	18,244	11,244
Field / consignment inventory	36,662	49,197
Deferred cost of sales	—	2,335
Inventories	$ 76,847	$ 81,330

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 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 $15.9 million, $18.3 million and $19.0 million for the years ended December 31, 2018, 2017 and 2016, 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.

(U.S. Dollars, in thousands)	December 31, 2018	December 31, 2017
Cost		
Buildings	$ 3,746	$ 3,725
Plant and equipment	45,744	47,588
Instrumentation	75,542	75,818
Computer software	47,322	48,604
Furniture and fixtures	6,599	7,605
Construction in progress	2,909	769
	181,862	184,109
Accumulated depreciation	(139,027)	(138,970)
Property, plant and equipment, net	$ 42,835	$ 45,139

The Company capitalizes system development costs related to its 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.

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. Patents and other intangible assets

Patents and other 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, 2018	December 31, 2017
Cost			
Patents	10 years	$ 39,085	$ 38,621
Developed technology	10 years	12,400	—
IPR&D	Indefinite	26,800	—
License and other	7 years	14,654	10,276
Trademarks—finite lived	9 years	840	533
	9 years	93,779	49,430
Accumulated amortization			
Patents		$ (35,016)	$ (34,151)
Developed technology		(827)	—
IPR&D		—	—
License and other		(5,744)	(4,625)
Trademarks—finite lived		(295)	(193)
		(41,882)	(38,969)
Patents and other intangible assets, net		$ 51,897	$ 10,461

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 will not be amortized but will be 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.

In February 2019, the Company obtained FDA approval of the M6-C artificial cervical disc. As such, amortization of the IPR&D intangible asset attributable to these research and development activities will commence starting in February 2019, for which the Company expects to use a 10 year amortization period.

Amortization expense for intangible assets was $2.7 million, $1.8 million and $1.8 million for the years ended December 31, 2018, 2017 and 2016, respectively. Future amortization expense for intangible assets, including IPR&D, is estimated as follows:

(U.S. Dollars, in thousands)	Amortization
2019	$ 6,604
2020	6,205
2021	6,146
2022	6,138
2023	5,495
Thereafter	21,309
Total	$ 51,897

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.

At the beginning of the fourth quarters of 2018 and 2017, 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, 2017, by reportable segment:

(U.S. Dollars, in thousands)	December 31, 2017	Spinal Kinetics Acquisition	December 31, 2018
Bone Growth Therapies	$ 42,678	$ —	$ 42,678
Spinal Implants	—	18,836	18,836
Biologics	10,887	—	10,887
Orthofix Extremities	—	—	—
Goodwill	$ 53,565	$ 18,836	$ 72,401

8. Investments

Debt security

On March 4, 2015, the Company entered into an Option Agreement (the "Option Agreement") with eNeura, Inc. ("eNeura"), a privately held medical technology company that is developing devices for the treatment of migraines. The Option Agreement provided the Company with an exclusive option to acquire eNeura (the "Option") during the 18-month period following the grant of the Option, which expired in September 2016 without the Company exercising the option. In consideration for the Option, (i) the Company paid a non-refundable $0.3 million fee to eNeura, and (ii) the Company loaned eNeura $15.0 million pursuant to a Convertible Promissory Note (the "eNeura Note") that was issued to the Company. The principal amount of the eNeura Note is $15.0 million and interest accrues at 8.0%. The eNeura Note will mature on March 4, 2019 and interest is due when the eNeura Note matures, provided that if a change in control of eNeura (generally defined as a third party acquisition of fifty percent or more of eNeura's voting equity or all or substantially all of eNeura's assets) occurs prior to the maturity date, the eNeura Note will automatically convert into preferred stock of eNeura at a fixed price equal to $7.30 per share. The investment is recorded in other long-term assets as an available for sale debt security at fair value and interest is recorded in interest income; however, the Company discontinued recognition of interest income on the eNeura Note in the first quarter of 2017. The eNeura Note is collateralized by eNeura's intellectual property in the event of default or nonpayment. In the event the Company were to obtain eNeura's intellectual property, the Company believes the value of such intellectual property equals or exceeds the value of the eNeura Note. Refer to Note 11 for additional discussion regarding the valuation of this debt security.

Currently, the Company does not expect to collect the complete principal and interest on March 4, 2019 and is in negotiations with eNeura to possibly extend and/or modify other terms of the eNeura Note. Any significant changes to the term of the eNeura Note, including extending the due date, could have a material impact on the fair value of the security.

Equity investment and warrants

As of December 31, 2018, the Company holds common stock of Bone Biologics and warrants to purchase approximately 13 thousand shares at a weighted average exercise price of $14.32 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. These instruments are recorded within other long-term assets.

Prior to 2018, these instruments were accounted for at cost as the fair value of these instruments was not readily determinable. Effective January 1, 2018, the Company is required to measure these equity investments at fair value and recognize any changes in fair value in net income as a result of adopting ASU 2016-01 (see Note 2). Under this guidance, the Company has elected to account for these 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. During the first quarter of 2018, the Company purchased an additional 25,000 shares of Bone Biologics common stock, after

giving effect to a reverse stock split by Bone Biolgics subsequent to the purchase, for $0.5 million. During the three months ended September 30, 2018, Bone Biologics executed a series of equity financing activities which significantly diluted the Company's ownership interest in the outstanding stock. After considering the new observable prices in these equity financing activities, and after giving consideration to other matters disclosed by Bone Biologics, the Company determined this investment was impaired and recorded an impairment charge of $4.4 million relating to its investments in Bone Biologics. These changes are included in other expense, net. Refer to Note 11 for additional discussion regarding the valuation of this investment.

9. Other current liabilities

	December 31,	
(U.S. Dollars, in thousands)	2018	2017
Accrued expenses	$ 6,206	$ 6,984
Salaries, bonuses, commissions and related taxes payable	21,608	24,635
Accrued distributor commissions	10,073	9,192
Accrued legal and settlement expenses	4,196	7,673
Contingent consideration liability	13,600	—
Non-income taxes payable	3,638	3,180
Other payables	8,598	9,631
Other current liabilities	$ 67,919	$ 61,295

Orthofix Extremities restructuring plan

In December 2016, the Company approved and initiated a planned restructuring, which primarily affects the Orthofix Extremities reporting segment, to streamline costs, improve operational performance, and wind down a non-core business. The Orthofix Extremities restructuring plan consisted of primarily severance charges, professional fees and the write-down of certain assets. The Company incurred total pre-tax expense of approximately $3.2 million in connection with this restructuring activity, largely within cost of sales and operating expenses. In 2016, the Company incurred expenses of $2.0 million, including $0.4 million of inventory write-down charges, and made payments of $0.1 million, resulting in an accrual of $1.5 million as of December 31, 2016. In 2017, the Company incurred costs of $1.3 million and made payments of $2.1 million, resulting in an accrual of $0.7 million as of December 31, 2017. In 2018, the Company made adjustments of $0.1 million to decrease the accrual and payments of $0.5 million, resulting in a remaining accrual of $0.1 million as of December 31, 2018 within other current liabilities.

U.S. restructuring plan

In September 2017, the Company approved and executed an additional restructuring plan, which primarily affected the entity's corporate shared services in the U.S. to streamline costs and to improve operational performance. The U.S. restructuring plan consisted primarily of severance charges. The Company incurred total pre-tax expense of approximately $1.7 million in connection with this restructuring activity, all of which was recognized in 2017, within cost of sales and operating expenses. Payments were made in 2017 of $0.6 million, resulting in an accrual of $1.1 million as of December 31, 2017 in other current liabilities related to the planned restructuring and made further payments of $1.1 million in 2018 to complete the U.S. restructuring plan.

10. Long-term debt

On August 31, 2015, the Company, through its subsidiaries Orthofix Holdings, Inc. and Victory Medical Limited (collectively the "Borrowers"), entered into a Credit Agreement (the "Credit Agreement") with JPMorgan Chase, N.A., as Administrative Agent, and certain lenders party thereto. The Credit Agreement provides for a five year $125 million secured revolving credit facility (the "Facility"). The Credit Agreement has a maturity date of August 31, 2020. As of December 31, 2018, the Company has no borrowings outstanding under the Credit Agreement.

Borrowings under the 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) of the Company and certain of its subsidiaries. The Facility is generally available in U.S. Dollars with up to $50 million of the Facility also available to be borrowed in Euros and British Pounds (together with U.S. Dollars, the "Agreed Currencies"). The Credit Agreement further permits up to $25 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 by an aggregate amount of up to $50 million (which increase may take the form of one or more increases to the revolving credit commitments and/or the issuance of one or more new Term A loans) upon satisfaction of certain conditions precedent 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 plus an applicable margin ranging from 1.75% to 2.5% or a base rate plus an applicable margin ranging from 0.75% to 1.5% (in each case subject to adjustment based on the Company's total leverage ratio). An unused commitment fee ranging from 0.25% to 0.4% (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.

The Company and certain of its subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of the Borrowers' obligations under the Credit Agreement. The obligations of the Borrowers and each of the Guarantors with respect to the Credit Agreement are secured by a pledge of substantially all of the tangible and intangible personal property of the Borrowers and each of the Guarantors, including accounts receivable, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their subsidiaries. The 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, repay subordinated indebtedness and enter into affiliate transactions.

In addition, the 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 leverage ratio of not more than 3.0 to 1.0 and an interest coverage ratio of at least 3.0 to 1.0. The Company is in compliance with all required financial covenants as of December 31, 2018. 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.

In conjunction with obtaining the Facility, the Company incurred debt issuance costs of $1.8 million which 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, 2018 and 2017, debt issuance costs, net of accumulated amortization, were $0.6 million and $1.0 million, respectively. Debt issuance costs amortized or expensed related to the Facility and the Amendment totaled $0.4 million, $1.0 million, and $0.4 million for the years ended December 31, 2018, 2017, and 2016, respectively.

On December 8, 2017, the Company amended the Credit Agreement to add the Company's subsidiary, Orthofix International B.V., as a Borrower, Guarantor, and a loan party. In addition, two of the Company's subsidiaries, Orthofix Limited and Orthofix II B.V. were also added as Guarantors and loan parties.

On July 31, 2018, the Company amended and restated the Credit Agreement pursuant to a First Amended and Restated Credit Agreement ("Amended Credit Agreement"). The Amended Credit Agreement is substantially the same as the previous Credit Agreement, except for certain amendments to, among other things, (i) effectuate the Domestication of the Company from a Curaçao company to a Delaware corporation, (ii) limit the pledge by the Company and each domestic subsidiary of the Company of equity interests in their respective first tier foreign subsidiaries to 65% of the voting interests in such foreign subsidiaries, (iii) limit the guarantee and joint and several obligations of each subsidiary guarantor that is a foreign subsidiary so that such foreign subsidiary guarantors are only providing guarantees, or are jointly and severally obligated, for obligations of other foreign subsidiaries, and (iv) limit the secured obligations that are secured by collateral provided by subsidiary guarantors that are foreign subsidiaries to secured obligations of foreign subsidiaries.

The Company has an unused available line of credit of €5.8 million ($6.7 million and $7.0 million) at December 31, 2018 and 2017, 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 $0.7 million for the years ended December 31, 2018, 2017, and 2016, respectively.

11. 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. 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, 2018	Level 1	Level 2	Level 3
Assets				
Treasury securities	$ 490	$ 490	$ —	$ —
Equity warrants	—	—	—	—
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)

(U.S. Dollars, in thousands)	Balance December 31, 2017	Level 1	Level 2	Level 3
Assets				
Collective trust funds	$ 100	$ —	$ 100	$ —
Treasury securities	556	556	—	—
Debt security	16,050	—	—	16,050
Total	$ 16,706	$ 556	$ 100	$ 16,050
Liabilities				
Deferred compensation plan	$ (1,379)	$ —	$ (1,379)	$ —
Total	$ (1,379)	$ —	$ (1,379)	$ —

The fair value of treasury securities are determined based on quoted prices in active markets for identical assets, therefore, the Company has 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 while the warrants' value was reduced to zero in 2018. Prior to this reduction in value, the warrants were recorded within other current assets or other long-term assets, dependent upon the expiration date. Prior to 2018, these instruments were accounted for at cost as the fair value of these instruments was not readily determinable.

Effective January 1, 2018, the Company is required to measure these equity investments at fair value and recognize any changes in fair value in net income as a result of adopting ASU 2016-01. However, for certain equity investments that do not have readily determinable fair values, the new guidance allows entities to choose to measure these 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 changes in valuation of these securities for the years ended December 31, 2018 and 2017 are shown below:

(U.S. Dollars, in thousands)	2018	2017	2016
Equity securities and warrants at January 1	$ 2,768	$ 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	$ 2,768	$ 2,768

Debt Security

The Company holds a debt security of eNeura, Inc., a privately held medical technology company that is developing devices for the treatment of migraines. The debt security matures on March 4, 2019. The fair value of the debt security, including accrued interest, is based upon significant unobservable inputs, including the use of a discounted cash flows model, requiring the Company to develop its own assumptions; therefore, the Company has categorized this asset as a Level 3 financial asset. Some of the more significant unobservable inputs used in the fair value measurement of the debt security are the estimated likelihood of conversion to equity and the discount rate. Holding other inputs constant, changes in these assumptions could result in a significant change in the fair value of the debt security. As of December 31, 2018, the Company reassessed its estimate of fair value based on current financial information and other assumptions, resulting in a fair value of $17.8 million, a net increase of $1.8 million during 2018, which the Company recorded in other comprehensive income as an unrealized gain on debt securities. This compares to an amortized cost basis of $9.0 million.

The Company evaluates any declines in fair value, if any, each quarter to determine if impairments are other-than-temporary. Based upon the Company's best estimate of the amount it expected to recover at the time, the Company recorded an other-than-temporary impairments of $5.6 million in 2017 and $2.7 million in 2016. These other-than-temporary impairments were reclassified from accumulated other comprehensive loss and included within other expense, net.

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)	2018	2017
Balance at January 1	$ 16,050	$ 12,220
Accrued interest income	—	—
Gains (losses) recorded for the period		
Recognized in net income	—	(5,585)
Recognized in other comprehensive income	1,770	9,415
Balance at December 31	$ 17,820	$ 16,050

Currently, the Company does not expect to collect the complete principal and interest on March 4, 2019 and is in negotiations with eNeura to possibly extend and/or modify other terms of the eNeura Note. Any significant changes to the term of the eNeura Note, including extending the due date, could have a material impact on the fair value of the security.

Contingent Consideration

The 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 if 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 April 30, 2018 to trigger applicable payments. Approximately $13.6 million of this liability is included within other current liabilities and $15.0 million is included within other long-term liabilities.

The Company estimated the fair value of the contingent consideration attributable to the FDA Milestone using a probability-weighted discounted cash flow model. This fair value is based on significant inputs not observable in the market and thus represents a Level 3 measurement. The key assumptions in applying the probability-weighted discounted cash flow model include the Company's estimation of the probability and timing of obtaining FDA approval for the M6-C artificial cervical disc. The Company's expectation as of December 31, 2018, was to obtain approval from the FDA mid-2019. Significant changes in these assumptions could result in a significantly higher or lower fair value.

The Company estimated 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, 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, discount rate applied, and assumptions for potential volatility of the Company's forecasted revenue. Significant changes in these assumptions could result in a significantly higher or lower fair value.

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)	2018
Contingent consideration at January 1	$ —
Acquisition date fair value	25,491
Increase in fair value recognized in operating expenses	3,069
Contingent consideration at December 31	$ 28,560

On February 6, 2019, the Company obtained FDA approval of the M6-C artificial cervical disc for patients suffering from cervical disease degeneration. This approval triggered the Company's payment obligation of $15.0 million of contingent consideration. The Company has accrued a liability of $13.6 million within other current liabilities as of December 31, 2018, and paid the $15.0 million FDA Milestone payment on February 14, 2019. The difference of $1.4 million between the payment and the accrued liability as of December 31, 2018, will be recognized as an operating expense during the first quarter of 2019.

12. Commitments

Leases

The Company has entered into operating leases for facilities and equipment. These leases are non-cancellable and typically do not contain renewal options, except for certain facility leases. Certain leases contain rent escalation clauses for which the Company recognizes the expense on a straight-line basis. Rent expense under the Company's operating leases for the years ended December 31, 2018, 2017 and 2016 was approximately $3.5 million, $3.1 million and $3.0 million, respectively.

Future minimum lease payments under operating leases as of December 31, 2018 are as follows:

(U.S. Dollars, in thousands)		
2019	$	3,330
2020		2,729
2021		2,946
2022		2,818
2023		1,727
Thereafter		11,372
Total	$	24,922

In January 2019, subsequent to the adoption of ASU 2016-02, the Company entered into an amendment for its corporate headquarters lease. As a result of this amendment, the classification of the lease changed from an operating lease to a finance lease resulting in an increase in both the lease liability and lease asset of approximately $8 million during the first quarter of 2019.

Inventory purchase commitments

The Company had inventory purchase commitments with third-party manufacturers for $0.1 million and $1.9 million as of December 31, 2018, and 2017, respectively.

13. Contingencies

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 U.S. Securities and Exchange Commission (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. Both investigations were initiated in 2013 and involved matters self-reported to the SEC by the Company. The settlements approved by the SEC resolved these two matters, and included payments totaling $14.4 million by the Company to the SEC of amounts previously accrued and funded into escrow by the Company during 2016. In connection with the Brazil-related settlement, the Company agreed to retain an independent compliance consultant for one year to review and test the Company's compliance program related to the U.S. Foreign Corrupt Practices Act. The Company's engagement with its independent compliance consultant began in the first quarter of 2017 and concluded in the first quarter of 2018. In addition, in the fourth quarter of 2017 the Company received a favorable insurance

settlement of approximately $6 million associated with prior costs incurred related to these matters, which the Company has recognized within general and administrative expenses.

Discontinued Operations – Matters Related to Breg and Possible Indemnification Obligations

On May 24, 2012, the Company sold Breg, Inc. ("Breg"), a former subsidiary of the Company, 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.

At the time of its divestiture by the Company, Breg was engaged in the manufacturing and sales of motorized cold therapy units used to reduce pain and swelling. Several domestic product liability cases were filed, mostly in California state court. In September 2014, the Company entered into a master settlement agreement resolving then pending pre-close cold therapy claims. In May 2018, Breg settled and resolved a post-close cold therapy claim in California state court. Pursuant to the Company's indemnification obligations to Breg, the Company was obligated to make a final payment to its insurer in the amount of $1.7 million, which was the remaining balance on the Company's self-insured retention in its liability insurance policy, to help fund the Breg settlement.

Charges incurred as a result of this indemnification are reflected as discontinued operations in our consolidated statements of income and comprehensive income. Following the May 2018 settlement, 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 €0.9 million ($1.0 million), €0.8 million ($0.9 million), and €0.8 million ($0.9 million) for the years ended December 31, 2018, 2017, and 2016, respectively. As of December 31, 2018, the Company has accrued €3.2 million ($3.7 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 $2.6 million of the Company's cash, which the Company reclassified to restricted cash. The Company contests the underlying basis for the order. Based on information known to date, the Company does not believe that the Brazilian authorities' investigation will result in a material loss to the Company.

14. 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.

Share Repurchase Plan

In August 2015, the Company's Board of Directors authorized a share repurchase plan, authorizing the purchase of up to $75 million of the Company's common stock. The Company completed the share repurchase plan in 2016. Under the program, common shares repurchased consisted of open market transactions at prevailing market prices in accordance with the guidelines specified under Rule 10b-18 of the Exchange Act, as amended. Repurchases were made from cash on hand and cash generated from operations. For the year ended December 31, 2016, the Company repurchased 1,544,681 shares of common stock for $63.4 million with an average price per share of $41.06, which were all retired upon repurchase.

Accumulated Other Comprehensive Income

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

(U.S. Dollars, in thousands)	Currency Translation Adjustments	Debt Security	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2016	$ (5,115)	$ (1,465)	$ (6,580)
Other comprehensive income	4,552	3,830	8,382
Income taxes	—	(1,475)	(1,475)
Reclassification adjustments to:			
Other expense, net	—	5,585	5,585
Income taxes	—	(2,125)	(2,125)
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

15. Revenue recognition and accounts receivable

Adoption of ASU 2014-09, "Revenue from Contracts with Customers"

Effective January 1, 2018, the Company adopted ASU 2014-09, *Revenue from Contracts with Customers (Topic 606)* using the modified retrospective transition method, which was applied to all contracts. Results for the year ended December 31, 2018 are presented under Topic 606, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting under the previous revenue recognition standard, Topic 605.

The Company recorded a net increase to opening retained earnings of $4.8 million as of January 1, 2018 due to the cumulative impact of adopting Topic 606 as presented in the table below.

(U.S. Dollars, in thousands)	December 31, 2017	Impact of Adoption of Topic 606	January 1, 2018
Assets			
Current assets			
Cash and cash equivalents	$ 81,157	$ —	$ 81,157
Accounts receivable, net	63,437	8,648	72,085
Inventories	81,330	(2,338)	78,992
Prepaid expenses and other current assets	25,877	—	25,877
Total current assets	251,801	6,310	258,111
Deferred income taxes	23,315	(1,549)	21,766
Other long-term assets	130,238	—	130,238
Total assets	**$ 405,354**	**$ 4,761**	**$ 410,115**
Liabilities and shareholders' equity			
Total liabilities	$ 108,746	$ —	$ 108,746
Shareholders' equity			
Common shares	1,828	—	1,828
Additional paid-in capital	220,591	—	220,591
Retained earnings	70,402	4,761	75,163
Accumulated other comprehensive income	3,787		3,787
Total shareholders' equity	296,608	4,761	301,369
Total liabilities and shareholders' equity	**$ 405,354**	**$ 4,761**	**$ 410,115**

The impact primarily related to an increase in trade accounts receivable, net, from the Company's stocking distributors, for which revenue was historically recognized when cash payment was received, and the recognition of previously deferred cost of sales for certain stocking distributor transactions, which were historically included within inventory. Adoption of Topic 606 had no impact on the consolidated statement of cash flows.

The table below presents the impact to the Company's consolidated statement of income for the year ended December 31, 2018 as a result of the adoption of Topic 606.

	Year Ended December 31, 2018		
(U.S. Dollars, in thousands)	Based on historical accounting under Topic 605	Impact of adoption	As reported under Topic 606
Net sales	$ 445,343	$ 7,699	$ 453,042
Cost of sales	95,145	1,483	96,628
Gross profit	350,198	6,216	356,414
Sales and marketing	205,538	(11)	205,527
Other operating expenses	120,793	—	120,793
Operating income	$ 23,867	$ 6,227	$ 30,094
Income tax expense	(7,656)	(1,418)	(9,074)
Net income from continuing operations	$ 9,002	$ 4,809	$ 13,811
Net income from continuing operations per common share—basic	$ 0.48	$ 0.25	$ 0.73
Net income from continuing operations per common share—diluted	$ 0.47	$ 0.25	$ 0.72

Revenue Recognition Under Topic 606

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.

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, in connection with the sale of the Company's stimulation products. Revenue is recognized 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. Adoption of Topic 606 had an immaterial impact to the Bone Growth Therapies reporting segment.

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, through which the Company markets tissue for bone repair and reconstruction under the brand names Trinity Evolution and Trinity ELITE. Under the terms of the agreement, MTF sources the tissue, processes it to create the bone growth matrix, packages and delivers it 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 and therefore the Company recognizes these marketing service fees on a net basis within net sales upon shipment of the product to the customer. Adoption of Topic 606 had an immaterial impact to the Biologics reporting segment.

Spinal Implants and Orthofix Extremities

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

Commercial revenue is largely related to the sale of the Company's Spinal Implants and Orthofix 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.

Certain revenues within the Spinal Implants and Orthofix Extremities reporting segments 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. 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.

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 to these stocking distributors. In instances where the stocking distributor was determined to be financially viable, the Company deferred the costs of sales until the 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, 2018, 2017, and 2016.

	For the year ended December 31,		
(U.S. Dollars, in thousands)	**2018**	**2017**	**2016**
Product sales	$ 395,589	$ 373,538	$ 355,652
Marketing service fees	57,453	60,285	54,136
Net sales	$ 453,042	$ 433,823	$ 409,788

Product sales primarily consist of bone growth stimulation devices and internal and external fixation products. Marketing service fees are received from MTF based on total sales of biologics tissues and relates solely to the Biologics reporting segment. Marketing service fees received from MTF were $57.5 million, or approximately 96% of total Biologics revenues, for the year ended December 31, 2018. As MTF is the Company's single supplier for the Trinity Evolution and Trinity EITE 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 $2.7 million, $3.0 million and $2.0 million for the years ended December 31, 2018, 2017 and 2016, 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. During 2018, 2017, and 2016 the Company sold €9.8 million, €9.8 million, and €10.0 million ($11.5 million, $11.2 million, and $11.1 million) of receivables, respectively. The estimated related fee for 2018, 2017, and 2016 was $0.3 million, $0.3 million and $0.4 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.

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 $1.9 million and $1.0 million as of December 31, 2018 and 2017, respectively.

Other contract assets are amortized on a straight-line basis over the term of the related contract. There were no changes to such treatment as a result of adoption of Topic 606. No impairments were incurred for other contract assets in 2018 or 2017. Further, the Company has applied the practical expedient allowed within the guidance to expense sales commissions when incurred as the amortization period would be for one year or less.

16. Business segment information

We manage our business by our four reporting segments: Bone Growth Therapies, Spinal Implants, Biologics, and Orthofix Extremities. These reporting segments represent the operating segments for which our 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 non-GAAP net margin, an internal metric that the Company defines as gross profit less sales and marketing expense. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information. Accordingly, our reporting segment information has been prepared based on our four reporting segments.

Bone Growth Therapies

The Bone Growth Therapies reporting segment 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 cervical and lumbar spine as well as a therapeutic treatment for non-spine fractures that have not healed (non-unions). This reporting segment uses distributors and sales representatives to sell its devices to hospitals, healthcare providers, and patients, primarily in the U.S.

Spinal Implants

The Spinal Implants reporting segment designs, develops and markets a broad portfolio of motion preservation and 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.

Biologics

The Biologics reporting segment provides a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. This reporting segment 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 employed and independent sales representatives. Our partnership with MTF allows us to exclusively market the Trinity Evolution and Trinity ELITE tissue forms for musculoskeletal defects to enhance bony fusion.

Orthofix Extremities

The Orthofix 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. Orthofix 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 four reporting segments.

The table below presents net sales by reporting segment:

	Year Ended December 31,					
	2018		2017		2016	
(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	$ 195,252	43.1%	$ 185,900	42.9%	$ 176,561	43.1%
Spinal Implants	91,658	20.2%	81,957	18.9%	72,632	17.7%
Biologics	59,684	13.2%	62,724	14.4%	57,912	14.1%
Orthofix Extremities	106,448	23.5%	103,242	23.8%	102,683	25.1%
Net sales	$ 453,042	100.0%	$ 433,823	100.0%	$ 409,788	100.0%

The following table presents Non-GAAP net margin, and internal metric that the Company defines as gross profit less sales and marketing expense, by reporting segment:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2018	2017	2016
Bone Growth Therapies	$ 86,252	$ 77,369	$ 75,469
Spinal Implants	7,628	8,730	8,650
Biologics	26,298	25,692	26,891
Orthofix Extremities	31,391	31,071	30,526
Corporate	(682)	(446)	(888)
Non-GAAP net margin	$ 150,887	$ 142,416	$ 140,648
General and administrative	84,506	71,905	76,409
Research and development	33,218	29,700	28,803
Changes in fair value of contingent consideration	3,069	—	—
Charges related to U.S. Government resolutions	—	—	14,369
Operating income	$ 30,094	$ 40,811	$ 21,067
Interest income (expense), net	(828)	(416)	763
Other expense, net	(6,381)	(4,004)	(2,806)
Income before income taxes	$ 22,885	$ 36,391	$ 19,024

The following table presents depreciation and amortization by reporting segment:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2018	2017	2016
Bone Growth Therapies	$ 1,770	$ 2,133	$ 2,754
Spinal Implants	7,294	6,949	8,118
Biologics	448	752	1,011
Orthofix Extremities	5,342	6,040	5,742
Corporate	3,805	4,250	3,216
Total	$ 18,659	$ 20,124	$ 20,841

Geographical information

The following data includes net sales by geographic destination:

(U.S. Dollars, in thousands)	2018	2017	2016
U.S.	$ 355,353	$ 345,145	$ 316,873
Italy	19,331	17,059	16,664
Germany	11,606	7,063	6,448
United Kingdom	8,731	8,725	10,362
Brazil	7,120	10,356	11,334
Others	50,901	45,475	48,107
Net sales	$ 453,042	$ 433,823	$ 409,788

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

(U.S. Dollars, in thousands)	2018	2017	2016
Bone Growth Therapies			
U.S.	$ 195,189	$ 185,853	$ 176,510
International	63	47	51
Total Bone Growth Therapies	195,252	185,900	176,561
Spinal Implants			
U.S.	72,137	69,704	57,772
International	19,521	12,253	14,860
Total Spinal Implants	91,658	81,957	72,632
Biologics			
U.S.	59,668	62,670	57,574
International	16	54	338
Total Biologics	59,684	62,724	57,912
Orthofix Extremities			
U.S.	28,359	26,918	25,017
International	78,089	76,324	77,666
Total Orthofix Extremities	106,448	103,242	102,683
Consolidated			
U.S.	355,353	345,145	316,873
International	97,689	88,678	92,915
Net sales	$ 453,042	$ 433,823	$ 409,788

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

(U.S. Dollars, in thousands)	2018	2017
U.S.	$ 31,344	$ 34,008
Italy	7,732	7,658
Germany	861	933
United Kingdom	896	382
Brazil	191	475
Others	1,811	1,683
Total	$ 42,835	$ 45,139

17. Share-based compensation

At December 31, 2018, and 2017, 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, subject to shareholder approval, 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 and consultants and advisors who perform services for the Company and the Company's 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, 2018, 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, 2018, there were 971,763 options outstanding under the 2012 LTIP, of which 520,748 were exercisable. In addition, there were 339,452 shares of unvested restricted stock outstanding, some of which contain performance-based vesting conditions, and 371,676 restricted stock units outstanding, some of which contain performance-based or market-based vesting conditions, under the 2012 LTIP as of December 31, 2018.

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, 2018, there were 25,500 options outstanding under the 2004 LTIP, all of which were exercisable; in addition, there were no shares of unvested restricted stock outstanding.

Inducement Plan for Spinal Kinetics Employees

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 material to the individual's entering into and continuing employment with the Company. At December 31, 2018, there were 28,624 options outstanding under the Spinal Kinetics Inducement Plan, none of which were exercisable; in addition, there were 19,914 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 annual or other director compensation paid in cash for the current plan year. 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 year (which is a calendar year, running from January 1 to December 31) or, if lower, on the last day of the plan year.

Due to the compensatory nature of such plan, the Company records the related share-based compensation in the consolidated statement of income. As of December 31, 2018, the aggregate number of shares reserved for issuance under the Stock Purchase Plan is 2,350,000. As of December 31, 2018, 1,628,045 shares had been issued.

Share-Based Compensation Expense

Share-based compensation expense is recorded in the same line of the consolidated statements of income 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, 2018, 2017 and 2016:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2018**	**2017**	**2016**
Cost of sales	$ 522	$ 486	$ 553
Sales and marketing	1,802	1,471	1,230
General and administrative	15,197	9,671	13,132
Research and development	1,409	929	1,051
Total	$ 18,930	$ 12,557	$ 15,966

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2018**	**2017**	**2016**
Stock options	$ 3,061	$ 2,388	$ 2,021
Time-based restricted stock awards and stock units	7,265	5,540	6,016
Performance-based restricted stock awards and stock units	1,998	462	5,716
Market-based restricted stock units	5,256	2,904	948
Stock purchase plan	1,350	1,263	1,265
Total	$ 18,930	$ 12,557	$ 15,966

The income tax benefit related to this expense was $3.8 million, $3.4 million, and $4.3 million for the years ended December 31, 2018, 2017, and 2016, 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,		
	2018	**2017**	**2016**
Assumptions:			
Expected term (in years)	4.5	4.5	4.5
Expected volatility	28.7% – 30.1%	31.2%	30.6% – 32.3%
Risk free interest rate	2.55% – 2.79%	1.93%	1.07% – 1.92%
Dividend yield	—	—	—
Weighted average grant date fair value	$ 16.28	$ 13.32	$ 11.79

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 award. Expected volatility is estimated based on the historical volatility of the Company's stock.

Summaries of the status of the Company's stock option plans as of December 31, 2018 and 2017 and changes during the year ended December 31, 2018 are presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at December 31, 2017	1,086,822	$ 37.47	
Granted	231,548	$ 57.66	
Exercised	(100,821)	$ 27.80	
Forfeited	(41,662)	$ 48.80	
Outstanding at December 31, 2018	1,175,887	$ 41.87	6.61
Vested and expected to vest at December 31, 2018	1,175,887	$ 41.87	6.61
Exercisable at December 31, 2018	696,248	$ 36.67	5.36

As of December 31, 2018, the unamortized compensation expense relating to options granted and expected to be recognized was $3.0 million. This amount is expected to be recognized through April 2022 or over a weighted average period of approximately 1.4 years. The total intrinsic value of options exercised was $3.2 million, $2.2 million and $4.3 million for the years ended December 31, 2018, 2017 and 2016, respectively. For the year ended December 31, 2018 we received $2.8 million in cash from stock option exercises, with the tax benefit realized for the tax deductions from these exercises of $0.8 million.The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2018 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for the shares that had exercise prices that were lower than the $52.49 closing price of the Company's stock on December 31, 2018. The aggregate intrinsic value of options outstanding was $13.6 million, $18.7 million and $3.3 million for the years ended December 31, 2018, 2017, and 2016, respectively. The aggregate intrinsic value of options exercisable was $11.0 million, $12.4 million and $2.2 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Time-based Restricted Stock Awards and Stock Units

During the year ended December 31, 2018, the Company granted to employees and non-employee directors 172,108 shares of time-based restricted stock awards or stock units, which vest at various dates through December 2022. 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 at December 31, 2018 there are 27,982 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, 2018, 2017 and 2016 was $8.0 million, $7.3 million and $7.2 million, respectively. Unamortized compensation expense related to time-based restricted stock awards and stock units amounted to $12.2 million at December 31, 2018, and is expected to be recognized over a weighted average period of approximately 2.4 years. The aggregate intrinsic value of time-based restricted stock awards and stock units outstanding was $18.8 million, $17.8 million and $13.0 million for the years ended December 31, 2018, 2017 and 2016, 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. During the years ended December 31, 2018, 2017, or 2016, the Company did not grant any performance-based restricted stock awards or stock units to employees.

During the year ended December 31, 2015, the Company granted to employees 110,660 shares of performance-based restricted stock awards, which vest based upon the achievement of certain earnings or return on invested capital targets as of and for any of the years ended December 31, 2016, 2017, or 2018. Approximately $0.4 million, $0.5 million and $5.7 million of compensation expense has been recorded for the years ended December 31, 2018, 2017 and 2016, respectively, associated with these performance-based restricted stock awards. The fair value of performance-based restricted stock awards that vested during the year ended December 31, 2017, was $4.9 million. No performance-based restricted stock awards vested during the years ended December 31, 2018 or 2016. No unamortized compensation expense related to performance-based restricted stock awards remains as of December 31, 2018. The aggregate intrinsic value of performance-based restricted stock awards outstanding was $2.9 million, $3.0 million and $7.0 million for the years ended December 31, 2018, 2017, and 2016, respectively.

During the year ended December 31, 2015, the Company also granted 55,330 shares of performance-based restricted stock units to employees, which vest based upon the achievement of certain earnings or return on invested capital targets for the year ended December 31, 2018. Approximately $1.6 million of compensation expense has been recognized for the year ended December 31, 2018, associated with these 2015 performance-based restricted stock units. The Company did not record any compensation expense for the years ended December 31, 2017 or 2016 related to these 2015 performance-based restricted stock units as the requisite service period had not yet begun. No unamortized compensation expense related to these 2015 performance-based restricted stock units remains as of December 31, 2018. The aggregate intrinsic value of performance-based restricted stock units outstanding was $2.5 million, $3.0 million, and $2.0 million for the years ended December 31, 2018, 2017, and 2016, 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. During the years ended December 31, 2018, 2017 and 2016, the Company granted 97,420, 94,902 and 96,245 shares, respectively, of market-based restricted stock units to executive officers and certain employees. 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 2018, 2017, and 2016 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 in April 2018, July 2017, and July 2016, respectively. The Company recorded $5.3 million $2.9 million, and $0.9 million in compensation expense for the years ended December 31, 2018, 2017, and 2016, respectively, related to market-based restricted stock units. Unamortized compensation expense for market-based restricted stock units amounted to $6.5 million at December 31, 2018, and is expected to be recognized over a weighted average period of approximately 1.4 years. The aggregate intrinsic value of market-based restricted stock units outstanding was $14.2 million, $10.2 million, and $3.5 million for the years ended December 31, 2018, 2017, and 2016, 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, 2018 and 2017 and changes during the year ended December 31, 2018 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, 2017	325,874	$ 42.44	109,880	$ 33.12	187,314	$ 51.99
Granted	172,108	$ 57.18	—	$ —	97,420	$ 68.38
Vested and settled	(112,249)	$ 40.08	—	$ —	—	$ —
Cancelled	(28,141)	$ 48.84	(7,725)	$ 33.12	(13,439)	$ 60.83
Outstanding at December 31, 2018	357,592	$ 49.77	102,155	$ 33.12	271,295	$ 57.44

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, 2018, 2017 and 2016, expenses incurred relating to the 401(k) Plan, including matching contributions, were approximately $2.3 million, $2.0 million and $1.9 million, respectively.

The Company also operates defined contribution pension plans for its international employees meeting minimum service requirements. The Company's expenses for such pension contributions during each of the years ended December 31, 2018, 2017 and 2016 were $1.1 million, $1.1 million and $1.0 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 3.5% of total commissions earned from the Company. The Company's relations with its Italian employees, who represent 19.6% of total employees at December 31, 2018, 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.

There were $0.1 million in deferred compensation payments made in 2018, $0.2 million in 2017, and $0.1 million in 2016. The balance in other long-term liabilities as of December 31, 2018 and 2017 was $1.3 million and $1.4 million, respectively, 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)	2018	2017	2016
U.S.	$ 28,642	$ 27,774	$ 23,006
Non-U.S.	(5,757)	8,617	(3,982)
Income before income taxes	$ 22,885	$ 36,391	$ 19,024

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

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2018	2017	2016
U.S.			
Current	$ 9,480	$ 3,620	$ 558
Deferred	(3,430)	20,222	9,296
	6,050	23,842	9,854
Non-U.S.			
Current	2,255	4,062	4,509
Deferred	769	1,196	1,164
	3,024	5,258	5,673
Income tax expense	$ 9,074	$ 29,100	$ 15,527

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, 2018, 2017, and 2016 consist of the following:

	2018		2017[1]		2016[1]	
(U.S. Dollars, in thousands, except percentages)	Amount	Percent	Amount	Percent	Amount	Percent
Statutory U.S. federal income tax rate	$ 4,806	21.0%	$ 12,737	35.0%	$ 6,658	35.0%
State taxes, net of U.S. federal benefit	1,038	4.5	1,598	4.4	395	2.1
Foreign rate differential, including withholding taxes	784	3.4	(3,849)	(10.6)	(805)	(4.2)
Charges related to U.S. Government resolutions	—	—	—	—	2,050	10.8
Valuation allowances, net	4,116	18.0	3,548	9.7	6,149	32.3
Change in estimate on compensation expenses	—	—	—	—	(2,151)	(11.3)
Italian subsidiary intangible asset	(230)	(1.0)	(381)	(1.0)	(1,477)	(7.8)
Change of intention for foreign earnings	—	—	—	—	1,300	6.8
Domestic manufacturing deduction	—	—	(818)	(2.2)	—	—
Unrecognized tax benefits, net of settlements	81	0.4	6,002	16.5	3,049	16.0
Impact of the Tax Act	(560)	(2.4)	8,347	22.9	—	—
Equity compensation	(1,646)	(7.2)	272	0.7	334	1.8
Contingent consideration	528	2.3	—	—	—	—
Other, net	157	0.7	1,644	4.5	25	0.1
Income tax expense/effective rate	$ 9,074	39.7%	$ 29,100	80.0%	$ 15,527	81.6%

[1] The rate reconciliations for 2017 and 2016 are based on the U.S. federal income tax rate, rather than the Company's country of domicile rate. The Company believes, given the large proportion of taxable income earned in the U.S., this presentation is more meaningful.

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.

In January 2018, the FASB released guidance on the accounting for tax on the global intangible low taxed income ("GILTI") provisions of the Tax Act. The GILTI provisions impose a tax on foreign income in excess of deemed return on tangible assets of foreign corporations. The guidance indicated that either accounting for deferred taxes related to GILTI inclusion or to treat any taxes on GILTI inclusion as a period cost are both acceptable methods subject to an accounting policy election. The Company has made a policy election to treat any taxes on GILTI inclusion as a period cost.

The Company paid cash relating to taxes totaling $15.6 million, $3.3 million, and $4.4 million for the years ended December 31, 2018, 2017, and 2016, respectively.

During 2016, the Company revised its estimate relating to the deductibility of certain compensation expenses. This change in estimate reduced income tax expense and increased net income from continuing operations by $2.4 million and increased earnings per share by $0.13 for the year ended December 31, 2016.

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

	December 31,	
(U.S. Dollars, in thousands)	**2018**	**2017**
Intangible assets and goodwill	$ 1,682	$ 2,271
Inventories and related reserves	12,151	11,298
Deferred revenue and cost of goods sold	4,652	6,816
Other accruals and reserves	2,799	2,336
Accrued compensation	8,317	4,054
Allowance for doubtful accounts	2,346	2,617
Net operating loss and tax credit carryforwards	52,664	43,296
Other, net	2,200	1,748
	86,811	74,436
Valuation allowance	(49,014)	(46,271)
Deferred tax asset	$ 37,797	$ 28,165
Withholding taxes	—	(381)
Property, plant and equipment	(4,569)	(4,469)
Deferred tax liability	(4,569)	(4,850)
Net deferred tax assets	$ 33,228	$ 23,315

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 increase in the valuation allowance of $2.7 million during the year principally relates to the increase of valuation allowances on net operating loss carryforwards in foreign jurisdictions.

The Company has federal net operating loss carryforwards of $24.4 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 $49.0 million, of which $35.2 million relates to Spinal Kinetics and begins to expire in 2019. Additionally, the Company has net operating loss carryforwards in various foreign jurisdictions of approximately $159.5 million that begin to expire in 2019, the majority of which relate to the Company's Netherlands and Brazil operations.

During 2016, the Company changed its intention related to unremitted foreign earnings in its Puerto Rico subsidiary and certain United Kingdom subsidiaries. As a result of the change in intention, the Company recorded $1.3 million of income tax expense for the remitted and unremitted earnings in each of these subsidiaries. During the first quarter of 2017, the Company changed its intention related to unremitted foreign earnings in its Seychelles subsidiary. The tax impact was minimal.

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 $335.7 million at December 31, 2017 to $50.4 million at December 31, 2018. The substantial decrease is due to the elimination of US accumulated earnings and other impacts as a result of the Domestication. As a result of the 2017 Tax Act, current year earnings have been deemed to be repatriated. 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 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 $21.4 million and $22.5 million for the years ended December 31, 2018 and 2017, respectively. The Company recorded net interest and penalties on unrecognized tax benefits of $1.4 million, $2.3 million, and $2.1 million for the years ended December 31, 2018, 2017, and 2016, respectively, and had approximately $6.7 million and $5.3 million accrued for payment of interest and penalties as of December 31, 2018 and 2017, 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 related to the resolution of federal, state and foreign matters could be reduced by $3.3 million to $3.8 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, 2018, 2017, and 2016 follows:

(U.S. Dollars, in thousands)	2018	2017
Balance as of January 1,	$ 23,676	$ 19,400
Additions for current year tax positions	170	787
Increases for prior year tax positions	1,653	3,498
Settlements of prior year tax positions	(1,499)	—
Expiration of statutes	(2,649)	(9)
Balance as of December 31,	$ 21,351	$ 23,676

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 2014.

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 expects to recognize a benefit of approximately $2.0 million during 2019. The Company cannot reasonably determine if any state and local tax 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, 2018, 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,		
	2018	2017	2016
Weighted average common shares-basic	18,494,002	18,117,405	18,144,019
Effect of diluted securities:			
Unexercised stock options and employee stock purchase plan	313,648	209,691	161,092
Unvested time-based restricted stock awards	—	123,592	138,291
Unvested performance-based restricted stock awards	103,960	48,057	19,759
Weighted average common shares-diluted	18,911,610	18,498,745	18,463,161

There were 349,930, 418,859 and 542,555 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, 2018, 2017 and 2016, 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)

	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.

	2017				
(U.S. Dollars, in thousands, except per share data)	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter	Year
Net sales	$ 102,738	$ 108,942	$ 105,247	$ 116,896	$ 433,823
Cost of sales	22,581	23,177	23,717	23,562	93,037
Gross profit	80,157	85,765	81,530	93,334	340,786
Operating expense	74,238	77,767	72,496	75,474	299,975
Operating income	5,919	7,998	9,034	17,860	40,811
Net income (loss) from continuing operations	(2,308)	4,735	3,348	1,516	7,291
Net income (loss)	$ (2,654)	$ 3,853	$ 3,456	$ 1,568	$ 6,223
Net income (loss) per common share — basic:					
Net income (loss) from continuing operations	$ (0.13)	$ 0.26	$ 0.18	$ 0.08	$ 0.40
Net income (loss)	$ (0.15)	$ 0.21	$ 0.19	$ 0.09	$ 0.34
Net income (loss) per common share — diluted:					
Net income (loss) from continuing operations	$ (0.13)	$ 0.26	$ 0.18	$ 0.08	$ 0.39
Net income (loss)	$ (0.15)	$ 0.21	$ 0.19	$ 0.08	$ 0.34

22. Subsequent events

Options Medical, LLC 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 the 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 and, as an inducement to enter into employment with the Company, the Company provided 25,478 restricted stock units, with a fair value of $1.4 million, to the Options Medical founder, which will vest in one-third annual increments beginning on the first anniversary of the grant date and are contingent upon continued employment.

FDA Approval of M6-C Artificial Cervical Disc

On February 6, 2019, the Company obtained FDA approval of the M6-C artificial cervical disc for patients suffering from cervical disease degeneration. The M6-C artificial disc was developed by Spinal Kinetics, a company acquired by the Company in April 2018. This approval triggered the Company's payment obligation of $15.0 million of contingent consideration attributable to the Spinal Kinetics purchase price. The Company has accrued a liability of $13.6 million within other current liabilities as of December 31, 2018, and paid the $15.0 million FDA Milestone payment on February 14, 2019 from cash on hand. The difference of $1.4 million between the payment and the liability as of December 31, 2018, will be recognized as an operating expense during the first quarter of 2019.

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 have agreed that Mr. Mason will continue to serve in his current role until his successor is appointed by the Board and commences employment (the "Retirement Date"). The parties have agreed that Mr. Mason will 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.

Under the Retirement Agreement, Mr. Mason will be eligible on the Retirement Date to receive full vesting acceleration of his unvested time-based equity awards, and he will continue to receive service credit under his performance based equity awards during the term of his consulting arrangement. 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 has agreed to provide, the parties have agreed that he will be granted an award of restricted stock units with a grant date fair market value of $2,000,000 that will vest one year following the date of grant, subject to him continuing to provide transition consulting services through his Retirement Date.

Exhibit 10.12

ORTHOFIX MEDICAL INC.
SECOND AMENDED AND RESTATED
STOCK PURCHASE PLAN, AS AMENDED

1. Purpose

The purpose of the Plan is to encourage eligible employees and directors to become owners of common stock of Orthofix Medical Inc., thereby giving them a greater interest in the growth and success of its business.

2. Definitions

The following definitions are used throughout the Plan:

(a) "Board of Directors" means the Board of Directors of the Company.

(b) "Code" means the Internal Revenue Code of 1986, as amended.

(c) "Committee" means the Compensation Committee of the Board of Directors. If, at any time, there is no acting Compensation Committee of the Board of Directors, the term "Committee" shall mean the Board of Directors.

(d) "Company" means Orthofix Medical Inc., a Delaware corporation, or any successor to substantially all of its business.

(e) "Director" means a member of the Board of Directors who is not also an employee of the Company or of a Subsidiary and is not an Employee for purposes of this Plan.

(f) "Effective Date" means the date determined in accordance with Section 11.

(g) "Employee" means a full-time or part-time employee of the Company or of a Subsidiary that has been designated as a participating employer under the Plan. Notwithstanding the foregoing, unless otherwise prohibited by the laws of the local jurisdiction, "Employee" shall not mean a temporary employee.

(h) "Fair Market Value" means, as of any date that requires the determination of the Fair Market Value of Orthofix Stock under this Plan, the value of a share of Orthofix Stock on such date of determination, calculated as follows:

(i) If shares of Orthofix Stock are then listed or admitted to trading on a Nasdaq market system or a stock exchange which reports closing sale prices, the Fair Market Value shall be the closing sale price on such date on such Nasdaq market system or principal stock exchange on which the share is then listed or admitted to trading, or, if no closing sale

price is quoted on such day, then the Fair Market Value shall be the closing sale price of the share on such Nasdaq market system or such exchange on the next preceding day on which a closing sale price is reported;

(ii) If shares of Orthofix Stock are not then listed or admitted to trading on a Nasdaq market system or a stock exchange which reports closing sale prices, the Fair Market Value shall be the average of the closing bid and asked prices of the share in the over-the-counter market on such date, or, if no closing bid and asked prices are reported on such day, then the Fair Market Value shall be the average of the closing bid and asked prices of the share in the over-the-counter market on the next preceding day on which closing bid and asked prices are reported; or

(iii) If neither (i) nor (ii) is applicable as of such date, then the Fair Market Value shall be determined by the Committee in good faith using any reasonable method of evaluation, which determination shall be conclusive and binding on all interested parties.

(i) "Orthofix Stock" means the Common Stock of the Company, $.10 par value. Unless the context indicates otherwise, the terms "share" or "shares" shall refer to a share or shares of Orthofix Stock.

(j) "Participant" means an Employee or Director who elects to participate in the Plan; provided, however, that no employee shall be allowed to be a Participant at any time if such employee, after exercising his or her rights to purchase shares under the Plan, would beneficially own shares of the Company's Common Stock (including shares that may be acquired under any outstanding options) representing five percent or more of the total combined voting power of all classes of stock of the Company. For purposes of the foregoing sentence, (i) an individual shall be considered as beneficially owning the stock owned, directly or indirectly, by or for his brothers and sisters (whether by the whole or half blood), spouse, ancestors, and lineal descendants, and (ii) stock owned, directly or indirectly, by or for a corporation, partnership, estate, or trust, shall be considered as being beneficially owned proportionately by or for its shareholders, partners, or beneficiaries.

(k) "Plan" means the Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as further amended from time to time.

(l) "Plan Year" means the 12-month period beginning on January 1 and ending on December 31; provided, that, pursuant to Section 7, the Committee may change the duration, frequency, start and end dates of future Plan Years. (Consistent with the foregoing, the Committee has resolved that, commencing with the 2019 calendar year, the "Plan Year" shall be the 12-month period beginning on November 1 and ending on October 31, and that to accommodate a transition to the new beginning and ending Plan Year dates, a one-time Plan Year shall begin on January 1, 2019 and end on October 31, 2019.)

(m) "Subsidiary" means (i) a domestic or foreign corporation, limited liability company, partnership or other entity with respect to which the Company, directly or indirectly, has the power, whether through the ownership of voting securities, by contract or otherwise, to

elect at least a majority of the members of such entity's board of directors or analogous governing body or (ii) any other domestic or foreign corporation, limited liability company, partnership or other entity in which the Company, directly or indirectly, has an equity or similar interest and which the Committee designates as a Subsidiary for purposes of the Plan.

3. Shares Subject to the Plan

(a) The total number of shares of Orthofix Stock reserved and available for issuance pursuant to the Plan shall not exceed 2,350,000 shares. The shares of Orthofix Stock purchasable pursuant to the Plan may be authorized but previously unissued shares of Orthofix Stock or shares of Orthofix Stock held in treasury or purchased in the open market or in privately negotiated transactions. The Company shall bear all costs in connection with issuance or transfer of any shares and all commissions, fees and other charges incurred in purchasing shares for distribution pursuant to the Plan.

(b) A Participant shall have no rights as a shareholder with respect to shares of Orthofix Stock purchasable pursuant to the Plan until the date the Participant or his nominee becomes the holder of record of such shares. No adjustment shall be made for dividends or other rights for which the record date is prior to such date.

(c) If the Committee determines that the total number of shares of Orthofix Stock to be purchased pursuant to the Plan on any particular date exceeds the number of shares then available for issuance under the Plan, the Committee shall make a pro rata allocation of the available shares on a uniform and non-discriminatory basis, and the payroll and other deductions of each Participant, to the extent in excess of the aggregate purchase price payable for the Orthofix Stock pro-rated to such individual, shall be refunded pursuant to Section 6.

4. Eligibility

Each Employee and Director (subject to Section 5(b) hereof) shall be eligible to participate in the Plan on the first day of any Plan Year, provided that he or she is actively employed or is a Director of the Company on such day.

5. Participation

(a) An eligible Employee shall become a Participant for any Plan Year by electing to contribute to the Plan, through payroll deductions, either a fixed amount or a percentage of his or her compensation for the Plan Year; provided, however, that such fixed amount or percentage shall not be less than 1% nor more than 25% (or such other percentage as the Committee may determine) of his or her compensation for the Plan Year. For purposes of the Plan, an Employee's compensation shall mean (i) for non-commissioned employees, his or her regular salary or straight-time wages, overtime, bonuses, and all other forms of compensation, excluding any car allowance or relocation expense reimbursements; and (ii) for commissioned employees, his or her commissions, guaranteed payments, overtime, bonuses, and all other forms of compensation, excluding any car allowance or relocation expense reimbursements. An Employee's election to participate in the Plan for any Plan Year shall be made prior to the

beginning of such Plan Year on an authorized form and shall be made in accordance with procedures established by the Committee from time to time.

(b) An eligible Director shall become a Participant for any Plan Year by electing to contribute to the Plan, through a deduction of his or her annual director or other compensation paid in cash, either a fixed amount or a percentage of such director compensation for the Plan Year. A Director's election to participate in the Plan for any Plan Year shall be made prior to the beginning of such Plan Year or, if later, within 30 days after the date on which such individual first becomes an eligible Director, on an authorized form and shall be made in accordance with procedures established by the Committee from time to time. Notwithstanding the foregoing, a Director's election to participate in the Plan for the Plan Year in which he or she first becomes eligible to participate may be made within 30 days after the date on which such individual first becomes eligible to participate; provided, however, such election shall apply only to an amount of his or her annual or other director compensation paid in cash for such Plan Year equal to the total amount of the Director's annual or other compensation paid in cash for such Plan Year multiplied by the ratio of the number of days remaining in the Plan Year after such election is made over the total number of days in the Plan Year for which such Director receives annual director or other compensation.

(c) A Participant must complete a new election with respect to each Plan Year in order to participate in the Plan for such Plan Year. During any Plan Year, a Participant may make a one-time election to decrease (including to zero) his or her rate of payroll deductions applicable to such Plan Year. Such one-time decrease shall not limit Participant's ability to withdraw from the Plan pursuant to Section 5(e) below. To make such one-time decrease, the Participant may submit a new election authorizing the new rate of payroll deductions at any time but no later than thirty (30) days before the last day of the Plan Year and in accordance with such other procedures as are established by the Committee from time to time.

(d) Participant contributions (i) in the case of Employees, shall be credited or deposited as soon as practicable following each payday, and (ii) in the case of Directors, shall be credited or deposited as soon as practicable following the Company's deduction of all or a portion of the Director's annual or other compensation. The Company shall maintain bookkeeping accounts of all Participant contributions but shall have no obligation to pay interest or to hold such amounts in a separate interest-bearing account at a bank or other financial institution (except as required by applicable law). To the extent separate interest-bearing accounts at a bank or other financial institution are required by applicable law, each such account shall be maintained in the name of the Plan for the benefit of Participants, and the balance of each such account shall remain the property of the Participants until transferred to the Company pursuant to Section 6. After the close of each Plan Year, the balance of the account will be used by (or transferred to) the Company to purchase Orthofix Stock for distribution to Participants and to pay cash in lieu of fractional shares as provided in Section 6.

(e) A Participant may elect to withdraw from the Plan by providing notice to the Committee before the last day of the Plan Year. Upon withdrawal from the Plan, all payroll and other deductions under the Plan shall immediately cease, and a Participant shall receive, in lieu of any other benefits under the Plan, the following: (i) a refund of his or her contributions as

soon as practicable following the date of withdrawal from the Plan, and in any event no later than the date that is two and one-half months following the last day of the Plan Year in which such Participant withdrew from the Plan, and (ii) to the extent a separate interest-bearing account at a bank or other financial institution was required by applicable law, a refund of the interest, if any, accrued through the date of payment at the rate in effect at the bank or other financial institution holding Participant contributions, which refund of accrued interest, if any, shall be paid immediately following the end of the Plan Year in which such Participant withdrew from the Plan, and in any event no later than the date that is two and one-half months following the last day of such Plan Year.

(f) An Employee's participation in the Plan shall terminate upon his or her termination of employment. An Employee's participation in the Plan shall, unless otherwise required by applicable law, terminate upon his or her leave of absence or absence from active employment for any other reason only if such Employee does not continue to make contributions to the Plan during such leave in accordance with procedures established by the Committee. An Employee whose participation in the Plan has terminated pursuant to this Section 5(f) shall be deemed to have withdrawn from the Plan for purposes of this Section 5.

(g) A Director's participation in the Plan shall terminate if, during any Plan Year, such Director ceases to be a member of the Board of Directors for any reason. A Director whose participation in the Plan has terminated pursuant to this Section 5(g) shall be deemed to have withdrawn from the Plan for purposes of this Section 5.

(h) A Participant who withdraws his or her contributions or otherwise ceases participation before the last day of the Plan Year may again participate in the Plan for any subsequent Plan Year, provided he or she satisfies the eligibility requirements of Section 4 and makes a timely election to contribute for such Plan Year.

(i) If any law, rule, or regulation applicable to an eligible Employee or Director prohibits the use of payroll or other deductions for purposes of the Plan, or if such deductions impair or hinder the operation of the Plan or affect the composition of the Board of Directors or any committee thereof, an alternative method of payment approved by the Committee may be substituted for such eligible Employee or Director, as applicable; provided, however, that if any law, rule or regulation relating to a Director participating in the Plan, in the sole discretion of the Board of Directors, would affect the composition of the Board of Directors or any committee thereof, the Board of Directors may terminate such Director's participation in the Plan.

6. Distribution of Common Stock

(a) As soon as practicable following the last day of each Plan Year, but in any event no later than the date that is two and one-half months following the last day of such Plan Year, the Committee shall distribute to each Employee and Director who was a Participant for the entire Plan Year (or, in the event of the death of an Employee or Director prior to such distribution, to the Employee's or Director's beneficiary, as applicable) a certificate or certificates representing the number of whole shares of Orthofix Stock determined by dividing (i)

the amount of the Participant's contributions for the Plan Year (plus interest, if any, accrued to the extent required by applicable law on such contributions through the end of the Plan Year) by (ii) 85% of the Fair Market Value of the Orthofix Stock on the first day of the Plan Year or, if lower, on the last day of the Plan Year. Cash in the amount of any fractional share shall be paid to the Participant by check as soon as practicable following the last day of each Plan Year, but in any event, no later than the date that is two and one-half months following the last day of such Plan Year.

(b) The Committee may, in its discretion, require a Participant to pay to the Company or its Subsidiary, as appropriate, prior to the distribution of the Orthofix Stock, the amount that the Committee deems necessary to satisfy the Company's obligation to withhold applicable taxes, at the minimum statutory rate, that the Participant incurs as a result of the Participant's participation in the Plan. To satisfy the minimum statutory tax withholding requirements, a Participant may (i) deliver to the Company or its Subsidiary, as appropriate, sufficient shares of Orthofix Stock (based upon the Fair Market Value of the Orthofix Stock at the date of withholding) to satisfy the Company's tax withholding obligations, (ii) deliver sufficient cash to the Company or its Subsidiary, as appropriate, to satisfy tax withholding obligations, or (iii) irrevocably elect for the Company or its Subsidiary, as appropriate, to withhold from the shares of Orthofix Stock to be distributed to the Participant the number of shares necessary (based upon the Fair Market Value of the Orthofix Stock at the date of withholding) to satisfy the Company's tax withholding obligations. In the event the Committee subsequently determines that the aggregate Fair Market Value (on the date of withholding) of shares of Orthofix Stock withheld as payment of any tax withholding obligation is insufficient to discharge that tax withholding obligation, then the Participant shall pay to the Company, or its Subsidiary, as appropriate, immediately upon the Committee's request, the amount of that deficiency. The Company or its Subsidiary, as appropriate, shall also have the right to deduct from all cash payments made to a Participant (whether or not such payment is made in connection with the Plan) any applicable taxes required to be withheld with respect to such payments.

7. Administration of the Plan

(a) The Committee shall administer the Plan and shall keep a written record of its actions and proceedings regarding the Plan and all dates, records and documents relating to its administration of the Plan. The Committee is authorized to interpret the Plan, to make, amend and rescind such rules as it deems necessary for the proper administration of the Plan, to make all other determinations necessary or advisable for the administration of the Plan and to correct any defect or supply any omission or reconcile any inconsistency in the Plan in the manner and to the extent that the Committee deems desirable to carry the Plan into effect. The powers and duties of the Committee shall include, without limitation, the following:

(i) Determining the amount of benefits payable to Participants and authorizing and directing the Company with respect to the payment of benefits under the Plan;

(ii) Determining the duration, frequency, start and end dates of future Plan Years;

(iii) Construing and interpreting the Plan in its sole discretion whenever necessary to carry out its intention and purpose and making and publishing such rules for the regulation of the Plan as are not inconsistent with the terms of the Plan;

(iv) Compiling and maintaining all records it determines to be necessary, appropriate or convenient in connection with the administration of the Plan; and

(v) Administering the Plan as necessary to take account of tax, securities law and other regulatory requirements of foreign jurisdictions.

(b) Any action taken or determination made by the Committee shall, except as otherwise provided in Section 8 below, be conclusive on all parties. No member of the Committee shall vote on any matter relating specifically to such member. In the event that a majority of the members of the Committee would be specifically affected by any action proposed to be taken (as opposed to being affected in the same manner as each other Participant in the Plan), such action shall be taken by the Board of Directors.

(c) The Committee may designate one or more of its members or the Chief Executive Officer or the Chief Financial Officer to carry out its responsibilities under such conditions or limitations as it may set, except that the Committee may not delegate its authority with regard to participation in the Plan by eligible Directors or by eligible Employees who are officers for purposes of Section 16(b) of the Securities Exchange Act of 1934, as amended.

(d) No member of the Board of Directors or the Committee, the Chief Executive Officer, the Chief Financial Officer, or any other officer or employee of the Company or any of its Subsidiaries to whom any duties or responsibilities are delegated hereunder shall be liable for any action or determination made in connection with the operation, administration or interpretation of the Plan, and the Company shall indemnify, defend and hold harmless each such person from any liability arising from or in connection with the Plan, except where such liability results directly from such person's fraud, willful misconduct or failure to act in good faith. In the performance of its responsibilities with respect to the Plan, the Committee shall be entitled to rely upon information and advice furnished by the Company's officers, the Company's accountants, the Company's counsel and any other person the Committee deems necessary, and no member of the Committee shall be liable for any action taken or not taken in reliance upon any such advice.

(e) Anything in the Plan to the contrary notwithstanding, any authority or responsibility that, under the terms of the Plan, may be exercised by the Committee may alternatively be exercised by the Board of Directors.

8. Claims Procedure

(a) If a Participant does not receive the timely payment of the benefits which the Participant believes are due under the Plan, the Participant may make a claim for benefits in the manner hereinafter provided.

(i) All claims for benefits under the Plan shall be made in writing and shall be signed by the Participant. Claims shall be submitted to the Committee, or to a representative designated by the Committee. If the Participant does not furnish sufficient information with the claim for the Committee to determine the validity of the claim the Committee shall indicate to the Participant any additional information which is necessary for the Committee to determine the validity of the claim.

(ii) Each claim hereunder shall be acted on and approved or disapproved by the Committee within 90 days following the receipt by the Committee of the information necessary to process the claim.

(iii) In the event the Committee denies a claim for benefits in whole or in part, the Committee shall notify the Participant in writing of the denial of the claim and notify the Participant of his or her right to a review of the Committee's decision. Such notice by the Committee shall also set forth, in a manner calculated to be understood by the Participant, the specific reason for such denial, the specific provisions of the Plan on which the denial is based and a description of any additional material or information necessary to perfect the claim with an explanation of the Plan's appeals procedure as set forth in this Section.

(iv) If no action is taken by the Committee on a Participant's claim within 90 days after receipt by the Committee, such claim shall be deemed to be denied for purposes of the following appeals procedure.

(b) Any Participant whose claim for benefits is denied in whole or in part may appeal for a review of the decision by the full Committee. Such appeal must be made within three months after the Participant has received actual or constructive notice of the denial as provided above. An appeal must be submitted in writing within such period and must:

(i) request a review by the full Committee of the claim for benefits under the Plan;

(ii) set forth all of the grounds upon which the Participant's request for review is based and any facts in support thereof; and

(iii) set forth any issues or comments which the Participant deems pertinent to the appeal.

(c) The Committee shall regularly review appeals by Participants. The Committee shall act upon each appeal within 60 days after receipt thereof unless special circumstances require an extension of the time for processing, in which case a decision shall be rendered by the Committee as soon as possible but not later than 120 days after the appeal is received by the Committee.

(d) The Committee shall make a full and fair review of each appeal and any written materials submitted by the Participant in connection therewith. The Committee may require the Participant to submit such additional facts, documents or other evidence as the Committee in its discretion deems necessary or advisable in making its review. The Participant

shall be given the opportunity to review pertinent documents or materials upon submission of a written request to the Committee, provided the Committee finds the requested documents or materials are pertinent to the appeal.

(e) On the basis of its review, the Committee shall make an independent determination of the Participant's eligibility for benefits under the Plan. The decision of the Committee on any claim for benefits shall be final and conclusive upon all parties thereto.

(f) In the event the Committee denies an appeal in whole or in part, the Committee shall give written notice of the decision to the Participant, which notice shall set forth, in a manner calculated to be understood by the Participant, the specific reasons for such denial and which shall make specific reference to the pertinent provisions of the Plan on which the Committee's decision is based.

9. Amendment and Termination

(a) The Plan may be amended or terminated by the Board of Directors at any time, provided that no such action shall have the effect of decreasing a Participant's accrued benefits as of the effective date of such action. Upon termination of the Plan, each Participant shall receive a refund of his or her contributions for the Plan Year (plus interest, if any, accrued to the extent required by applicable law through the date of termination).

(b) Without shareholder consent and without regard to whether any Participant rights may be considered to have been "decreased," the Committee shall be entitled to establish the exchange ratio applicable to payroll and other deductions, in a currency other than United States Dollars, permit payroll and other deductions in excess of the amount designated by a Participant in order to adjust for delays or mistakes in the Company's processing of properly completed payroll and other deduction elections, establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of shares of Orthofix Stock for each Participant properly correspond with amounts deducted from the Participant's compensation, and establish such other limitations or procedures as the Committee determines in its sole discretion advisable which are consistent with the Plan.

10. Beneficiary Designation

A Participant may file a written designation of a beneficiary who is to receive any Orthofix Stock or cash under the Plan in the event of such Participant's death prior to delivery to such Participant of such Orthofix Stock or cash. If a Participant is married and the designated beneficiary is not the spouse, spousal consent shall be required for such designation to be effective to the extent required by applicable law. Such beneficiary designation may be changed by the Participant at any time by written notice to the Committee. All beneficiary designations shall be made in such form and manner as the Committee may prescribe from time to time.

11. Effective Date

The Plan, as currently amended, became effective on July 17, 2018, the date that the most recent amendment increasing the number of shares authorized under the Plan was approved by the Company's shareholders.

12. Participants in Non-U.S. Jurisdictions

(a) To the extent that Participants are domiciled or resident outside of the U.S. or are domiciled or resident in the U.S. but are subject to the tax laws of a jurisdiction outside of the U.S., the Committee shall have the authority and discretion to adopt such modifications and procedures as it shall deem necessary or desirable to comply with the provisions of the laws of such non-U.S. jurisdictions in order to assure the viability of the benefits paid to such Participants. The authority granted under the previous sentence shall include the discretion for the Committee to adopt, on behalf of the Company, one or more sub-plans applicable to separate classes of eligible Employees and Directors who are subject to the laws of jurisdictions outside of the U.S.

(b) Notwithstanding any other provision of the Plan to the contrary, to the extent the Company is required to comply with the EU Prospectus Directive in any jurisdiction with respect to awards made to eligible Employees or Directors in such jurisdiction, the Committee may suspend the right of all eligible Employees and Directors in such jurisdiction to participate in the Plan.

13. Miscellaneous

(a) Nothing in the Plan shall confer upon a Participant the right to continue in the employ or continue to be a Director of the Company or a Subsidiary or shall limit or restrict the right of the Company or a Subsidiary to terminate the employment of a Participant at any time with or without cause.

(b) No right or benefit under the Plan shall be subject to anticipation, alienation, sale, assignment, pledge, encumbrance or charge, and any attempt to anticipate, alienate, sell, assign, pledge, encumber or charge such right or benefit shall be void. No such right or benefit shall in any manner be liable for or subject to the debts, liabilities or torts of a Participant.

(c) Neither the Company nor any Subsidiary shall be under any obligation to issue or deliver certificates for shares of Orthofix Stock pursuant to the Plan if such issuance or delivery would, in the opinion of the Committee, cause the Company to violate any provision of applicable law. The Company and its subsidiaries will use their best efforts to comply with applicable laws but will not be liable for any failure to comply.

(d) If any provision in the Plan is held by a court of competent jurisdiction to be invalid, void, or unenforceable, the remaining provisions shall nevertheless continue in full force and effect without being impaired or invalidated in any way.

(e) The Plan shall be construed and governed in accordance with the law of the State of New York and without giving effect to principles of conflicts of laws.

(f) All notices or other communications by a Participant to the Committee, the Company, or any Subsidiary under or in connection with the Plan shall be deemed to have been duly given when received in the form specified by the Committee at the location, or by the person, designated by the Committee for the receipt thereof.

(g) Notwithstanding anything to the contrary contained in the Plan, notices and other elections under this Plan may be delivered or made electronically, in the discretion of the Committee. In addition, in the discretion of the Committee, shares otherwise deliverable under the Plan may be delivered or otherwise evidenced through book entry or other electronic format without the need to deliver an actual share certificate; provided, however, an actual share certificate shall be delivered if requested by the Participant.

(h) The Board of Directors or the Committee may extend or terminate the benefits of the Plan to any Subsidiary at any time without the approval of the shareholders of the Company.

(i) The proceeds received by the Company from the sale of Orthofix Stock pursuant to the Plan shall be used for general corporate purposes.

(j) No shares of Orthofix Stock may be issued under this Plan unless the issuance of such shares has been registered under the Securities Act of 1933, as amended, and qualified under applicable state "blue sky" laws and any applicable non-U.S. securities laws, or the Company has determined that an exemption from registration and from qualification under such state "blue sky" laws and applicable non-U.S. securities laws is available. The Committee may require each Participant purchasing shares under the Plan to represent to and agree with the Company in writing that such eligible Employee or Director, as applicable, is acquiring the shares for investment purposes and not with a view to the distribution thereof. All certificates for shares delivered under the Plan shall be subject to such stock-transfer orders and other restrictions as the Committee may deem advisable under the rules, regulations, and other requirements of the Securities and Exchange Commission, any exchange upon which the shares are then listed, and any applicable securities law, and the Committee may cause a legend or legends to be put on any such certificates to make appropriate reference to such restrictions.

14. Compliance with Code Section 409A

The Plan and any options granted hereunder are intended to meet the short term deferral exemption from Code Section 409A and shall be interpreted and construed consistent with this intent. Notwithstanding any provision of the Plan to the contrary, in the event that the Board of Directors determines that the Plan or any option granted hereunder may be subject to Code Section 409A, the Board of Directors may, without the consent of Participants, including the affected Participant, adopt such amendments to the Plan or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Board of Directors determines are necessary or appropriate to (i) exempt the

Plan or any option granted hereunder from Code Section 409A or (ii) comply with the requirements of Code Section 409A and Department of Treasury regulations and other interpretive guidance issued thereunder. Notwithstanding the foregoing, the Company shall not be required to assume any increased economic burden in connection therewith.

Exhibit 10.13

ORTHOFIX MEDICAL INC.
AMENDED AND RESTATED 2012 LONG-TERM INCENTIVE PLAN

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ORTHOFIX MEDICAL INC.
AMENDED AND RESTATED 2012 LONG-TERM INCENTIVE PLAN

1. PURPOSE

The Plan is intended to (a) provide eligible persons with an incentive to contribute to the success of the Company and to operate and manage the Company's business in a manner that will provide for the Company's long-term growth and profitability, and (b) provide a means of obtaining, rewarding and retaining key personnel. To this end, the Plan provides for the grant of options, stock appreciation rights, restricted stock, stock units (including deferred stock units), unrestricted stock, dividend equivalent rights, other equity-based awards and cash bonus awards. Any of these Awards may, but need not, be made as performance incentives to reward the holders of such Awards for the achievement of annual or long-term performance goals in accordance with the terms of the Plan. Options granted under the Plan may be Non-qualified Stock Options or Incentive Stock Options, as provided herein.

2. DEFINITIONS

For purposes of interpreting the Plan and related documents (including Award Agreements), the following definitions shall apply, unless the context clearly indicates otherwise:

2.1 **"Affiliate"** means any company or other trade or business that controls, is controlled by or is under common control with the Company within the meaning of Rule 405 of Regulation C under the Securities Act, including any Subsidiary. For purposes of grants of Options or Stock Appreciation Rights, an entity may not be considered an Affiliate unless the Company holds a "controlling interest" in such entity within the meaning of Treasury Regulation Section 1.414(c)-2(b)(2)(i), *provided,* that (a) except as specified in clause (b) below, an interest of "at least 50 percent" shall be used instead of an interest of "at least 80 percent" in each case where "at least 80 percent" appears in Treasury Regulation Section 1.414(c)-2(b)(2)(i) and (b) where the grant of Options or Stock Appreciation Rights is based upon a legitimate business criterion, an interest of "at least 20 percent" shall be used instead of an interest of "at least 80 percent" in each case where "at least 80 percent" appears in Treasury Regulation Section 1.414(c)-2(b)(2)(i).

2.2 **"Annual Incentive Award"** means an Award, denominated in cash, made subject to the attainment of performance goals (as provided in **Section 14**) over a Performance Period of up to one (1) year, which shall be the Company's fiscal year, unless otherwise specified by the Committee.

2.3 **"Applicable Laws"** means the legal requirements relating to the Plan and the Awards under (a) applicable provisions of the Code, the Securities Act, the Exchange Act, any rules or regulations thereunder, and any other laws, rules, regulations, and government orders of any jurisdiction applicable to the Company or its Affiliates, (b) applicable provisions of the corporate, securities, tax, and other laws, rules, regulations, and government orders of any jurisdiction applicable to Awards granted to residents thereof, and (c) the rules of any Stock Exchange or Securities Market on which the Stock is listed.

2.4 **"Award"** means a grant under the Plan of an Option, a Stock Appreciation Right, Restricted Stock, a Stock Unit, Unrestricted Stock, a Dividend Equivalent Right, a Performance Award, an Other Equity-Based Award, an Annual Incentive Award or cash.

2.5 **"Award Agreement"** means the agreement, in such paper, electronic or other form as determined by the Committee, between the Company and a Grantee that evidences and sets out the terms and conditions of an Award.

2.6 **"Benefit Arrangement"** shall have the meaning set forth in **Section 15**.

2.7 **"Board"** means the Board of Directors of the Company.

2.8 **"Cause"** shall have the meaning set forth in the applicable agreement between the Grantee and the Company or an Affiliate, and in the absence of such agreement, means, as determined by the Committee, (i) gross negligence or willful misconduct in connection with the performance of duties; (ii) conviction of a criminal offense (other than minor traffic offenses); or (iii) material breach of any term of any employment, consulting or other services, confidentiality, intellectual property or non-competition agreements, if any, between the Service Provider and the Company or an Affiliate. Any determination by the Committee regarding whether an event constituting Cause shall have occurred shall be finding, binding and conclusive.

2.9 **"Code"** means the Internal Revenue Code of 1986, as amended, as now in effect or as hereafter amended, and any successor thereto. References in the Plan to any Code Section shall be deemed to include, as applicable, regulations and guidance promulgated under such Code Section.

2.10 **"Committee"** means a committee of, and designated from time to time by resolution of, the Board, which shall be constituted as provided in **Section 3.1** (or, if no Committee has been so designated, the entire Board itself).

2.11 **"Company"** means Orthofix Medical Inc., a Delaware corporation, and any successor thereto.

2.12 "**Corporate Transaction**" means, subject to **Section 18.10**, (a) a "Person" or "group" (within the meaning of Sections 13(d) and 14(d)(2) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 under the Exchange Act) of more than fifty percent (50%) of the total voting power of all classes of stock of the Company; (b) individuals who on the Effective Date constitute the Board (together with any new Directors whose election by such Board or whose nomination by such Board for election by the shareholders of the Company was approved by a vote of at least a majority of the members of such Board then in office who either were members of such Board on the Effective Date or whose election or nomination for election was previously so approved) cease for any reason to constitute a majority of the members of such Board then in office; (c) the Company consummates a transaction with, or merger with or into, any Person, or any Person consummates a transaction with, or merger with or into, the Company, other than any such transaction in which the holders of securities that represented one hundred percent (100%) of the voting stock of the Company immediately prior to such transaction (or other securities into which such securities are converted as part of such merger or consolidation transaction) own directly or indirectly at least a majority of the voting power of the surviving Person in such merger or consolidation transaction immediately after such transaction; (d) there is consummated any direct or indirect sale, lease, transfer, conveyance or other disposition (other than by way of merger or consolidation), in one transaction or a series of related transactions, of all or substantially all of the assets of the Company and its Subsidiaries, taken as a whole, to any "Person" or "group" (within the meaning of Sections 13(d) and 14(d)(2) of the Exchange Act); or (e) the shareholders of the Company adopt a plan or proposal for the liquidation, winding up or dissolution of the Company. The Board shall have full and final authority, in its sole discretion, to determine conclusively whether a Corporate Transaction has occurred pursuant to the above definition, the date of the occurrence of such Corporate Transaction, and any incidental matters relating thereto.

2.13 **"Disability"** means the Grantee is unable to engage in any substantial gainful activity by reason of a medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.

2.14 **"Dividend Equivalent Right"** means a right, granted to a Grantee pursuant to **Section 13**, to receive cash, Stock, other Awards or other property equal in value to dividends or other periodic payments paid or made with respect to a specified number of shares of Stock.

2.15 **"Effective Date"** means July 17, 2018, the date of the approval of the Plan, as amended and restated, by the Company's shareholders, the Plan, as amended and restated, having been approved by the Board on April 23, 2018.

2.16 **"Exchange Act"** means the Securities Exchange Act of 1934, as amended, as now in effect or as hereafter amended.

2.17 **"Fair Market Value"** means the fair market value of a share of Stock for purposes of the Plan, which shall be determined as follows, subject to **Section 18.3**:

(a) If on the Grant Date or other determination date the shares of Stock are listed on an established national or regional stock exchange (a "**Stock Exchange**"), or are publicly traded on an established securities market (a "**Securities Market**"), the Fair Market Value of a share of Stock shall be the closing price of the Stock as reported on such Stock Exchange or Securities Market (provided that if there is more than one such Stock Exchange or Securities Market, the Committee shall designate the appropriate Stock Exchange or Securities Market for purposes of the Fair Market Value determination) on the Grant Date or other determination date. If there is no such reported closing price on such date, the Fair Market Value of a share of Stock shall be, as determined by the Committee, the mean between (i) the highest bid price and the lowest asked price of the Stock as reported on such Stock Exchange or such Securities Market on such date or (ii) the high and low sale prices of the Stock as reported on such Stock Exchange or such Securities Market on such date, or if no sale of Stock shall have been so reported for such date, on the immediately preceding day on which any sale of Stock shall have been reported on such Stock Exchange or Securities Market.

(b) If on such Grant Date or other determination date the shares of Stock are not listed on a Stock Exchange or publicly traded on a Securities Market, the Fair Market Value of a share of Stock shall be the value of the Stock as determined by the Committee by the reasonable application of a reasonable valuation method, in a manner consistent with Code Section 409A.

2.18 **"Family Member"** means, with respect to any Grantee as of any date of determination, (a) a person who is a spouse, former spouse, child, stepchild, grandchild, parent, stepparent, grandparent, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother, sister, brother-in-law, or sister-in-law, including adoptive relationships, of such Grantee, (b) any person sharing such Grantee's household (other than a tenant or employee), (c) a trust in which any one or more of the persons specified in clauses (a) and (b) above (and such Grantee) own more than fifty percent (50%) of the beneficial interest, (d) a foundation in which any one or more of the persons specified in clauses (a) and (b) above (and such Grantee) control the management of assets, and (e) any other entity in which one or more of the persons specified in clauses (a) and (b) above (and such Grantee) own more than fifty percent (50%) of the voting interests.

2.19 **"Grant Date"** means, as determined by the Committee, the later to occur of (a) the date as of which the Company completes the corporate action constituting the Award, or (b) such date subsequent to the date specified in clause (a) as may be specified by the Committee.

2.20 **"Grantee"** means a person who receives or holds an Award under the Plan.

2.21 **"Incentive Stock Option"** means an "incentive stock option" within the meaning of Code Section 422.

2.22 **"Non-qualified Stock Option"** means an Option that is not an Incentive Stock Option.

2.23 **"Option"** means an option to purchase one or more shares of Stock at a specified Option Price pursuant to **Section 8**.

2.24 **"Option Price"** means the exercise price for each share of Stock subject to an Option.

2.25 **"Original Effective Date**" means April 13, 2012.

2.26 **"Other Agreement"** shall have the meaning set forth in **Section 15**.

2.27 **"Other Equity-Based Award"** means an Award representing a right or other interest that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on, or related to, Stock, other than an Option, a Stock Appreciation Right, Restricted Stock, a Stock Unit, Unrestricted Stock, a Dividend Equivalent Right, a Performance Award or an Annual Incentive Award.

2.28 **"Outside Director"** means a member of the Board who is not an officer or employee of the Company or any Subsidiary.

2.29 **"Parachute Payment"** shall have the meaning set forth in **Section 15**.

2.30 **"Performance Award"** means an Award made subject to the attainment of performance goals (as provided in **Section 14**) over a Performance Period of up to ten (10) years.

2.31 **"Performance Measures"** means objective performance criteria on which performance goals under Performance Awards are based, such as: (a) net earnings or net income; (b) operating earnings; (c) pretax earnings; (d) earnings per share; (e) share price, including growth measures and total shareholder return; (f) earnings before interest and taxes; (g) earnings before interest, taxes, depreciation and/or amortization; (h) earnings before interest, taxes, depreciation and/or amortization as adjusted to exclude any one or more of the following: stock-based compensation expense; income from discontinued operations; gain on cancellation of debt; debt extinguishment and related costs; restructuring, separation and/or integration charges and costs; reorganization and/or recapitalization charges and costs; impairment charges; gain or loss related to investments; sales and use tax settlement; and gain on non-monetary transactions; (i) sales or revenue growth, whether in general, by type of product or service, or by type of customer; (j) gross or operating margins; (k) return measures, including return on assets, capital, investment, equity, sales or revenue; (l) cash flow, including: operating cash flow; free cash flow, defined as earnings before interest, taxes, depreciation and/or amortization (as adjusted to exclude any one or more of the items that may be excluded pursuant to the Performance Measure specified in clause (h) above) less capital expenditures; levered free cash flow, defined as free cash flow less interest expense; cash flow return on equity; and cash flow return on investment; (m) productivity ratios; (n) expense targets; (o) market share; (p) financial ratios as provided in credit agreements of the Company and its Subsidiaries; (q) working capital targets; (r) completion of acquisitions of businesses or companies; (s) completion of divestitures and asset sales; and (t) any combination of the foregoing business criteria.

2.32 **"Performance Period"** means the period of time during which the performance goals under Performance Awards and Annual Incentive Awards must be met in order to determine the degree of payout and/or vesting with respect to any such Performance Awards or Annual Incentive Awards.

2.33 **"Plan"** means this Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan, as it may be further amended from time to time.

2.34 **"Prior Plan"** means the Orthofix International N.V. Amended and Restated 2004 Long-Term Incentive Plan.

2.35 **"Purchase Price"** means the purchase price, if any, for each share of Stock subject to an Award of Restricted Stock, Stock Units or Unrestricted Stock.

2.36 **"Restricted Stock"** means shares of Stock awarded to a Grantee pursuant to **Section 10**.

2.37 **"SAR Exercise Price"** means the per share exercise price of a SAR granted to a Grantee pursuant to **Section 9**.

2.38 **"Securities Act"** means the Securities Act of 1933, as amended, as now in effect or as hereafter amended.

2.39 **"Service"** means service of a Grantee as a Service Provider to the Company or any Affiliate. Unless otherwise provided in the applicable Award Agreement, a Grantee's change in position or duties with the Company or any Affiliate shall not result in interrupted or terminated Service, so long as the Grantee continues to be a Service Provider to the Company or any Affiliate. If a Service Provider's employment or other Service relationship is with an Affiliate and the applicable entity ceases to be an Affiliate, a termination of Service shall be deemed to have occurred when such entity ceases to be an Affiliate unless the Service Provider transfers his or her employment or other Service relationship to the Company or any other Affiliate. Any determination by the Committee whether a termination of Service shall have occurred for purposes of the Plan shall be final, binding and conclusive.

2.40 **"Service Provider"** means, as of any date of determination, (a) an employee, officer, or director of the Company or an Affiliate, or (b) a consultant (who is a natural person) or adviser (who is a natural person) of the Company or any Affiliate who provides bona fide services to the Company or any Affiliate and whose services are not in connection with the Company's sale of securities in a capital-raising transaction and do not directly or indirectly promote or maintain a market for the Company's stock.

2.41 **"Share Limit"** shall have the meaning set forth in **Section 4.1(a)**.

2.42 **"Stock"** means the common stock, par value $0.10 per share, of the Company, or any security for which the shares of Stock may be exchanged or into which the shares of Stock may be converted.

2.43 **"Stock Appreciation Right"** or **"SAR"** means a right granted to a Grantee pursuant to **Section 9**.

2.44 **"Stock Unit"** means a bookkeeping entry representing the equivalent of one share of Stock awarded to a Grantee pursuant to **Section 10** that may be settled, subject to the terms and conditions of the applicable Award Agreement, in shares of Stock, cash or a combination thereof.

2.45 **"Subsidiary"** means any corporation (other than the Company) or non-corporate entity with respect to which the Company and Subsidiaries collectively own, directly or indirectly, fifty percent (50%) or more of the total combined voting power of all classes of stock, membership interests or other ownership interests of any class or kind ordinarily having the power to vote for the directors, managers or other voting members of the governing body of such corporation or non-corporate entity. In addition, any other entity may be designated by the Committee as a Subsidiary, *provided* that (a) such entity could be

considered as a subsidiary according to generally accepted accounting principles in the United States of America and (b) in the case of an Award of Options or Stock Appreciation Rights, such Award would be considered to be granted in respect of "service recipient stock" under Code Section 409A.

2.46 **"Substitute Award"** means an Award granted upon assumption of, or in substitution for, outstanding awards previously granted under a compensatory plan by a business entity acquired or to be acquired by the Company or an Affiliate or with which the Company or an Affiliate has combined or will combine.

2.47 **"Ten Percent Shareholder"** means a natural person who owns more than ten percent (10%) of the total combined voting power of all classes of outstanding voting securities of the Company, the Company's parent (if any) or any of the Company's Subsidiaries. In determining stock ownership, the attribution rules of Code Section 424(d) shall be applied.

2.48 **"Unrestricted Stock"** shall have the meaning set forth in **Section 11**.

Unless the context otherwise requires, all references in the Plan to "including" shall mean "including without limitation."

3. ADMINISTRATION OF THE PLAN

3.1 Committee.

(a) The Committee shall administer the Plan and shall have such powers and authorities related to the administration of the Plan as are consistent with the Company's articles of incorporation and bylaws and Applicable Laws. Without limiting the generality of the foregoing, the Committee shall have full power and authority to take all actions and to make all determinations required or provided for under the Plan, any Award or any Award Agreement, and shall have full power and authority to take all such other actions and make all such other determinations not inconsistent with the specific terms and provisions of the Plan which the Committee deems to be necessary or appropriate to the administration of the Plan, any Award or any Award Agreement. All such actions and determinations shall be made by (i) the affirmative vote of a majority of the members of the Committee present at a meeting at which a quorum is present, or (ii) the unanimous consent of the members of the Committee executed in writing or evidenced by electronic transmission in accordance with the Company's articles of incorporation and bylaws and Applicable Laws. Unless otherwise expressly determined by the Board, the interpretation and construction by the Committee of any provision of the Plan, any Award or any Award Agreement shall be final, binding and conclusive whether or not expressly provided for in any provision of the Plan, such Award or such Award Agreement.

(b) In the event that the Plan, any Award or any Award Agreement provides for any action to be taken by or any determination to be made by the Board, such action may be taken or such determination may be made by the Committee or another committee constituted in accordance with this **Section 3.1** if the Board has delegated the power and authority to do so to the Committee or such other committee pursuant to this **Section 3.1**. Unless otherwise expressly determined by the Board, any such action or determination by the Committee or other committee shall be final, binding and conclusive whether or not expressly provided for in any provision of the Plan, such Award or such Award Agreement.

(c) Except as provided in **Section 3.2** and except as the Board may otherwise determine, the Committee shall consist of two or more Outside Directors of the Company who: (a) meet such requirements as may be established from time to time by the Securities and Exchange Commission for plans intended to qualify for exemption under Rule 16b-3 (or its successor) under the Exchange Act,

and (b) comply with the independence requirements of the Stock Exchange or Securities Market on which the Stock is listed or publicly traded; *provided,* that any action taken by the Committee shall be valid and effective whether or not members of the Committee at the time of such action are later determined not to have satisfied the requirements for membership set forth in this **Section 3.1** or otherwise provided in any charter of the Committee; *provided, further* that, notwithstanding anything in the Plan to the contrary, to the extent necessary to satisfy any transition rule or applicable transition guidance pertaining to Awards intended to satisfy the criteria for performance-based compensation under Code Section 162(m), the Committee administering such Awards shall consist of two or more Outside Directors who qualify as "outside directors" within the meaning of Code Section 162(m) and the applicable guidance thereunder. Without limiting the generality of the foregoing, the Committee may be the Compensation Committee of the Board or a subcommittee thereof if the Compensation Committee of the Board or such subcommittee satisfies the foregoing requirements.

(d) The Board may also appoint one or more committees of the Board, each composed of one or more directors of the Company who need not be Outside Directors, who may administer the Plan with respect to employees or other Service Providers who are not "executive officers" as defined in Rule 3b-7 under the Exchange Act or directors of the Company, may grant Awards under the Plan to such employees or other Service Providers, and may determine all terms of such Awards, subject to the requirements of Rule 16b-3 under the Exchange Act and any Stock Exchange or Securities Market on which the Stock is listed or publicly traded. Any reference to "Committee" in the Plan, any Award or any Award Agreement shall be deemed, as applicable, to refer to any committee appointed by the Board pursuant to this **Section 3.1**.

(e) To the extent permitted by Applicable Laws, the Committee may, by resolution, delegate some or all of its authority with respect to the Plan and Awards to the Chief Executive Officer of the Company and/or any other officer of the Company designated by the Committee, provided that the Committee may not delegate its authority hereunder (i) to make Awards to directors of the Company, (ii) to make Awards to employees who are (A) "executive officers" as defined in Rule 3b-7 under the Exchange Act, or (B) officers of the Company who are delegated authority by the Committee pursuant to this **Section 3.1**, or (iii) to interpret the Plan, any Award or any Award Agreement. Any delegation hereunder will be subject to the restrictions and limits that the Committee specifies at the time of such delegation or thereafter. Nothing in the Plan will be construed as obligating the Committee to delegate authority to any officer of the Company, and the Committee may at any time rescind the authority delegated to an officer of the Company appointed hereunder and delegate authority to one or more other officers of the Company. At all times, an officer of the Company delegated authority pursuant to this **Section 3.1** will serve in such capacity at the pleasure of the Committee. Any action undertaken by any such officer of the Company in accordance with the Committee's delegation of authority will have the same force and effect as if undertaken directly by the Committee, and any reference to the "Committee" in the Plan, any Award or any Award Agreement shall be deemed, to the extent consistent with the terms and limitations of such delegation, to refer to each officer delegated authority by the Committee pursuant to this **Section 3.1**.

3.2 Board.

The Board from time to time may exercise any or all of the powers and authorities related to the administration and implementation of the Plan, as set forth in **Section 3.1** and other applicable provisions of the Plan, as the Board shall determine, consistent with the Company's articles of incorporation and bylaws and Applicable Laws.

3.3 Terms of Awards.

Subject to the other terms and conditions of the Plan, the Committee shall have full and final authority to:

(a) designate Grantees;

(b) determine the type or types of Awards to be made to a Grantee;

(c) determine the value or number of shares of Stock to be subject to an Award;

(d) establish the terms and conditions of each Award (including the Option Price of any Option, the SAR Exercise Price of any SAR, and the Purchase Price of shares of Restricted Stock or vested Stock Units, the nature and duration of any restriction or condition (or provision for lapse thereof) relating to the vesting, exercise, transfer, or forfeiture of an Award or the shares of Stock subject thereto, the treatment of an Award in the event of a Corporate Transaction (subject to applicable agreements), and any terms or conditions that may be necessary to qualify Options as Incentive Stock Options);

(e) prescribe the form of each Award Agreement evidencing an Award;

(f) amend, modify, reprice (except as such practice is prohibited by **Section 3.5** herein), or supplement the terms of any outstanding Award, which authority shall include the authority, in order to effectuate the purposes of the Plan but without amending the Plan, to make Awards or to modify outstanding Awards made to eligible natural persons who are foreign nationals or are natural persons who are employed outside the United States to reflect differences in local law, tax policy, or custom, *provided* that, notwithstanding the foregoing, no amendment, modification or supplement of the terms of any outstanding Award shall, without the consent of the Grantee thereof, materially impair the Grantee's rights under such Award; and

(g) make Substitute Awards.

3.4 Forfeiture; Recoupment

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(a) The Committee may reserve the right in an Award Agreement to cause a forfeiture of the gain realized by a Grantee with respect to an Award thereunder on account of actions taken by, or failed to be taken by, such Grantee in violation or breach of, or in conflict with, any (i) employment agreement, (ii) non-competition agreement, (iii) agreement prohibiting solicitation of Employees or clients of the Company or an Affiliate, (iv) confidentiality obligation with respect to the Company or an Affiliate, (v) Company or Affiliate policy or procedure, (vi) other agreement, or (vii) other obligation of such Grantee to the Company or an Affiliate, as and to the extent specified in such Award Agreement. If the Grantee of an outstanding Award is an employee of the Company or an Affiliate and such Grantee's Service is terminated for Cause, the Committee may annul such Grantee's outstanding Award as of the date of the Grantee's termination of Service for Cause.

(b) Any Award granted pursuant to the Plan, to the extent provided in any Award Agreement relating thereto, shall be subject to mandatory repayment by the Grantee of such Award to the Company to the extent that such Grantee is or in the future becomes subject to (i) any Company or Affiliate "clawback" or recoupment policy or (ii) any Applicable Laws, in each case that require the repayment by such Grantee to the Company or Affiliate of compensation paid to such Grantee by the Company or an Affiliate in the event that such Grantee fails to comply with, or violates, the terms or requirements of such policy.

(c) If the Company is required to prepare an accounting restatement due to the material noncompliance by the Company, as a result of misconduct, with any financial reporting requirement under the federal securities laws, any Grantee of an Award under such Award Agreement who knowingly engaged in such misconduct, was grossly negligent in engaging in such misconduct, knowingly failed to prevent such misconduct or was grossly negligent in failing to prevent such misconduct, shall reimburse the Company the amount of any payment in settlement of such Award earned or accrued during the period of twelve (12) months following the first public issuance or filing with the United States Securities and Exchange Commission (whichever first occurred) of the financial document that contained information affected by such material noncompliance.

(d) Notwithstanding any other provision of the Plan or any provision of any Award Agreement, if the Company is required to prepare an accounting restatement, then Grantees shall forfeit any cash or Stock received in connection with an Award (or an amount equal to the Fair Market Value of such Stock on the date of delivery thereof to the Grantee if the Grantee no longer holds the shares of Stock) if pursuant to the terms of the Award Agreement for such Award, the amount of the Award earned or the vesting in the Award was expressly based on the achievement of pre-established performance goals set forth in the Award Agreement (including earnings, gains, or other performance goals) that are later determined, as a result of the accounting restatement, not to have been achieved.

3.5 No Repricing.

Notwithstanding anything in the Plan to the contrary, except in connection with a Corporate Transaction involving the Company (including, without limitation, any stock dividend, stock split, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination, or exchange of shares), the Company may not (a) amend the terms of outstanding Options or SARs to reduce the Option Price or SAR Price, as applicable, of such outstanding Options or SARs; (b) cancel or assume outstanding Options or SARs in exchange for or substitution of Options or SARs with an Option Price or SAR Price, as applicable, that is less than the Option Price or SAR Price, as applicable, of the original Options or SARs; or (c) cancel or assume outstanding Options or SARs with an Option Price or SAR Price, as applicable, above the current Fair Market Value in exchange for cash, Awards, or other securities, in each case, unless such action (i) is subject to and approved by the Company's shareholders, or (ii) is an appropriate adjustment pursuant **Section 17**.

3.6 Deferral Arrangement.

The Committee may permit or require the deferral of any payment pursuant to any Award into a deferred compensation arrangement, subject to such rules and procedures as it may establish, which may include provisions for the payment or crediting of interest or Dividend Equivalent Rights and, in connection therewith, provisions for converting such credits into deferred Stock equivalents and for restricting deferrals to comply with hardship distribution rules affecting tax-qualified retirement plans subject to Code Section 401(k)(2)(B)(IV), *provided* that no Dividend Equivalent Rights may be granted in connection with, or related to, an Award of Options or SARs. Any such deferrals shall be made in a manner that complies with Code Section 409A.

3.7 No Liability.

No member of the Board or the Committee shall be liable for any action or determination made in good faith with respect to the Plan, any Award, or any Award Agreement. Notwithstanding any provision of the Plan to the contrary, neither the Company, an Affiliate, the Board, the Committee, nor any person acting on behalf of the Company, an Affiliate, the Board, or the Committee will be liable to any Grantee or to the estate or beneficiary of any Grantee or to any other holder of an Award under the Plan by reason of

any acceleration of income, or any additional tax (including any interest and penalties), asserted by reason of the failure of an Award to satisfy the requirements of Code Section 422 or Code Section 409A or by reason of Code Section 4999, or otherwise asserted with respect to the Award; *provided*, that this **Section 3.7** shall not affect any of the rights or obligations set forth in an applicable agreement between the Grantee and the Company or an Affiliate.

3.8 Stock Issuance; Book-Entry.

Notwithstanding any provision of the Plan to the contrary, the ownership of the shares of Stock issued under the Plan may be evidenced in such a manner as the Committee, in its discretion, deems appropriate, including by book-entry or direct registration or by the issuance of one or more stock certificates.

4. STOCK SUBJECT TO THE PLAN

4.1 Number of Shares of Stock Available for Awards.

(a) Subject to adjustment pursuant to **Section 17**, the maximum number of shares of Stock reserved for issuance under the Plan shall be equal to the sum of (i) Four Million Seven Hundred Fifty Thousand (4,750,000) shares, plus (ii) the number of shares of Stock available for awards under the Prior Plan as of the Original Effective Date, plus (iii) the number of shares of Stock subject to awards outstanding under the Prior Plan as of the Original Effective Date which thereafter (A) terminate by expiration, forfeiture, cancellation, or otherwise without the issuance of such shares, (B) are settled in cash in lieu of such shares or (C) are exchanged with the Committee's permission, before the issuance of such shares, for compensatory awards not involving shares (the "**Share Limit**").

(b) Any of the shares of Stock reserved and available for issuance under the Plan may be used for any type of Award under the Plan, and any or all of the shares of Stock reserved for issuance under the Plan shall be available for issuance pursuant to Incentive Stock Options.

(c) Shares of Stock to be issued under the Plan shall be authorized but unissued shares, or, to the extent permitted by Applicable Laws, shares of treasury stock and issued shares that have been reacquired by the Company.

4.2 Adjustments in Authorized Shares of Stock.

In connection with mergers, reorganizations, separations, or other transactions involving the Company or a Subsidiary to which Code Section 424(a) applies, the Committee shall have the right to cause the Company to assume awards previously granted under a compensatory plan by another business entity that is a party to such transaction and to grant Substitute Awards under the Plan therefor. The Share Limit shall not be increased by the number of shares of Stock subject to any such assumed awards and Substitute Awards. Shares available for issuance under a shareholder-approved plan of a business entity that is a party to such transaction (as appropriately adjusted to reflect such transaction) may be used for Awards under the Plan and shall not reduce the number of shares of Stock otherwise available for issuance under the Plan, subject to applicable rules of any Stock Exchange or Securities Market on which the Stock is listed or publicly traded.

4.3 Share Usage.

(a) Shares of Stock subject to an Award shall be counted against the Share Limit as used as of the Grant Date.

(b) Any shares of Stock that are subject to Awards of Options and SARs shall be counted against the Share Limit set forth in **Section 4.1(a)** as one (1) share of Stock for every one (1) share of Stock subject to such Award. Any shares of Stock that are subject to Awards other than Options or SARs shall be counted against the Share Limit set forth in **Section 4.1(a)** as 1.84 shares for every one (1) share of Stock subject to such Award. With respect to SARs, the number of shares of Stock subject to an award of SARs shall be counted against the Share Limit under the Plan regardless of the number of shares of Stock actually issued to settle such SARs upon exercise. With respect to Performance Awards and Annual Incentive Awards, a number of shares of Stock at least equal to the target number of shares issuable under such Award, and with giving effect to the share counting rules set forth in this section, shall be counted against the Share Limit as of the Grant Date, but such number shall be adjusted to equal the actual number of shares issued, with giving effect to the share counting rules set forth in this section, upon settlement of the Performance Awards and Annual Incentive Awards, to the extent different from such number of shares.

(c) Any shares of Stock related to Awards under the Plan or awards outstanding under Prior Plan as of the Original Effective Date which thereafter terminate by expiration, forfeiture, cancellation, or otherwise without the issuance of such shares or is settled in cash in lieu of shares shall be available again for grant under the Plan in an amount determined in accordance with the methodology set forth in **Section 4.3(b)**.

(d) The number of shares of Stock available for issuance under the Plan shall not be increased by the number of shares of Stock (i) tendered or withheld or subject to an Award surrendered in connection with the purchase of shares of Stock upon exercise of an Option or Stock Appreciation Right, (ii) that were not issued upon the net settlement or net exercise of an Option or Stock-settled SAR granted under the Plan, (iii) deducted or delivered from payment of an Award in connection with the Company's tax withholding obligations as provided in **Section 18.3** or (iv) purchased by the Company with proceeds from Option or Stock Appreciation Right exercises.

5. EFFECTIVE DATE, DURATION AND AMENDMENTS

5.1 Effective Date.

The Plan became effective on the Original Effective Date. The Plan, as amended and restated, shall be effective as of the Effective Date. The Plan as in effect prior to its amendment and restatement shall apply to all awards granted on and after the Original Effective Date and prior to the Effective Date. Following the Original Effective Date, no awards shall be made under the Prior Plan. Notwithstanding the foregoing, shares of Stock reserved under the Prior Plans to settle awards which are made under the Prior Plans prior to the Effective Date may be issued and delivered following the Effective Date to settle such awards.

Notwithstanding any other provision of the Plan or any Award, each Award made under the Plan prior to November 2, 2017 that was intended to qualify as "performance-based compensation" within the meaning of Section 162(m)(4)(C) of the Code prior to its repeal ("**162(m) Awards**") and each Award which was otherwise not subject to the deduction limitation of Section 162(m) of the Code shall be subject to any additional limitations as the Committee determines necessary for such 162(m) Award to qualify as "performance-based compensation" as described in Section 162(m)(4)(C) of the Code prior to its repeal (or to be so exempt) pursuant to the transition relief rules in the Tax Cuts and Jobs Act of 2017, and to the extent any of the provisions of the Plan or any Award (or any amendments hereto pursuant to this amendment and restatement of the Plan) would cause any 162(m) Awards to fail to so qualify or other Awards to be so exempt, any such provisions shall not apply to such Awards to the extent necessary to ensure the continued qualification or exemption of such Awards. To the extent permitted by Applicable

Law, the Plan and any such Awards shall be deemed amended to the extent necessary to conform to such requirements.

5.2 Term.

The Plan shall terminate automatically on the first to occur of (a) the day before the tenth (10th) anniversary of the Effective Date, (b) the date determined in accordance with **Section 5.3**, and (c) the date determined in accordance with **Section 17.3**. Upon such termination of the Plan, all outstanding Awards shall continue to have full force and effect in accordance with the provisions of the terminated Plan and the applicable Award Agreement (or other documents evidencing such Awards).

5.3 Amendment, Suspension and Termination.

The Board may, at any time and from time to time, amend, suspend or terminate the Plan, *provided*, that with respect to Awards theretofore granted under the Plan, no amendment, suspension, or termination of the Plan shall, without the consent of the Grantee, materially impair the Grantee's rights under any such Award. The effectiveness of any amendment to the Plan shall be contingent on approval of such amendment by the Company's shareholders to the extent provided by the Board or required by Applicable Laws (including the rules of any Stock Exchange or Securities Market on which the Stock is then listed or publicly traded), *provided* that no amendment shall be made to the no-repricing provisions of **Section 3.5**, the Option Price provisions of **Section 8.1**, or the SAR Exercise Price provisions of **Section 9.1** without the approval of the Company's shareholders.

6. AWARD ELIGIBILITY AND LIMITATIONS

6.1 Eligible Grantees.

Subject to this **Section 6**, Awards may be made under the Plan to any Service Provider, as the Committee shall determine and designate from time to time.

6.2 Limitation on Shares of Stock Subject to Awards and Cash Awards.

During any time when the Company has a class of equity securities registered under Section 12 of the Exchange Act:

(a) The maximum number of shares of Stock subject to Options or SARs that may be granted under the Plan to a Grantee other than an Outside Director is 400,000 shares per fiscal year; *provided, however*, the maximum number of shares of Stock subject to Options or SARs that can be granted under the Plan to a Grantee other than an Outside Director in the fiscal year that the person is first employed by the Company or its Affiliates is 800,000 shares.

(b) The maximum number of shares of Stock that may be granted under the Plan, other than pursuant to Options or SARs, to a Grantee other than an Outside Director is 200,000 shares per fiscal year; *provided, however*, the maximum number of shares of Stock subject to Awards other than Options or SARs that can be granted under the Plan to a Grantee other than an Outside Director in the fiscal year that the person is first employed by the Company or its Affiliates is 400,000 shares.

(c) The maximum amount that may be paid as a cash-denominated Annual Incentive Award (whether or not cash-settled) in respect of a Performance Period of 12 months or less to a Grantee other than an Outside Director shall be $3,000,000, and the maximum amount that may be paid as a cash-

denominated Performance Award (whether or not cash-settled) in respect of a Performance Period greater than 12 months to a Grantee other than an Outside Director shall be $6,000,000.

(d) The maximum total compensation (including cash payments and the aggregate Grant Date fair value of Awards (computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or its successors)) that may be granted under the Plan) that may be paid to or granted in a fiscal year to an Outside Director for his or her service as a member of the Board or a committee of the Board is $1,000,000.

The preceding limitations in this **Section 6.2** are subject to adjustment as provided in **Section 17**.

6.3 Stand-Alone, Additional, Tandem and Substitute Awards.

Subject to **Section 3.5**, Awards granted under the Plan may, in the discretion of the Committee, be granted either alone or in addition to, in tandem with, or in substitution or exchange for, (a) any other Award, (b) any award granted under another plan of the Company, any Affiliate, or any business entity to be acquired by the Company or any Affiliate, or (c) any other right of a Grantee to receive payment from the Company or any Affiliate. Such additional, tandem and substitute or exchange Awards may be granted at any time. Subject to **Section 3.5,** if an Award is granted in substitution or exchange for another Award, or for an award granted under another plan of the Company, any Affiliate, or any business entity acquired by the Company or any Affiliate, the Committee shall require the surrender of such other Award or award under such other plan in consideration for the grant of such substitute or exchange Award. In addition, Awards may be granted in lieu of cash compensation, including in lieu of cash payments under other plans of the Company or any Affiliate. Notwithstanding **Section 8.1** and **Section 9.1**, but subject to **Section 3.5**, the Option Price of an Option or the grant price of an SAR that is a Substitute Award may be less than one hundred percent (100%) of the Fair Market Value of a share of Stock on the original Grant Date; *provided* that, the Option Price or grant price is determined in accordance with the principles of Code Section 424 for any Incentive Stock Option and consistent with Code Section 409A for any other Option or SAR.

6.4 Minimum Vesting Requirements.

Except with respect to a maximum of five percent (5%) of the Share Limit, (a) no portion of any Award (other than Substitute Awards) that vests on the basis of the Grantee's continued Service shall be granted with vesting conditions under which vesting occurs earlier than the one (1) year anniversary of the Grant Date, and (b) no portion of any Award (other than Substitute Awards) that vests upon the attainment of Performance Measures shall be granted with a Performance Period of less than twelve (12) months. Notwithstanding the preceding, the Committee may provide for the earlier vesting, exercisability, and/or settlement under any such Award (i) in the event of the Grantee's death, Disability or retirement, or (ii) in connection with a Corporate Transaction. The foregoing five percent (5%) limit shall be subject to adjustment consistent with the share usage rules of **Section 4.3** and the adjustment provisions of **Section 17**.

7. AWARD AGREEMENT

Each Award granted pursuant to the Plan shall be evidenced by an Award Agreement, which shall be in such form or forms as the Committee shall from time to time determine. Award Agreements employed under the Plan from time to time or at the same time need not contain similar provisions but shall be consistent with the terms of the Plan. Each Award Agreement evidencing an Award of Options shall specify whether such Options are intended to be Non-qualified Stock Options or Incentive Stock Options, and in the absence of such specification, such Options shall be deemed to constitute Non-qualified Stock Options.

In the event of any inconsistency between the Plan and an Award Agreement, the provisions of the Plan shall control.

8. TERMS AND CONDITIONS OF OPTIONS

8.1 Option Price.

The Option Price of each Option shall be fixed by the Committee and stated in the Award Agreement evidencing such Option. Except in the case of Substitute Awards, the Option Price of each Option shall be at least the Fair Market Value of a share of Stock on the Grant Date; *provided,* that in the event that a Grantee is a Ten Percent Shareholder, the Option Price of an Option granted to such Grantee that is intended to be an Incentive Stock Option shall be not less than one hundred ten percent (110%) of the Fair Market Value of a share of Stock on the Grant Date. In no case shall the Option Price of any Option be less than the par value of a share of Stock.

8.2 Vesting and Exercisability.

Subject to **Sections 6.4, 8.3** and **17.3**, each Option granted under the Plan shall become exercisable at such times and under such conditions as shall be determined by the Committee and stated in the Award Agreement; *provided,* that no Option relying on the five percent (5%) exception set forth in **Section 6.4** shall be granted to Grantees who are entitled to overtime under Applicable Laws that will vest or be exercisable within a six (6)-month period starting on the Grant Date. For purposes of this **Section 8.2**, fractional numbers of shares of Stock subject to an Option shall be rounded down to the next nearest whole number.

8.3 Term.

Each Option granted under the Plan shall terminate, and all rights to purchase shares of Stock thereunder shall cease, on the day before the tenth (10th) anniversary of the Grant Date of such Option, or under such circumstances and on such date prior thereto as is set forth in the Plan or as may be fixed by the Committee and stated in the Award Agreement relating to such Option; *provided,* that in the event that the Grantee is a Ten Percent Shareholder, an Option granted to such Grantee that is intended to be an Incentive Stock Option shall not be exercisable after the day before the fifth (5th) anniversary of the Grant Date of such Option; and *provided, further*, that, to the extent deemed necessary or appropriate by the Committee to reflect differences in local law, tax policy or custom with respect to any Option granted to a Grantee who is a foreign national or is a natural person who is employed outside the United States, such Option may terminate, and all rights to purchase shares of Stock thereunder may cease, upon the expiration of a period longer than ten (10) years from the Grant Date of such Option as the Committee shall determine.

8.4 Termination of Service.

Each Award Agreement with respect to the grant of an Option shall set forth the extent to which the Grantee thereof, if at all, shall have the right to exercise such Option following termination of such Grantee's Service. Such provisions shall be determined in the sole discretion of the Committee, need not be uniform among all Options issued pursuant to the Plan, and may reflect distinctions based on the reasons for termination of Service.

8.5 Limitations on Exercise of Option.

Notwithstanding any other provision of the Plan, in no event may any Option be exercised, in whole or in part, prior to the date on which the Plan is approved by the shareholders of the Company as provided

herein or after the occurrence of an event referred to in **Section 17** which results in the termination of such Option.

8.6 Method of Exercise.

Subject to the terms of **Sections 12** and **18.3**, an Option that is exercisable may be exercised by the Grantee's delivery to the Company or its designee or agent of notice of exercise on any business day, at the Company's principal office or the office of such designee or agent, on the form specified by the Company and in accordance with any additional procedures specified by the Committee. Such notice shall specify the number of shares of Stock with respect to which such Option is being exercised and shall be accompanied by payment in full of the Option Price of the shares of Stock for which such Option is being exercised, plus the amount (if any) of federal and/or other taxes which the Company may, in its judgment, be required to withhold with respect to the exercise of such Option.

8.7 Rights of Holders of Options.

A Grantee or other person holding or exercising an Option shall have none of the rights of a shareholder of the Company (for example, the right to receive cash or dividend payments or distributions attributable to the shares of Stock subject to such Option, to direct the voting of the shares of Stock subject to such Option, or to receive notice of any meeting of the Company's shareholders) until the shares of Stock subject thereto are fully paid and issued to such Grantee or other person. Except as provided in **Section 17**, no adjustment shall be made for dividends, distributions or other rights with respect to any shares of Stock subject to an Option for which the record date is prior to the date of issuance of such shares of Stock.

8.8 Delivery of Stock.

Promptly after the exercise of an Option by a Grantee and the payment in full of the Option Price with respect thereto, such Grantee shall be entitled to receive such evidence of such Grantee's ownership of the shares of Stock subject to such Option as shall be consistent with **Section 3.8**.

8.9 Transferability of Options.

Except as provided in **Section 8.10**, during the lifetime of a Grantee of an Option, only such Grantee (or, in the event of such Grantee's legal incapacity or incompetency, such Grantee's guardian or legal representative) may exercise such Option. Except as provided in **Section 8.10**, no Option shall be assignable or transferable by the Grantee to whom it is granted, other than by will or the laws of descent and distribution.

8.10 Family Transfers.

If authorized in the applicable Award Agreement and by the Committee, in its sole discretion, a Grantee may transfer, not for value, all or part of an Option which is not an Incentive Stock Option to any Family Member. For the purpose of this **Section 8.10**, a transfer "not for value" is a transfer which is (a) a gift, (b) a transfer under a domestic relations order in settlement of marital property rights, or (c) unless Applicable Laws do not permit such transfer, a transfer to an entity in which more than fifty percent (50%) of the voting interests are owned by Family Members (and/or the Grantee) in exchange for an interest in such entity. Following a transfer under this **Section 8.10**, any such Option shall continue to be subject to the same terms and conditions as were applicable immediately prior to such transfer, and the shares of Stock acquired pursuant to such Option shall be subject to the same restrictions with respect to transfers of shares as would have applied to the Grantee thereof. Subsequent transfers of transferred Options shall be prohibited except to Family Members of the original Grantee in accordance with this **Section 8.10** or by

will or the laws of descent and distribution. The provisions of **Section 8.4** relating to termination of Service shall continue to be applied with respect to the original Grantee of the Option, following which such Option shall be exercisable by the transferee only to the extent, and for the periods specified, in **Section 8.4**.

8.11 Limitations on Incentive Stock Options.

An Option shall constitute an Incentive Stock Option only (a) if the Grantee of such Option is an employee of the Company or any corporate Subsidiary, (b) to the extent specifically provided in the related Award Agreement and (c) to the extent that the aggregate Fair Market Value (determined at the time such Option is granted) of the shares of Stock with respect to which all Incentive Stock Options held by such Grantee become exercisable for the first time during any calendar year (under the Plan and all other plans of the Company and its Affiliates) does not exceed one hundred thousand dollars ($100,000). Except to the extent provided in the regulations under Code Section 422, this limitation shall be applied by taking Options into account in the order in which they were granted.

8.12 Notice of Disqualifying Disposition.

If any Grantee shall make any disposition of shares of Stock issued pursuant to the exercise of an Incentive Stock Option under the circumstances provided in Code Section 421(b) (relating to certain disqualifying dispositions), such Grantee shall notify the Company of such disposition immediately but in no event later than ten (10) days thereafter.

9. TERMS AND CONDITIONS OF STOCK APPRECIATION RIGHTS

9.1 Right to Payment and SAR Exercise Price.

A SAR shall confer on the Grantee to whom it is granted a right to receive, upon exercise thereof, the excess of (a) the Fair Market Value of one share of Stock on the date of exercise over (b) the SAR Exercise Price as determined by the Committee. The Award Agreement for a SAR shall specify the SAR Exercise Price, which shall be no less than the Fair Market Value of a share of Stock on the Grant Date of such SAR. SARs may be granted in tandem with all or part of an Option granted under the Plan or at any subsequent time during the term of such Option, in combination with all or part of any other Award or without regard to any Option or other Award; *provided,* that a SAR that is granted subsequent to the Grant Date of a related Option must have a SAR Exercise Price that is no less than the Fair Market Value of one share of Stock on the Grant Date of such SAR.

9.2 Other Terms.

Subject to **Sections 6.4**, **9.3** and **17.3**, the Committee shall determine, on the Grant Date or thereafter, the time or times at which and the circumstances under which a SAR may be exercised in whole or in part (including based on achievement of performance goals and/or future Service requirements), the time or times at which SARs shall cease to be or become exercisable following termination of Service or upon other conditions, the method of exercise, method of settlement, form of consideration payable in settlement, method by or forms in which shares of Stock shall be delivered or deemed to be delivered to Grantees, whether or not a SAR shall be granted in tandem or in combination with any other Award, and any and all other terms and conditions of any SAR; *provided*, that no SARs relying on the five percent (5%) exception set forth in **Section 6.4** shall be granted to Grantees who are entitled to overtime under Applicable Laws that will vest or be exercisable within a six (6)-month period starting on the Grant Date.

9.3 Term.

Each SAR granted under the Plan shall terminate, and all rights thereunder shall cease, on the day before the tenth (10th) anniversary of the Grant Date of such SAR, or under such circumstances and on such date prior thereto as is set forth in the Plan or as may be fixed by the Committee and stated in the Award Agreement relating to such SAR.

9.4 Rights of Holders of SARs

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A Grantee or other person holding or exercising a SAR shall have none of the rights of a shareholder of the Company (for example, the right to receive cash or dividend payments or distributions attributable to the shares of Stock underlying such SAR, to direct the voting of the shares of Stock underlying such SAR, or to receive notice of any meeting of the Company's shareholders) until the shares of Stock underlying such SAR, if any, are issued to such Grantee or other person. Except as provided in **Section 17**, no adjustment shall be made for dividends, distributions or other rights with respect to any shares of Stock underlying a SAR for which the record date is prior to the date of issuance of such shares of Stock, if any.

9.5 Transferability of SARs.

Except as provided in **Section 9.6**, during the lifetime of a Grantee of a SAR, only the Grantee (or, in the event of such Grantee's legal incapacity or incompetency, such Grantee's guardian or legal representative) may exercise such SAR. Except as provided in **Section 9.6**, no SAR shall be assignable or transferable by the Grantee to whom it is granted, other than by will or the laws of descent and distribution.

9.6 Family Transfers.

If authorized in the applicable Award Agreement and by the Committee, in its sole discretion, a Grantee may transfer, not for value, all or part of a SAR to any Family Member. For the purpose of this **Section 9.6**, a transfer "not for value" is a transfer which is (a) a gift, (b) a transfer under a domestic relations order in settlement of marital property rights or (c) unless Applicable Laws do not permit such transfers, a transfer to an entity in which more than fifty percent (50%) of the voting interests are owned by Family Members (and/or the Grantee) in exchange for an interest in such entity. Following a transfer under this **Section 9.6**, any such SAR shall continue to be subject to the same terms and conditions as were in effect immediately prior to such transfer, and shares of Stock acquired pursuant to a SAR shall be subject to the same restrictions on transfers of shares as would have applied to the Grantee or such SAR. Subsequent transfers of transferred SARs shall be prohibited except to Family Members of the original Grantee in accordance with this **Section 9.6** or by will or the laws of descent and distribution.

10. TERMS AND CONDITIONS OF RESTRICTED STOCK AND STOCK UNITS

10.1 Grant of Restricted Stock or Stock Units.

Awards of Restricted Stock or Stock Units may be made for consideration or for no consideration (other than the par value of the shares of Stock, which shall be deemed paid by past or future Services by the Grantee to the Company or an Affiliate).

10.2 Restrictions.

Subject to **Sections 6.4 and 17.3**, at the time a grant of Restricted Stock or Stock Units is made, the Committee may, in its sole discretion, (a) establish a period of time (a "**restricted period**") applicable to such Restricted Stock or Stock Units and (b) prescribe restrictions in addition to or other than the

expiration of the restricted period, including the satisfaction of corporate or individual performance goals, which may be applicable to all or any portion of such Restricted Stock or Stock Units as provided in **Section 14**. Awards of Restricted Stock or Stock Units may not be sold, transferred, assigned, pledged or otherwise encumbered or disposed of during the restricted period or prior to the satisfaction of any other restrictions prescribed by the Committee with respect to such Awards.

10.3 Restricted Stock Certificates; Book-Entry Registration.

Subject to **Section 3.8** and the immediately following sentence, the Company may issue, in the name of each Grantee to whom Restricted Stock has been granted, stock certificates representing the total number of shares of Restricted Stock granted to the Grantee, as soon as reasonably practicable after the Grant Date of such Restricted Stock. The Committee may provide in an Award Agreement that either (a) the Secretary of the Company shall hold such certificates for such Grantee's benefit until such time as such shares of Restricted Stock are forfeited to the Company or the restrictions applicable thereto lapse and such Grantee shall deliver a stock power to the Company with respect to each certificate, or (b) such certificates shall be delivered to such Grantee, *provided,* that such certificates shall bear legends that comply with applicable securities laws and regulations and make appropriate reference to the restrictions imposed on such Award of Restricted Stock under the Plan and such Award Agreement. Pursuant to **Section 3.8**, to the extent Restricted Stock is represented by a book-entry, such book entry shall be notated to evidence the restrictions imposed on such Award of Restricted Stock under the Plan and the applicable Award Agreement.

10.4 Rights of Holders of Restricted Stock.

Holders of Restricted Stock shall have the right to vote such shares of Restricted Stock and the right to receive any dividends declared or paid with respect to such shares of Restricted Stock. Notwithstanding the foregoing, cash dividends declared or paid on shares of Restricted Stock (i) shall not be paid currently but instead shall be accrued, (ii) shall be subject to the same vesting conditions and restrictions applicable to such underlying shares of Restricted Stock, and (iii) shall not vest or become payable unless and until the shares of Restricted Stock to which the dividends apply become vested and nonforfeitable. All stock distributions, if any, received by a Grantee with respect to Restricted Stock as a result of any stock split, stock dividend, combination of stock, or other similar transaction shall be subject to the same vesting conditions and restrictions applicable to such underlying shares of Restricted Stock.

10.5 Rights of Holders of Stock Units.

10.5.1 Voting and Dividend Rights.

Holders of Stock Units shall have no rights as shareholders of the Company (for example, the right to receive cash or dividend payments or distributions attributable to the shares of Stock subject to such Stock Units, to direct the voting of the shares of Stock subject to such Stock Units, or to receive notice of any meeting of the Company's shareholders). Subject to the restrictions on Dividend Equivalent Rights set forth in **Section 13**, the Committee may provide in an Award Agreement evidencing a grant of Stock Units that the holder of such Stock Units shall be entitled to receive Dividend Equivalent Rights.

10.5.2 Creditor's Rights.

A holder of Stock Units shall have no rights other than those of a general unsecured creditor of the Company. Stock Units represent an unfunded and unsecured obligation of the Company, subject to the terms and conditions of the applicable Award Agreement.

10.6 Termination of Service.

Unless the Committee provides otherwise in an Award Agreement or in writing after such Award Agreement is issued, but prior to termination of Grantee's Service, upon the termination of such Grantee's Service, any Restricted Stock or Stock Units held by such Grantee that have not vested, or with respect to which all applicable restrictions and conditions have not lapsed, shall immediately be deemed forfeited. Upon forfeiture of such Restricted Stock or Stock Units, the Grantee thereof shall have no further rights with respect thereto, including any right to vote such Restricted Stock or any right to receive dividends or Dividend Equivalent Rights, as applicable, with respect to such Restricted Stock or Stock Units.

10.7 Purchase of Restricted Stock and Shares of Stock Subject to Stock Units.

The Grantee shall be required, to the extent required by Applicable Laws, to purchase the Restricted Stock or shares of Stock subject to vested Stock Units from the Company at a Purchase Price equal to the greater of (a) the aggregate par value of the shares of Stock represented by such Restricted Stock or Stock Units or (b) the Purchase Price, if any, specified in the Award Agreement relating to such Restricted Stock or Stock Units. The Purchase Price shall be payable in a form provided in **Section 12** or, in the sole discretion of the Committee, in consideration for past or future Services rendered to the Company or an Affiliate.

10.8 Delivery of Shares of Stock.

Upon the expiration or termination of any restricted period and the satisfaction of any other conditions prescribed by the Committee, the restrictions applicable to Restricted Stock or Stock Units settled in shares of Stock shall lapse, and, unless otherwise provided in the applicable Award Agreement, a book-entry or direct registration or a stock certificate evidencing ownership of such shares of Stock shall, consistent with **Section 3.8**, be issued, free of all such restrictions, to the Grantee thereof or such Grantee's beneficiary or estate, as the case may be. Neither the Grantee, nor the Grantee's beneficiary or estate, shall have any further rights with regard to a Stock Unit once the shares of Stock represented by the Stock Unit have been delivered in accordance with this **Section 10.8**.

11. TERMS AND CONDITIONS OF UNRESTRICTED STOCK AWARDS AND OTHER EQUITY- BASED AWARDS

(a) In each case subject to the five percent (5%) limit set forth in **Section 6.4**, the Committee may, in its sole discretion, grant (or sell at the par value of a share of Stock or at such other higher purchase price determined by the Committee) an Award to any Grantee pursuant to which such Grantee may receive shares of Stock free of any restrictions ("**Unrestricted Stock**") under the Plan. Awards of Unrestricted Stock may be granted or sold to any Grantee as provided in the immediately preceding sentence in respect of past or future Service and other valid consideration, or in lieu of, or in addition to, any cash compensation due to such Grantee.

(b) The Committee may, in its sole discretion, grant Awards in the form of Other Equity-Based Awards, as deemed by the Committee to be consistent with the purposes of the Plan. Subject to **Section 6.4**, Awards granted pursuant to this **Section 11(b)** may be granted with vesting, value and/or payment contingent upon the achievement of one or more performance goals. The Committee shall determine the terms and conditions of Other Equity-Based Awards at the Grant Date or thereafter. Unless the Committee otherwise provides in an Award Agreement or in writing after such Award Agreement is issued, upon the termination of a Grantee's Service, any Other Equity-Based Awards held by such Grantee that have not vested, or with respect to which all applicable restrictions and conditions have not lapsed,

shall immediately be deemed forfeited. Upon forfeiture of any Other Equity-Based Award, the Grantee thereof shall have no further rights with respect to such Other Equity-Based Award.

12. FORM OF PAYMENT FOR OPTIONS AND RESTRICTED STOCK

12.1 General Rule.

Payment of the Option Price for the shares of Stock purchased pursuant to the exercise of an Option or the Purchase Price for Restricted Stock or vested Stock Units shall be made in cash or in cash equivalents acceptable to the Company.

12.2 Surrender of Shares of Stock.

To the extent that the applicable Award Agreement so provides, payment of the Option Price for shares of Stock purchased pursuant to the exercise of an Option or the Purchase Price for Restricted Stock or vested Stock Units may be made all or in part through the tender or attestation to the Company of shares of Stock, which shall be valued, for purposes of determining the extent to which such Option Price or Purchase Price has been paid thereby, at their Fair Market Value on the date of such tender or attestation.

12.3 Cashless Exercise.

With respect to an Option only (and not with respect to Restricted Stock or Stock Units), to the extent permitted by Applicable Laws and to the extent the Award Agreement so provides, payment of the Option Price for shares of Stock purchased pursuant to the exercise of an Option may be made all or in part by delivery (on a form acceptable to the Committee) of an irrevocable direction to a licensed securities broker acceptable to the Company to sell shares of Stock and to deliver all or part of the proceeds of such sale to the Company in payment of such Option Price and any withholding taxes described in **Section 18.3**.

12.4 Other Forms of Payment.

To the extent the Award Agreement so provides and/or unless otherwise specified in an Award Agreement, payment of the Option Price for shares of Stock purchased pursuant to exercise of an Option or the Purchase Price for Restricted Stock or vested Stock Units may be made in any other form that is consistent with Applicable Laws, including (a) Service to the Company or an Affiliate and (b) net exercise, net settlement or share withholding.

13. TERMS AND CONDITIONS OF DIVIDEND EQUIVALENT RIGHTS

13.1 Dividend Equivalent Rights.

A Dividend Equivalent Right is an Award entitling the recipient thereof to receive credits based on cash distributions that would have been paid on the shares of Stock specified in the Dividend Equivalent Right (or other Award to which such Dividend Equivalent Right relates) if such shares of Stock had been issued to and held by the recipient of such Dividend Equivalent Right as of the record date (with or without being subject to forfeiture or a repayment obligation). A Dividend Equivalent Right may be granted hereunder to any Grantee, *provided* that no Dividend Equivalent Rights may be granted in connection with, or related to, an Award of Options or SARs. Subject to this **Section 13**, the terms and conditions of Dividend Equivalent Rights shall be specified in the Award Agreement therefor. Dividend equivalents credited to the holder of a Dividend Equivalent Right may be paid currently (with or without being subject to forfeiture or a repayment obligation) or may be deemed to be reinvested in additional shares of Stock or Awards, which may thereafter accrue additional Dividend Equivalent Rights. Any such reinvestment in additional

shares of Stock shall be at the Fair Market Value thereof on the date of such reinvestment. Dividend Equivalent Rights may be settled in cash or shares of Stock or a combination thereof, in a single installment or in multiple installments, all as determined in the sole discretion of the Committee. Notwithstanding the foregoing, a Dividend Equivalent Right granted as a component of another Award (i) shall not be paid currently but instead shall be accrued, (ii) shall be subject to the same vesting conditions and restrictions applicable to the Award to which the Dividend Equivalent Rights correspond, and (iii) shall not vest or become payable unless and until the Award to which the Dividend Equivalent Rights correspond becomes vested and settled.

13.2 Termination of Service.

Unless the Committee otherwise provides in an Award Agreement or in writing after such Award Agreement is issued, a Grantee's rights in all Dividend Equivalent Rights shall automatically terminate upon the Grantee's termination of Service for any reason.

14. TERMS AND CONDITIONS OF PERFORMANCE AWARDS AND ANNUAL INCENTIVE AWARDS

14.1 Grant of Performance Awards and Annual Incentive Awards.

Subject to the terms and provisions of the Plan, the Committee, at any time and from time to time, may grant Performance Awards and/or Annual Incentive Awards to a Grantee in such amounts and upon such terms as the Committee shall determine.

14.2 Value of Performance Awards and Annual Incentive Awards.

Each Performance Award and Annual Incentive Award shall have an initial cash value or an actual or target number of shares of Stock that is established by the Committee at the time of grant. The Committee shall set performance goals in its discretion which, depending on the extent to which they are achieved, shall determine the value and/or the number shares of Stock subject to Performance Awards and Annual Incentive Awards that will be paid out to the Grantee thereof.

14.3 Earning of Performance Awards and Annual Incentive Awards.

Subject to the terms of the Plan, after the applicable Performance Period has ended, the Grantee of Performance Awards or Annual Incentive Awards shall be entitled to receive a payout of the value and/or the number shares of Stock subject to Performance Awards and Annual Incentive Awards earned by the Grantee over such Performance Period.

14.4 Form and Timing of Payment of Performance Awards and Annual Incentive Awards.

Payment of earned Performance Awards and Annual Incentive Awards shall be made, as determined by the Committee, in the form, at the time, and in the manner described in the applicable Award Agreement. Subject to the terms of the Plan, the Committee, in its sole discretion, (a) may pay earned Performance Awards in the form of cash, shares of Stock, other Awards, other property or a combination thereof and (b) shall pay the value of the earned Performance Awards and Annual Incentive Awards at the close of the applicable Performance Period, or as soon as reasonably practicable after the Committee has determined that the performance goal or goals have been achieved; *provided* that, unless specifically provided in the Award Agreement for such Awards, such payment shall occur no later than the fifteenth (15th) day of the third (3rd) month following the end of the calendar year in which such Performance Period ends. Any shares of Stock paid out under such Awards may be granted subject to any restrictions deemed

appropriate by the Committee. The determination of the Committee with respect to the form of payout of such Awards shall be set forth in the Award Agreement for the Awards.

14.5 Performance Conditions.

The right of a Grantee to exercise or receive a grant or settlement of any Performance Award or Annual Incentive Award, and the timing thereof, may be subject to the achievement of such Performance Measures as may be specified by the Committee. The Committee may use such business criteria and other measures of performance as it may deem appropriate in establishing any performance conditions. Performance under any of the Performance Measures (i) may be used to measure the performance of (A) the Company, its Subsidiaries and other Affiliates as a whole, (B) the Company, any Subsidiary, and/or any other Affiliate or any combination thereof, or (C) any one or more business units or operating segments of the Company, any Subsidiary, and/or any other Affiliate, in each case as the Committee, in its sole discretion, deems appropriate and (ii) may be compared to the performance of one or more other companies, or one or more published or special indices designated or approved by the Committee for such comparison, as the Committee, in its sole discretion, deems appropriate. In addition, the Committee, in its sole discretion, may select Performance Measure specified in **Section 2.31(e)** for comparison to performance under one or more stock market indices designated or approved by the Committee. The Committee also shall have the authority to provide for accelerated vesting of any Performance Award or Annual Incentive Award based on the achievement of performance goals pursuant to the Performance Measures specified in this **Section 14**. For the avoidance of doubt, nothing herein is intended to prevent the Committee from granting Awards subject to subjective performance conditions (including individual performance conditions); *provided,* that such Awards shall not be considered Performance Awards under the Plan.

14.5.1 Evaluation of Performance.

The Committee may provide in any Performance Award or Annual Incentive Award that any evaluation of performance may include or exclude any of the following events that occur during a Performance Period: (a) asset write-downs; (b) litigation or claims, judgments or settlements; (c) the effect of changes in tax laws, accounting principles, or other laws or provisions affecting reported results; (d) any reorganization or restructuring events or programs; (e) extraordinary, non-core, non-operating, or non-recurring items and items that are either of an unusual nature or of a type that indicates infrequency of occurrence as a separate component of income from continuing operations; (f) acquisitions or divestitures; (g) foreign exchange gains and losses; (h) impact of shares of Stock purchased through share repurchase programs; (i) tax valuation allowance reversals; (j) impairment expense; and (k) environmental expense.

15. PARACHUTE LIMITATIONS

If any Grantee is a "disqualified individual," as defined in Code Section 280G(c), then, notwithstanding any other provision of the Plan or of any other agreement, contract, or understanding heretofore or hereafter entered into by such Grantee with the Company or an Affiliate, except an agreement, contract, or understanding that expressly addresses Code Section 280G or Code Section 4999 (an "**Other Agreement**"), and notwithstanding any formal or informal plan or other arrangement for the direct or indirect provision of compensation to the Grantee (including groups or classes of Grantees or beneficiaries of which the Grantee is a member), whether or not such compensation is deferred, is in cash, or is in the form of a benefit to or for the Grantee (a "**Benefit Arrangement**"), any right of the Grantee to any exercise, vesting, payment or benefit under the Plan shall be reduced or eliminated:

(a) to the extent that such right to exercise, vesting, payment, or benefit, taking into account all other rights, payments, or benefits to or for the Grantee under the Plan, all Other Agreements, and all Benefit Arrangements, would cause any exercise, vesting, payment, or benefit to the Grantee under

the Plan to be considered a "parachute payment" within the meaning of Code Section 280G(b)(2) as then in effect (a "**Parachute Payment**"); and

(b) if, as a result of receiving such Parachute Payment, the aggregate after-tax amounts received by the Grantee from the Company under the Plan, all Other Agreements, and all Benefit Arrangements would be less than the maximum after-tax amount that could be received by the Grantee without causing any such payment or benefit to be considered a Parachute Payment.

Except as required by Code Section 409A or to the extent that Code Section 409A permits discretion, the Committee shall have the right, in the Committee's sole discretion, to designate those rights, payments, or benefits under the Plan, all Other Agreements, and all Benefit Arrangements that should be reduced or eliminated so as to avoid having such rights, payments, or benefits be considered a Parachute Payment; *provided, however,* to the extent any payment or benefit constitutes deferred compensation under Code Section 409A, in order to comply with Code Section 409A, the Company shall instead accomplish such reduction by first reducing or eliminating any cash payments (with the payments to be made furthest in the future being reduced first), then by reducing or eliminating any accelerated vesting of Options or SARs, then by reducing or eliminating any accelerated vesting of Restricted Stock or Stock Units, then by reducing or eliminating any other remaining Parachute Payments.

16. REQUIREMENTS OF LAW

16.1 General.

The Company shall not be required to offer, sell or issue any shares of Stock under any Award, whether pursuant to the exercise of an Option or SAR or otherwise, if the offer, sale or issuance of such shares of Stock would constitute a violation by the Grantee, the Company or an Affiliate, or any other person of any provision of the Company's articles of incorporation or bylaws or of Applicable Laws, including any federal or state securities laws or regulations. If at any time the Company shall determine, in its discretion, that the listing, registration or qualification of any shares of Stock subject to an Award upon any Stock Exchange or Securities Market or under any governmental regulatory body is necessary or desirable as a condition of, or in connection with, the offering, issuance, sale or purchase of shares of Stock in connection with any Award, no shares of Stock may be offered, issued or sold to the Grantee or any other person under such Award, whether pursuant to the exercise of an Option or SAR or otherwise, unless such listing, registration or qualification shall have been effected or obtained free of any conditions not acceptable to the Company, and any delay caused thereby shall in no way affect the date of termination of such Award. Without limiting the generality of the foregoing, upon the exercise of any Option or any SAR that may be settled in shares of Stock or the delivery of any shares of Stock underlying an Award, unless a registration statement under the Securities Act is in effect with respect to the shares of Stock subject to such Award, the Company shall not be required to offer, sell or issue such shares of Stock unless the Committee shall have received evidence satisfactory to it that the Grantee or any other person exercising such Option or SAR or accepting delivery of such shares may acquire such shares of Stock pursuant to an exemption from registration under the Securities Act. Any determination by the Committee in connection with the foregoing shall be final, binding, and conclusive. The Company may register, but shall in no event be obligated to register, any shares of Stock or other securities issuable pursuant to the Plan pursuant to the Securities Act. The Company shall not be obligated to take any affirmative action in order to cause the exercise of an Option or a SAR or the issuance of shares of Stock or other securities issuable pursuant to the Plan or any Award to comply with any Applicable Laws. As to any jurisdiction that expressly imposes the requirement that an Option or SAR that may be settled in shares of Stock shall not be exercisable until the shares of Stock subject to such Option or SAR are registered under the securities laws thereof or are exempt from such registration, the exercise of such Option or SAR under circumstances in which the laws

of such jurisdiction apply shall be deemed conditioned upon the effectiveness of such registration or the availability of such an exemption.

16.2 Rule 16b-3.

During any time when the Company has a class of equity security registered under Section 12 of the Exchange Act, it is the intention of the Company that Awards pursuant to the Plan and the exercise of Options and SARs granted hereunder that would otherwise be subject to Section 16(b) of the Exchange Act shall qualify for the exemption provided by Rule 16b-3 under the Exchange Act. To the extent that any provision of the Plan or action by the Committee does not comply with the requirements of such Rule 16b-3, such provision or action shall be deemed inoperative with respect to such Awards to the extent permitted by Applicable Laws and deemed advisable by the Committee, and shall not affect the validity of the Plan. In the event that such Rule 16b-3 is revised or replaced, the Board may exercise its discretion to modify the Plan in any respect necessary or advisable in its judgment to satisfy the requirements of, or to permit the Company to avail itself of the benefits of, the revised exemption or its replacement.

17. EFFECT OF CHANGES IN CAPITALIZATION

17.1 Changes in Stock.

If the number of outstanding shares of Stock is increased or decreased or the shares of Stock are changed into or exchanged for a different number of shares or kind of capital stock or other securities of the Company on account of any recapitalization, reclassification, stock split, reverse stock split, spin-off, combination of stock, exchange of stock, stock dividend or other distribution payable in capital stock, or other increase or decrease in such shares of Stock effected without receipt of consideration by the Company occurring after the Effective Date, the number and kinds of shares of stock for which grants of Options and other Awards may be made under the Plan, including the Share Limit set forth in **Section 4.1(a)**, the individual share limits set forth in **Section 6.2,** and the five percent (5%) limit set forth in **Section 6.4** shall be adjusted proportionately and accordingly by the Committee. In addition, the number and kind of shares of stock for which Awards are outstanding shall be adjusted proportionately and accordingly by the Committee so that the proportionate interest of the Grantee therein immediately following such event shall, to the extent practicable, be the same as immediately before such event. Any such adjustment in outstanding Options or SARs shall not change the aggregate Option Price or SAR Exercise Price payable with respect to shares that are subject to the unexercised portion of such outstanding Options or SARs, as applicable, but shall include a corresponding proportionate adjustment in the per share Option Price or SAR Exercise Price, as the case may be. The conversion of any convertible securities of the Company shall not be treated as an increase in shares effected without receipt of consideration. Notwithstanding the foregoing, in the event of any distribution to the Company's shareholders of securities of any other entity or other assets (including an extraordinary dividend, but excluding a non-extraordinary dividend, declared and paid by the Company) without receipt of consideration by the Company, the Committee shall, in such manner as it deems appropriate, adjust (a) the number and kind of shares of stock subject to outstanding Awards and/or (b) the aggregate and per share Option Price of outstanding Options and the aggregate and per share SAR Exercise Price of outstanding SARs as required to reflect such distribution.

17.2 Reorganization in Which the Company Is the Surviving Entity Which Does not Constitute a Corporate Transaction.

Subject to **Section 17.3**, if the Company shall be the surviving entity in any reorganization, merger, or consolidation of the Company with one or more other entities which does not constitute a Corporate Transaction, any Award theretofore granted pursuant to the Plan shall pertain to and apply to the securities to which a holder of the number of shares of Stock subject to such Award would have been entitled

immediately following such reorganization, merger, or consolidation, with a corresponding proportionate adjustment of the per share Option Price or SAR Exercise Price, if applicable, so that the aggregate Option Price or SAR Exercise Price thereafter shall be the same as the aggregate Option Price or SAR Exercise Price of the shares of Stock remaining subject to the Option or SAR as in effect immediately prior to such reorganization, merger, or consolidation. Subject to any contrary language in an Award Agreement, any restrictions applicable to such Award shall apply as well to any replacement shares received by the Grantee as a result of such reorganization, merger, or consolidation. In the event of any reorganization, merger, or consolidation of the Company referred to in this **Section 17.2**, Performance Awards and Annual Incentive Awards shall be adjusted (including any adjustment to performance goals applicable to such Awards deemed appropriate by the Committee) so as to apply to the securities that a holder of the number of shares of Stock subject to the Performance Awards or Annual Incentive Awards would have been entitled to receive immediately following such reorganization, merger, or consolidation.

17.3 Corporate Transaction in which Awards are not Assumed.

Except as otherwise provided in the applicable Award Agreement or with respect to Performance Awards and Annual Incentive Awards, in another agreement with the Grantee, or as otherwise set forth in writing, upon the occurrence of a Corporate Transaction in which outstanding Awards are not being assumed, continued, or substituted for, the following provisions shall apply to such Award, to the extent not assumed, continued, or substituted for:

(a) All Grantees of shares of Restricted Stock, Stock Units, and Dividend Equivalent Rights shall become vested in their Awards as of immediately prior to the occurrence of a Corporate Transaction and any shares of Stock or cash that become vested pursuant to the operation of this **Section 17.3(a)** shall be delivered, immediately prior to the occurrence of such Corporate Transaction;

(b) All Grantees of Options and SARs shall become immediately vested in their Awards as of immediately prior to the occurrence of a Corporate Transaction; and

(c) Either or both of the following two actions may be taken:

(i) At least fifteen (15) days prior to the scheduled consummation of such a Corporate Transaction, notice shall be given to all Grantees of vested Options and SARs outstanding hereunder (including Options and SARs that become vested pursuant to the operation of **Section 17.3(b)**) that such Options and SARs shall remain exercisable for a period of fifteen (15) days and shall thereafter be terminated. With respect to the Company's establishment of an exercise window, (A) any exercise of an Option or SAR during the fifteen (15)-day period referred to above shall be conditioned upon the consummation of the applicable Corporate Transaction and shall be effective only immediately before the consummation thereof, and (B) upon consummation of any Corporate Transaction, the Plan and all outstanding but unexercised Options and SARs shall terminate. The Committee shall send notice of an event that shall result in such a termination to all natural persons and entities who hold Options and SARs not later than the time at which the Company gives notice thereof to its shareholders.

and/or

(ii) The Committee may elect, in its sole discretion, to cancel any outstanding Awards of Options, SARs, Restricted Stock, Stock Units, and/or Dividend Equivalent Rights and pay or deliver, or cause to be paid or delivered, to the holder thereof an amount in cash or securities having a value (as determined by the Committee acting in good faith), in the case of Restricted Stock or Stock Units, equal to the formula or fixed price per share paid to holders of shares of Stock pursuant to such Corporate Transaction and, in the case of Options or SARs, equal to the product of the number of shares of Stock

subject such Options or SARs multiplied by the amount, if any, by which (A) the formula or fixed price per share paid to holders of shares of Stock pursuant to such transaction exceeds (B) the Option Price or SAR Exercise Price applicable to such Awards.

(d) For Performance Awards and Annual Incentive Awards denominated in Stock or Stock Units, if less than half of the Performance Period has lapsed, such Performance Awards and Annual Incentive Awards shall be converted into Restricted Stock or Stock Units assuming target performance has been achieved (or into Unrestricted Stock if no further restrictions apply). If more than half the Performance Period has lapsed, such Performance Awards and Annual Incentive Awards shall be converted into Restricted Stock or Stock Units based on actual performance to date (or into Unrestricted Stock if no further restrictions apply). If actual performance is not determinable, such Performance Awards and Annual Incentive Awards shall be converted into Restricted Stock or Stock Units assuming target performance has been achieved, based on the discretion of the Committee (or into Unrestricted Stock if no further restrictions apply).

(e) Other-Equity Based Awards shall be governed by the terms of the applicable Award Agreement.

17.4 Corporate Transaction in which Awards are Assumed.

Except as otherwise provided in the applicable Award Agreement, in another agreement with the Grantee, or as otherwise set forth in writing, upon the occurrence of a Corporate Transaction in which outstanding Awards are being assumed, continued, or substituted for, the following provisions shall apply to such Award, to the extent assumed, continued, or substituted for:

(a) The Plan and the Awards theretofore granted under the Plan shall continue in the manner and under the terms so provided in the event of any Corporate Transaction to the extent that provision is made in writing in connection with such Corporate Transaction for the assumption or continuation of such Awards, or for the substitution for such Awards of new common stock options, stock appreciation rights, restricted stock, common stock units, dividend equivalent rights and other equity-based awards relating to the stock of a successor entity, or a parent or subsidiary thereof, with appropriate adjustments as to the number of shares (disregarding any consideration that is not common stock) and option and stock appreciation rights exercise prices.

(b) In the event an Award is assumed, continued or substituted upon the consummation of any Corporate Transaction and the employment of such Grantee with the Company or an Affiliate is terminated without Cause within one year following the consummation of such Corporate Transaction, such Award shall be fully vested and may be exercised in full, to the extent applicable, beginning on the date of such termination and for the one-year period immediately following such termination or for such longer period as the Committee shall determine.

17.5 Adjustments

Adjustments under this **Section 17** related to shares of Stock or securities of the Company shall be made by the Committee, whose determination in that respect shall be final, binding and conclusive. No fractional shares or other securities shall be issued pursuant to any such adjustment, and any fractions resulting from any such adjustment shall be eliminated in each case by rounding downward to the nearest whole share. The Committee may provide in the applicable Award Agreements at the time of grant, or any time thereafter with the consent of the Grantee, for different provisions to apply to an Award in place of those provided in **Sections 17.1, 17.2, 17.3** and **17.4**. This **Section 17** shall not limit the Company's ability

to provide for alternative treatment of Awards outstanding under the Plan in the event of change in control events that are not Corporate Transactions.

17.6 No Limitations on Company.

The making of Awards pursuant to the Plan shall not affect or limit in any way the right or power of the Company to make adjustments, reclassifications, reorganizations, or changes of its capital or business structure or to merge, consolidate, dissolve, or liquidate, or to sell or transfer all or any part of its business or assets (including all or any part of the business or assets of any Subsidiary or other Affiliate) or to engage in any other transaction or activity.

18. GENERAL PROVISIONS

18.1 Disclaimer of Rights.

No provision in the Plan or in any Award or Award Agreement shall be construed to confer upon any individual the right to remain in the employ or Service of the Company or an Affiliate, or to interfere in any way with any contractual or other right or authority of the Company or an Affiliate either to increase or decrease the compensation or other payments to any natural person or entity at any time, or to terminate any employment or other relationship between any natural person or entity and the Company or an Affiliate. In addition, notwithstanding anything contained in the Plan to the contrary, unless otherwise stated in the applicable Award Agreement, no Award granted under the Plan shall be affected by any change of duties or position of the Grantee thereof, so long as such Grantee continues to provide Service. The obligation of the Company to pay any benefits pursuant to the Plan shall be interpreted as a contractual obligation to pay only those amounts provided herein, in the manner and under the conditions prescribed herein. The Plan and Awards shall in no way be interpreted to require the Company to transfer any amounts to a third party trustee or otherwise hold any amounts in trust or escrow for payment to any Grantee or beneficiary under the terms of the Plan.

18.2 Nonexclusivity of the Plan.

Neither the adoption of the Plan nor the submission of the Plan to the shareholders of the Company for approval shall be construed as creating any limitations upon the right and authority of the Board or the Committee to adopt such other incentive compensation arrangements (which arrangements may be applicable either generally to a class or classes of individuals or specifically to a particular individual or particular individuals) as the Board or the Committee, in its discretion, determines desirable.

18.3 Withholding Taxes.

(a) The Company or an Affiliate, as the case may be, shall have the right to deduct from payments of any kind otherwise due to a Grantee any federal, state, or local taxes of any kind required by Applicable Laws to be withheld with respect to the vesting of or other lapse of restrictions applicable to an Award or upon the issuance of any shares of Stock upon the exercise of an Option or pursuant to any other Award. At the time of such vesting, lapse, or exercise, the Grantee shall pay in cash to the Company or an Affiliate, as the case may be, any amount that the Company or such Affiliate may reasonably determine to be necessary to satisfy such withholding obligation; *provided, however,* that if there is a same day sale of shares of Stock subject to an Award, the Grantee shall pay such withholding obligation on the day on which the same-day sale is completed. Subject to the prior approval of the Company or an Affiliate, which may be withheld by the Company or such Affiliate, as the case may be, in its sole discretion, the Grantee may elect to satisfy such withholding obligation, in whole or in part, (a) by causing the Company or such Affiliate to withhold shares of Stock otherwise issuable to the Grantee or (b) by delivering to the

Company or such Affiliate shares of Stock already owned by the Grantee. The shares of Stock so withheld or delivered shall have an aggregate Fair Market Value equal to such withholding obligation. The Fair Market Value of the shares of Stock used to satisfy such withholding obligation shall be determined by the Company or such Affiliate as of the date on which the amount of tax to be withheld is to be determined. A Grantee who has made an election pursuant to this **Section 18.3** may satisfy such Grantee's withholding obligation only with shares of Stock that are not subject to any repurchase, forfeiture, unfulfilled vesting, or other similar requirements.

(b) The maximum number of shares of Stock that may be withheld from any Award to satisfy any federal, state, or local tax withholding requirements upon the exercise, vesting, or lapse of restrictions applicable to any Award or payment of shares of Stock pursuant to such Award, as applicable, may not exceed such number of shares of Stock having a Fair Market Value equal to the minimum statutory amount required by the Company or the applicable Affiliate to be withheld and paid to any such federal, state, or local taxing authority with respect to such exercise, vesting, lapse of restrictions, or payment of shares of Stock; *provided, however*, for so long as Accounting Standards Update 2016-09 or a similar rule remains in effect, the Board or the Committee has full discretion to choose, or to allow a Grantee to elect, to withhold a number of shares of Stock having an aggregate Fair Market Value that is greater than the applicable minimum required statutory withholding obligation (but such withholding may in no event be in excess of the maximum required statutory withholding amount(s) in such Grantee's relevant tax jurisdiction).

(c) Notwithstanding **Section 2.17** or this **Section 18.3**, for purposes of determining taxable income and the amount of the related tax withholding obligation pursuant to this **Section 18.3**, the Fair Market Value will be determined by the Committee in good faith using any reasonable method as it deems appropriate, to be applied consistently with respect to Grantees; *provided, further*, that the Committee shall determine the Fair Market Value of shares of Stock for tax withholding obligations due in connection with sales, by or on behalf of a Grantee, of such shares of Stock subject to an Award to pay the Option Price, SAR Exercise Price, and/or any tax withholding obligation on the same date on which such shares may first be sold pursuant to the terms of the applicable Award Agreement (including broker-assisted cashless exercises of Options and Stock Appreciation Rights and sell-to-cover transactions) in any manner consistent with applicable provisions of the Code, including but not limited to using the sale price of such shares on such date (or if sales of such shares are effectuated at more than one sale price, the weighted average sale price of such shares on such date) as the Fair Market Value of such shares, so long as such Grantee has provided the Company, or its designee or agent, with advance written notice of such sale.

18.4 Captions.

The use of captions in the Plan or any Award Agreement is for the convenience of reference only and shall not affect the meaning of any provision of the Plan or such Award Agreement.

18.5 Other Provisions.

Each Award granted under the Plan may contain such other terms and conditions not inconsistent with the Plan as may be determined by the Committee, in its sole discretion.

18.6 Number and Gender.

With respect to words used in the Plan, the singular form shall include the plural form, and the masculine gender shall include the feminine gender, as the context requires.

18.7 Severability.

If any provision of the Plan or any Award Agreement shall be determined to be illegal or unenforceable by any court of law in any jurisdiction, the remaining provisions hereof and thereof shall be severable and enforceable in accordance with their terms, and all provisions shall remain enforceable in any other jurisdiction.

18.8 Governing Law

The validity and construction of the Plan and the instruments evidencing the Awards hereunder shall be governed by, and construed and interpreted in accordance with, the laws of the State of Delaware, other than any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of the Plan and the instruments evidencing the Awards granted hereunder to the substantive laws of any other jurisdiction.

18.9 Foreign Jurisdictions

.

To the extent the Committee determines that the terms set by the Committee imposed by the Plan preclude the achievement of the purposes of the Plan in jurisdictions outside the United States, the Committee will have the authority and discretion to modify those terms and provide for such additional terms and conditions as the Committee determines to be necessary, appropriate, or desirable to accommodate differences in local law, policy, or custom or to facilitate administration of the Plan. The Committee may adopt or approve sub-plans, appendices, or supplements to, or amendments, restatements, or alternative versions of the Plan as in effect for any other purposes. The special terms and any sub-plans, appendices, supplements, amendments, restatements, or alternative versions, however, shall not include any provisions that are inconsistent with the terms of the Plan as in effect, unless the Plan could have been amended to eliminate such inconsistency without further approval by the Company's shareholders.

18.10 Section 409A of the Code.

The Plan is intended to comply with Code Section 409A to the extent subject thereto, and, accordingly, to the maximum extent permitted, the Plan will be interpreted and administered to be in compliance with Code Section 409A. Any payments described in the Plan that are due within the "short-term deferral period" within the meaning of Code Section 409A will not be treated as deferred compensation unless Applicable Laws require otherwise. Notwithstanding any provision of the Plan to the contrary, to the extent required to avoid accelerated taxation and tax penalties under Code Section 409A, amounts that would otherwise be payable and benefits that would otherwise be provided pursuant to the Plan during the six (6)-month period immediately following the Grantee's "separation from service" within the meaning of Code Section 409A will instead be paid on the first payroll date after the six (6)-month anniversary of the Grantee's Separation from Service (or the Grantee's death, if earlier).

Furthermore, notwithstanding anything in the Plan to the contrary, in the case of an Award that is characterized as deferred compensation under Code Section 409A, and pursuant to which settlement and delivery of the cash or shares of Stock subject to the Award is triggered based on a Corporate Transaction, in no event will a Corporate Transaction be deemed to have occurred for purposes of such settlement and delivery of cash or shares of Stock if the transaction is not also a "change in the ownership or effective control of" the Company or "a change in the ownership of a substantial portion of the assets of" the Company as determined under Treasury Regulation Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder). If an Award characterized as deferred compensation under Code Section 409A is not settled and delivered on account of the provision of the preceding sentence, the settlement and delivery shall occur on the next succeeding settlement and delivery triggering event that is a permissible

triggering event under Code Section 409A. No provision of this paragraph shall in any way affect the determination of a Corporate Transaction for purposes of vesting in an Award that is characterized as deferred compensation under Code Section 409A.

Notwithstanding the foregoing, neither the Company nor the Committee will have any obligation to take any action to prevent the assessment of any excise tax or penalty on any Grantee under Code Section 409A, and neither the Company or an Affiliate nor the Board or the Committee will have any liability to any Grantee for such tax or penalty.

To the extent that the Company determines that a Grantee would be subject to the additional twenty percent (20%) tax imposed on certain nonqualified deferred compensation plans pursuant to Code Section 409A as a result of any provision of any Award granted under the Plan, such provision shall be deemed amended to the minimum extent necessary to avoid application of such additional tax. The nature of any such amendment shall be determined by the Committee.

18.11 Non-Payment of Dividends or Dividend Equivalent Rights on Unvested Awards

For the avoidance of doubt, and notwithstanding anything in the Plan or any Award Agreement to the contrary, no dividends or Dividend Equivalent Rights shall be paid on any unvested Award and any dividends or Dividend Equivalent Rights granted in respect to any Award shall be paid at the time, if at all, that the Award to which it relates becomes vested.

* * *

Exhibit 10.39

TRANSITION AND RETIREMENT AGREEMENT

This Transition and Retirement Agreement (the "**Agreement**") is entered into by and among Orthofix Medical Inc. (the "**Company**") and Bradley R. Mason (the "**Executive**") (collectively, the "**Parties**").

WHEREAS, the Executive has, since March 2013, served as the President and Chief Executive Officer of the Company;

WHEREAS, the Parties have entered into a Change in Control and Severance Agreement, made and entered into as of November 1, 2016 (the "**Change in Control and Severance Agreement**");

WHEREAS, the Executive has received from the Company certain equity incentive awards (together, the "**Equity Awards**") previously granted to the Executive with respect to the Company pursuant to award agreements between the Company and the Executive (together, the "**Equity Award Agreements**");

WHEREAS, capitalized terms used, but not defined, herein shall have the meaning given such terms in the Change in Control and Severance Agreement; and

WHEREAS, the Company and the Executive desire to set forth certain promises, agreements and understandings relating to Executive's future retirement from the Company and the Company's selection of a successor President and Chief Executive Officer.

NOW, THEREFORE, upon execution and non-revocation of this Agreement, in exchange for the terms, conditions, and releases set forth below, the Parties agree as follows:

Effective Date

. This Agreement shall become effective on the eighth (8th) day after the Company receives this Agreement and the Release attached hereto as Exhibit A (the "**Release**") signed by the Executive (the "**Effective Date**"), provided that: (a) Executive does not revoke the Release within the seven (7) day period after he signs it; and (b) it is signed and delivered to the Company on or before February 25, 2019. For the avoidance of doubt, the Release and the Supplemental Release, as defined below, are considered incorporated into and part of this Agreement.

Target Retirement Date and Separation Date

.

(a) Executive's last day of employment will be the business day prior to the day that the successor President and Chief Executive Officer commences employment with the Company (such date, the "**Target Retirement Date**"), or such earlier date if Executive's employment is terminated prior to the Target Retirement Date pursuant to the terms of this Agreement. Executive's employment may be terminated in advance of the Target Retirement Date by the Company, with or without Cause, by the Executive with or without Good Reason (as modified by this Agreement) or due to the Executive's death or Disability. Further, notwithstanding the foregoing, the Target Retirement Date shall be no later than October 31, 2019. The date on which Executive separates from employment with the Company, regardless of whether such date is the Target Retirement Date or an earlier date, is referred to herein as the

"**Separation Date**". During the period from the Effective Date through the Separation Date (the "**Transition Period**"), the Executive will remain an employee of the Company, the Change in Control and Severance Agreement will remain in effect except to the extent modified pursuant to this Agreement, and the Executive will, in addition to his other duties and responsibilities, assist in the transition of his duties as requested from time to time by the Company.

(b) Effective as of the Separation Date, the Executive will resign his employment with the Company and from all offices, positions, directorships, chairmanships, and/or fiduciary responsibilities of any nature or description with the Company, its affiliates, and each of their respective subsidiaries, and each of their respective employee benefit plans.

Transition Period Consideration

. Provided that the Executive signs this Agreement, does not revoke it, and complies with all of its terms, during the Transition Period, the Company shall provide the Executive with the following:

(a) The Executive will continue to receive the Executive's base salary in effect as of the Effective Date, payable in the normal course in accordance with the Company's standard payroll practices, less applicable withholdings;

(b) The Company will pay Executive's reasonable attorneys' fees and expenses incurred since September 1, 2018, related to advising Executive with respect to his duties at the Company, his transition out of the Company, and this Agreement in an amount not to exceed fifteen thousand dollars ($15,000.00);

(c) The Executive will be eligible to continue to participate in the Company's annual cash incentive program, health insurance and other employee benefit plans, to the same extent as he was eligible on the Effective Date and in accordance with the terms of such annual cash incentive program, health insurance and other employee benefit plans;

(d) The Executive will be eligible to vest in any Equity Awards that vest in accordance with the current terms of the Equity Award Agreements during the Transition Period; and

(e) Provided the Executive continues to be employed on April 1, 2019, or if the Executive's employment is terminated by the Company without Cause prior to April 1, 2019 (in which case it is understood that Executive would remain a service provider to the Company as of the grant date as a result of the consulting services described in Section 12 hereof), the Company will grant to the Executive on April 1, 2019 restricted stock units under the Company's 2012 Long-Term Incentive Plan (pursuant to a form of grant agreement to be prepared and approved by the Compensation Committee of the Company's Board of Directors) with a grant date Fair Market Value of $2,000,000, which restricted stock units will become fully vested and delivered on April 1, 2020 subject to (i) Executive's remaining employed through the Target Retirement Date or otherwise being terminated by the Company without Cause prior to such Target Retirement Date, and (ii) Executive's complying with the terms of the Consulting Agreement (as defined herein) through April 1, 2020.

4. ***Separation Payments and Benefits.***

(a) If the Executive's employment terminates prior to the Target Retirement Date for any reason other than death, a termination by the Company without Cause or a termination by the Executive as a result of Disability (e.g., a voluntary retirement or resignation by the Executive or a termination for Cause by the Company), the Executive will be entitled to the payments and benefits, if any, as are set forth in the Change in Control and Severance Agreement and the Equity Award Agreements with respect to the applicable type of termination, and the Executive will not be entitled to the payments and benefits set forth in Section 4(b). For the avoidance of doubt, if the Executive determines to terminate his employment at any time prior to the Target Retirement Date, provided circumstances constituting Cause do not exist, the Executive will be treated as though he terminated employment as a result of a Qualified Retirement, in which case the Executive shall not receive the payments and benefits set forth in this Agreement, but will receive the payments and benefits payable in connection with a Qualified Retirement determined in accordance with the terms of the Change in Control and Severance Agreement and the Equity Award Agreements.

(b) If the Executive remains employed through the Target Retirement Date or the Executive's employment terminates prior to the Target Retirement Date as a result of death, a termination by the Company without Cause or a termination by the Executive as a result of Disability, subject to the Executive's signing (or, in the event of Executive's death, his duly authorized representative's signing) a supplemental release in the form attached as Exhibit A (the "**Supplemental Release**") on or within twenty-one (21) days after the Separation Date, and the Executive's (or the Executive's representative's) not revoking the Supplemental Release within seven (7) days after signing it, in full and final satisfaction of any amounts due or which could be due to the Executive pursuant to the Change in Control and Severance Agreement, the Equity Award Agreements or otherwise, the Executive's separation from service on the Separation Date will be treated as a Qualified Retirement by the Executive under the Change in Control and Severance Agreement as of the Separation Date and the Company will make and provide the following payments and benefits in connection with such Qualified Retirement (the "**Transition Benefits**"):

(i) (1) the Executive's annual base salary due through the Separation Date, (2) any amounts or benefits owing to the Executive as of the Separation Date under the then applicable benefit plans of the Company, at the time such amounts or benefits are due (including any accrued vacation payable), (3) any amounts owing to the Executive for reimbursement of expenses properly incurred by the Executive prior to the Separation Date, which shall be subject to and paid in accordance with the Company's expense reimbursement policy, (4) if, for the calendar year prior to the year during which the Separation Date occurs, Executive has achieved performance goals such that Executive has earned a bonus under the Company's annual cash incentive program (the "**Annual Cash Incentive Program**") and the Annual Cash Incentive Program bonus with respect to such prior calendar year has not yet been determined and/or paid, the amount of such bonus, payable at the same time as payments are made to other participants under the Annual Cash Incentive Program, and (5) a *pro rata* amount of the Annual Cash Incentive Program bonus, if any, with respect to the year during which the Separation Date occurs (based on the number of days the Executive was employed by the Company during such year of termination) based on the achievement of applicable performance

goals for such year, payable during the following year at the same time as payments are made to other participants under such Annual Cash Incentive Program;

(ii) With respect to the Equity Awards:

(1) all of Executive's outstanding unvested time-vesting restricted stock grants and stock options will become immediately vested and Executive will have four years from the Separation Date (or, if earlier, the expiration of the original term of the option) to exercise all outstanding options; and

(2) for outstanding unvested performance-vesting restricted stock and performance stock unit grants, Executive (1) will receive "Service" (as defined therein) credit through the date that he remains a consultant under the Consulting Agreement and (2) will be treated as having consummated a "Qualified Retirement" (as defined therein) thereunder on the date that such consulting services terminate.

(iii) As soon as administratively practicable after the Supplemental Release has become effective and irrevocable, the Company shall reimburse the Executive on a monthly basis for the Executive's monthly premium payments for COBRA health care coverage for the Executive and the Executive's eligible dependents for the period from the Separation Date through December 31, 2019.

(iv) The Transition Benefits will be subject to all applicable tax withholdings. The Transition Benefits will be in lieu of any severance pay the Executive may be entitled to receive under any other severance plan or arrangement, individual written employment agreement (including Section 3 of the Change in Control and Severance Agreement), or other agreement relating to payment upon separation from employment.

For the avoidance of doubt, (i) it is the intent of the parties that the foregoing payments and benefits are in excess of the payment and benefits that Executive would receive in the event of a Qualified Retirement under the Change in Control and Severance Agreement and the Equity Awards absent the existence of this Agreement, and (ii) the Transition Benefits (and the related separation from employment contemplated by Section 4(b)) do not include any right to receive the Severance Amount described in Section 3 of the Change in Control and Severance Agreement or the CiC Severance Amount described in Section 4 of the Change in Control and Severance Agreement.

5. ***Employee Covenants.*** Without limiting the generality of Section 11, the Executive acknowledges, and the Parties agree, that Section 9 (Restrictive Covenants) of the Change in Control and Severance Agreement will remain in full force and effect in accordance with its terms.

No Further Compensation

. The Executive acknowledges and agrees that, except with respect to the payments to be made and other benefits to be provided by the Company as set forth in this Agreement or otherwise pursuant to the Change in Control and Severance Agreement and the Equity Awards, (a) the Company has paid all salary, wages, bonuses, accrued vacation, commissions, and any and all other benefits and compensation that Executive has earned during his employment with the Company, (b) the Executive will not be

eligible for, or entitled to receive, any other bonus amounts following the Separation Date, and (c) all benefits and perquisites of employment with the Company will cease as of the Separation Date and the Executive will not receive any further salary, bonuses, vacation, vesting of benefits, or other forms of compensation after the Separation Date from the Company, except as required by applicable law. Nothing herein shall affect the Executive's right to, and the Company shall continue to provide, indemnification, advance, defense, or reimbursement pursuant to any applicable D&O or similar policies, the Company's bylaws, as they may be further amended, or applicable law. Furthermore, the Indemnity Agreement, dated August 1, 2018, between the Company and the Executive (the "**Indemnification Agreement**") shall remain in full force and effect.

Health Insurance

. Executive's group health insurance will cease on the last day of the month of the Separation Date. At that time, Executive will be eligible to continue his group health insurance benefits, subject to the terms and conditions of the benefit plan, federal COBRA law, and, as applicable, state insurance laws. Executive will receive additional information regarding his right to elect continued coverage under COBRA in a separate communication. Executive is not entitled to any additional compensation or remuneration to cover health care costs beyond the reimbursement provided for in Section 4(b)(iii), above.

Return of Company Property

. On or before the Separation Date, the Executive shall return to the Company any and all Company records and any and all Company property in his possession or under his control, including without limitation manuals, books, blank forms, documents, letters, memoranda, notes, notebooks, reports, printouts, computer disks, computer tapes, source codes, data, tables or calculations and all copies thereof, documents that in whole or in part may contain any trade secrets, confidential information, or other proprietary or secret information of the Company, and all copies thereof, and keys, vehicles, access cards, personal computers, telephones and other electronic equipment belonging to the Company or any of its Affiliates.

9. ***Compliance with Section 409A***. The terms of Section 8 of the Change of Control and Severance Agreement are incorporated into this Agreement.

10. ***Other Agreements***. The Change of Control and Severance Agreement, Equity Award Agreements, and the Indemnification Agreement will remain in full force and effect and will continue to bind Executive, except to the extent the terms of this Agreement contradict terms in the Change of Control and Severance Agreement or the Equity Award Agreements, in which event the terms of this Agreement shall control and shall operate as an amendment to such agreements as necessary. Otherwise, this Agreement represents the entire agreement between the Parties regarding the matters addressed herein, and it supersedes and replaces all prior agreements, representations, negotiations, or discussions between the Parties, whether written or oral.

Voluntary Execution of Agreement

. This Agreement is executed voluntarily and without any duress or undue influence on the part or behalf of the Parties hereto. The Parties acknowledge that (a) they have read this Agreement; (b) they have had the opportunity to seek legal counsel of their own choice; (c) they understand the terms and consequences of this

Agreement and of the releases it contains; and (d) they are fully aware of the legal and binding effect of this Agreement.

12. ***Consulting Services***. For a period of twelve months following the Separation Date, the Executive agrees to provide reasonable transition consulting services to the Company, when and as reasonably requested by the Company, and will receive payment of $40,000 per month for such services. Such services will include consulting with the Company in connection with historical information regarding the Company and providing certain introductions as requested by the Company, and assisting with other reasonable requests for information or other assistance that the Board of Directors of the Company or the Company may request. In connection with the foregoing, the Company and the Executive agree that on or about the Separation Date they will enter into a consulting agreement, materially consistent with the Company's standard form, to memorialize the foregoing terms (the "Consulting Agreement").

13. ***Miscellaneous.***

(a) Except for injunctive relief as set forth in Section 9 of the Change of Control and Severance Agreement, the parties agree that any dispute or controversy arising under or in connection with this Agreement shall be resolved exclusively and finally by binding arbitration in Lewisville, Texas, before a single arbitrator, with such arbitration to be conducted in accordance with the rules of the American Arbitration Association's Commercial Arbitration Rules then in effect. Judgment on the arbitrator's award may be entered by any court having jurisdiction. The Company shall be responsible for its own attorneys' fees, costs and expenses and shall pay to the Executive an amount equal to all reasonable attorneys' and related fees, costs and expenses incurred by the Executive in connection with such arbitration and entry of judgment, but only if the arbitrator determines that the Executive prevailed on a material issue of the arbitration. If there is any dispute between the Company and the Executive as to the payment of such fees and expenses, the arbitrator shall resolve such dispute, which resolution shall also be final and binding on the parties, and as to such dispute only, the burden of proof shall be on the Company.

(b) This Agreement shall be governed, construed and interpreted in accordance with the laws of the State of Texas (without regard to any provision of that State's rules on the conflicts of law that might make applicable the law of a jurisdiction other than that of the State of Texas). Subject to Section 13(a) hereof, all actions or proceedings for injunctive relief arising out of this Agreement shall exclusively be heard and determined in state or federal courts in the State of Texas having appropriate jurisdiction for Collin County, Texas. The parties expressly consent to the exclusive jurisdiction of such courts in any such action or proceeding and waive any objection to venue therein and any defense of forum non conveniens.

(c) This Agreement may be executed in any number of counterparts, each of which, when executed by both parties to this Agreement shall be deemed to be an original, and all of which counterparts together shall constitute one and the same instrument.

(d) The failure of either party hereto to enforce any right under this Agreement shall not be construed to be a waiver of that right, or of damages caused thereby, or of any other rights under this Agreement.

(e) This Agreement may not be amended or modified otherwise than by a written agreement executed by the parties hereto or their respective successors and legal representatives.

(f) This Agreement shall inure to the benefit of and be binding upon the Company and its successors and assigns. This Agreement shall bind any successor of or to the Company, its assets or its businesses (whether direct or indirect, by purchase, merger, consolidation or otherwise), in the same manner and to the same extent that the Company would be obligated under this Agreement if no succession had taken place. In the case of any transaction in which a successor would not by the foregoing provision or by operation of law be bound by this Agreement, the Company shall require such successor expressly and unconditionally to assume and agree to perform the Company's obligations under this Agreement, in the same manner and to the same extent that the Company would be required to perform if no such succession had taken place. All rights under this Agreement are personal to the Executive and, without the prior written consent of the Company, shall not be assignable by the Executive otherwise than by the laws of descent and distribution. This Agreement shall inure to the benefit of and be enforceable in the event of the Executive's death or disability by the Executive's legal representatives, heirs and legatees.

(g) The Executive and the Company acknowledge that the employment of the Executive by the Company is "at will" and may be terminated by either the Executive or the Company at any time. Nothing contained in the Agreement shall affect such rights to terminate, provided, however, that nothing in this Section 13(g) shall prevent the Executive from receiving any amounts payable pursuant to Section 4 hereof in the event of a termination described in such Section.

(h) Notwithstanding anything in this Agreement to the contrary, in no event shall anything in this Agreement (whether in the Release, the Supplemental Release, or otherwise) be interpreted to limit or restrict the Executive's right or ability to provide whistleblower information to the Securities and Exchange Commission regarding violations of the federal securities laws pursuant to Section 21F of the Exchange Act.

(i) Any provision in this Agreement which is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective only to the extent of such prohibition or unenforceability without invalidating or affecting the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction.

(j) Notices and all other communications contemplated by this Agreement shall be in writing and shall be deemed to have been duly given when personally delivered or when mailed by U.S. registered or certified mail, return receipt requested and postage prepaid or when sent by express U.S. mail or overnight delivery through a national delivery service (or an international delivery service in the case of an address outside the U.S.) with signature required. Notice to the Company shall be directed to the attention of the General Counsel of the Company at the address of the Company's headquarters, and notice to the Executive shall be directed to the Executive at the Executive's most recent personal residence on file with the Company.

(k) The Company shall deduct from the amounts payable to the Executive pursuant to this Agreement all required withholding amounts and deductions, including but not limited to federal, state and local withholding amounts in accordance all applicable laws and regulations and deductions authorized by the Executive. The Executive shall be solely responsible for and shall pay all taxes associated with the amounts payable under this Agreement.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have executed or caused to be executed this Transition and Retirement Agreement as of the date written below.

Bradley R. Mason

/s/ Bradley R. Mason Date: February 25, 2019
Bradley R. Mason

ORTHOFIX MEDICAL INC.

By: /s/ Ronald A. Matricaria Date: February 25, 2019
Ronald A. Matricaria
Chairman of the Board of Directors

EXHIBIT A

RELEASE AGREEMENT

You, for yourself, your spouse and your agents, successors, heirs, executors, administrators and assigns, hereby irrevocably and unconditionally forever release and discharge Orthofix Medical Inc., a corporation organized under the laws of the State of Delaware, and its direct and indirect subsidiaries (all such entities, collectively, the "Company"), its parents, divisions and affiliates and its and their current and former owners, directors, officers, stockholders, insurers, benefit plans, representatives, agents and employees, and each of their predecessors, successors, and assigns (collectively, the "Releasees"), from any and all actual or potential claims or liabilities of any kind or nature, including, but not limited to, any claims arising out of or related to your employment and separation from employment with the Company and any services that you provided to the Company; any claims for salary, commissions, bonuses, other severance pay, vacation pay, allowances or other compensation, or for any benefits under the Employee Retirement Income Security Act of 1974 ("ERISA") (except for vested ERISA benefits); any claims for discrimination, harassment or retaliation of any kind or based upon any legally protected classification or activity; any claims under Title VII of the Civil Rights Acts of 1964, the Civil Rights Act of 1866 and 1964, as amended, 42 U.S.C. § 1981, the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act, the Americans with Disabilities Act, 42 U.S.C. §1981, 42 U.S.C. § 1983, the Family Medical Leave Act and any similar state law, the Fair Credit Reporting Act and any similar state law, the Fair Credit Reporting Act, 15 U.S.C. § 1681, et seq., the Worker Adjustment and Retraining Notification Act, 29 U.S.C. § 2101, et seq., the Equal Pay Act and any similar state law, including the California Worker Adjustment and Retraining Notification Act, Cal. Labor Code § 1400, et seq., the California Fair Employment and Housing Act, Cal. Gov't Code § 12940, et seq., California Government Code Section 12900 et seq. (which prohibits discrimination based on protected characteristics including race, color, religion, sex, gender, sexual orientation, marital status, national origin, language restrictions, ancestry, physical or mental disability, medical condition, age, and denial of leave), California Civil Code Section 51 et seq. (which prohibits discrimination based on age, sex, race, color, religion, ancestry, national origin, disability, medical condition, marital status, or sexual orientation), the California Family Rights Act of 1993, the California Equal Pay Law, Cal. Lab. Code § 1197.5, et seq. or any California wage payment law, any other section of the California Labor Code, any section of the applicable Order of the California Industrial Welfare Commission, as well as any amendments to any such laws; any claims for any violation of any federal or state constitutions or executive orders; any claims for wrongful or constructive discharge, violation of public policy, breach of contract or promise (oral, written, express or implied), personal injury not covered by workers' compensation benefits, misrepresentation, negligence, fraud, estoppel, defamation, infliction of emotional distress, contribution and any claims under any other federal, state or local law, including those not specifically listed in this Release, that you, your heirs, executors, administrators, successors, and assigns now have, ever had or may hereafter have, whether known or unknown, suspected or unsuspected, up to and including the date of your execution of this Release.

For the purpose of implementing a full and complete release and discharge of the Releasees as set forth above, you acknowledge that this Release is intended to include in its effect, without limitation, all claims known or unknown that you have or may have against the Releasees which

arise out of or relate to your employment, including but not limited to compensation, performance or termination of employment with the Company, except for, and notwithstanding anything in this Release to the contrary, claims which cannot be released solely by private agreement. This Release also excludes any claims relating to any right you may have to payments pursuant to Sections 3 and/or 4 of the Transition and Retirement Agreement, entered into as of February 25, 2019, by and between the Company and you, any claim for workers' compensation benefits and any rights you may have to indemnification or directors' and officers' liability insurance under the Company's articles of association, certificates of incorporation or bylaws, any indemnification agreement to which you are a party or beneficiary or applicable law, as a result of having served as an officer, director or employee of the Company or any of its affiliates. You further acknowledge and agree that you have received all leave, compensation and reinstatement benefits to which you were entitled through the date of your execution of this Release, and that you were not subjected to any improper treatment, conduct or actions as a result of a request for leave, compensation or reinstatement.

You further acknowledge that you have read Section 1542 of the Civil Code of the State of California, which provides as follows:

A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS WHICH THE CREDITOR DOES NOT KNOW OR SUSPECT TO EXIST IN HIS OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE, WHICH IF KNOWN BY HIM OR HER MUST HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR.

You understand that Section 1542 gives you the right not to release existing claims of which you are not now aware, unless you voluntarily choose to waive this right. **Even though you are aware of this right, you nevertheless hereby voluntarily waive the right described in Section 1542 and any other statutes of similar effect, and elect to assume all risks for claims that now exist in your favor*, known or unknown*, arising from the subject matter of the Release.** You acknowledge that different or additional facts may be discovered in addition to what you now know or believe to be true with respect to the matters released in this Release, and you agree that this Release will be and remain in effect in all respects as a complete and final release of the matters released, notwithstanding any such different or additional facts.

You affirm, by signing this Release, that you have not suffered any unreported injury or illness arising from your employment, and that you have not filed, with any federal, state, or local court or agency, any actions or charges against the Releasees relating to or arising out of your employment with or separation from the Company. You further agree that while this Release does not preclude you from filing a charge with the National Labor Relations Board ("NLRB"), the Equal Employment Opportunity Commission ("EEOC") or a similar state or local agency, or from participating in any investigation or proceeding with them, you do waive your right to personally recover monies or reinstatement as a result of any complaint or charge filed against the Company with the NLRB, EEOC or any federal, state or local court or agency, except as to any action to enforce or challenge this Release, to recover any vested benefits under ERISA, or to recover workers' compensation benefits.

You acknowledge:

(a) That you were provided twenty-one (21) full days during which to consider whether to sign this Release. If you have signed this Agreement prior to the expiration of the twenty-one (21)-day period, you have voluntarily elected to forego the remainder of that period.

(b) That you have carefully read and fully understand all of the terms of this Release.

(c) That you understand that by signing this Release, you are waiving your rights under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, 29 U.S.C. § 621, et seq., and that you are not waiving any rights arising after the date that this Release is signed.

(d) That you have been given an opportunity to consult with anyone you choose, including an attorney, about this Release.

(e) That you understand fully the terms and effect of this Release and know of no claim that has not been released by this Release. And, you further acknowledge that you are not aware of, or that you have fully disclosed to the Company, any matters for which you are responsible or which has come to your attention as an employee of the Company that might give rise to, evidence, or support any claim of illegal conduct, regulatory violation, unlawful discrimination, or other cause of action against the Company.

(f) That you have made full and truthful disclosures to the Company's compliance department regarding any misconduct (including any violations of federal securities laws) relating to the Company or its subsidiaries of which you are aware, and that you understand that notwithstanding anything herein or in any other agreement to the contrary, in no event shall you be prohibited or limited from my right to provide truthful information to or otherwise assist U.S. governmental authorities in any investigation regarding the Company (whether pursuant to Section 21F of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise), and in the event of such assistance, nothing herein or in any other agreement shall be deemed to conflict with my right to receive any award payable pursuant to Section 21F of the Exchange Act.

(g) That these terms are final and binding on you.

(h) That you have signed this Release voluntarily, and not in reliance on any representations or statements made to you by any employee or officer of the Company or any of its subsidiaries.

(i) That you have seven (7) days following your execution of this Release to revoke it in writing, and that this Release is not effective or enforceable until after this seven (7) day period has expired without revocation. If you wish to revoke this Release after signing it, you must provide written notice of your decision to revoke this Release to the Company, to the attention of the General Counsel of the Company at the address of the Company's headquarters, by no later than 11:59 p.m. on the seventh calendar day after the date on which you have signed this Release.

PLEASE READ CAREFULLY. THIS RELEASE INCLUDES A RELEASE OF ALL KNOWN AND UNKNOWN CLAIMS.

ACKNOWLEDGED AND AGREED

Bradley R. Mason Date

Exhibit 21.1

The following is a list of our significant subsidiaries:

Company	Country of Incorporation	Ultimate Ownership by Parent
Orthofix Australia Pty Limited	Australia	100%
Orthofix do Brasil Ltda.	Brazil	100%
Orthofix S.A.	France	100%
Orthofix G.m.b.H.	Germany	100%
Orthofix Spine G.m.b.H.	Germany	100%
Orthofix S.r.l.	Italy	100%
Orthofix International B.V.	Netherlands	100%
Implantes y Sistemas Medicos, Inc.	Puerto Rico	100%
Inter Medical Supplies Limited	Seychelles	100%
Orthofix AG	Switzerland	100%
Colgate Medical Limited	UK	100%
Orthofix Limited	UK	100%
Orthosonics Limited	UK	100%
Victory Medical Limited	UK	100%
Orthofix Spinal Implants Inc. (formerly known as Blackstone Medical, Inc.)	US	100%
Orthofix Holdings, Inc.	US	100%
Orthofix Inc.	US	100%
Spinal Kinetics, LLC	US	100%
Spinal Kinetics GmbH	Germany	100%
Spinal Kinetics France SARL	France	100%
Spinal Kinetics Cayman Islands	Cayman Islands	100%
Orthofix III B.V.	Netherlands	100%

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Form S-8 No. 333-153389 pertaining to the Orthofix Medical Inc. (formerly Orthofix International N.V.) Amended and Restated 2004 Long-Term Incentive Plan and the Orthofix Medical Inc. (formerly Orthofix International N.V.) Amended and Restated Stock Purchase Plan;

(2) Form S-8 No. 333-226504 pertaining to the Orthofix Medical Inc. (formerly Orthofix International N.V.) Amended and Restated Stock Purchase Plan;

(3) Form S-8 No. 333-172697 pertaining to the Orthofix Medical Inc. (formerly Orthofix International N.V.) Amended and Restated Stock Purchase Plan;

(4) Form S-8 No. 333-226503 pertaining to the Orthofix Medical Inc. (formerly Orthofix International N.V.) 2012 Long-Term Incentive Plan;

(5) Form S-8 No. 333-195797 pertaining to the Inducement Grant Non-Qualified Stock Option Agreement between Orthofix Medical Inc. (formerly Orthofix International N.V.) and Bradley R. Mason, the Inducement Grant Non-Qualified Stock Option Agreement between Orthofix Medical Inc. (formerly Orthofix International N.V.) and Mark A. Heggestad and the Inducement Grant Restricted Stock Agreement between Orthofix Medical Inc. (formerly Orthofix International N.V.) and Mark A. Heggestad;

(6) Form S-8 No. 333- 206098 pertaining to the Orthofix Medical Inc. (formerly Orthofix International N.V.) 2012 Long-Term Incentive Plan;

(7) Registration Statement (Form S-8 No. 333-224548) pertaining to the Orthofix Medical Inc. (formerly Orthofix International N.V.) Inducement Plan for Spinal Kinetics Employees; and

(8) Registration Statement (Form S-8 No. 333-229500) pertaining to the Employee Inducement Restricted Stock Unit Agreement for Beth Stevenson of Orthofix Medical Inc.

of our reports dated February 25, 2019, with respect to the consolidated financial statements of Orthofix Medical Inc. (formerly Orthofix International N.V.) and the effectiveness of internal control over financial reporting of Orthofix Medical Inc. (formerly Orthofix International N.V.) included in this Annual Report (Form 10-K) of Orthofix Medical Inc. (formerly Orthofix International N.V.) for the year ended December 31, 2018.

/s/ Ernst & Young LLP

Dallas, Texas

February 25, 2019

Exhibit 31.1

CERTIFICATION

I, Bradley R. Mason, certify that:

1. I have reviewed this annual report on Form 10-K of Orthofix Medical Inc.;

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

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

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

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

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

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

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

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

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

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

Dated: February 25, 2019

By: /s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer, Director

Exhibit 31.2

CERTIFICATION

I, Doug Rice, certify that:

1. I have reviewed this annual report on Form 10-K of Orthofix Medical Inc.;

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

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

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

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

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

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

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

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

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

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

Dated: February 25, 2019

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

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Orthofix Medical Inc. ("Orthofix") on Form 10-K for the period ended December 31, 2018, (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, Bradley R. Mason, Chief Executive Officer and President of Orthofix, and Doug Rice, Chief Financial Officer, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Dated: February 25, 2019

/s/ BRADLEY R. MASON
Name: Bradley R. Mason
Title: President and Chief Executive Officer

Dated: February 25, 2019

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