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, 2020

or

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

For the transition period from _____ to _____.

Commission File Number: 0-19961

ORTHOFIX MEDICAL INC.

(Exact name of registrant as specified in its charter)

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

(214) 937-2000

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Emerging Growth Company	☐
Non-accelerated filer	☐	Smaller reporting company	☐		

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. §7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

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, 2020, as reported by the Nasdaq Global Select Market, was approximately $614.7 million.

As of February 22, 2021, 19,512,109 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. 2021 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, 2020
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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. Forward-looking statements include, but are not limited to, statements about:

- our intentions, beliefs, and expectations regarding our operations, sales, expenses, and future financial performance;
- our operating results;
- our plans for future products and enhancements of existing products;
- anticipated growth and trends in our business;
- the timing of and our ability to maintain and obtain regulatory clearances or approvals;
- our belief that our cash and cash equivalents, investments, and access to our revolving line of credit will be sufficient to satisfy our anticipated cash requirements;
- our expectations regarding our revenues, customers, and distributors;
- our expectations regarding our costs, suppliers, and manufacturing abilities;
- our beliefs and expectations regarding our market penetration and expansion efforts;
- our expectations regarding the benefits and integration of acquired businesses and/or products and our ability to make future acquisitions and successfully integrate any such future-acquired businesses;
- our anticipated trends and challenges in the markets in which we operate; and
- our expectations and beliefs regarding and the impact of investigations, claims and litigation.

These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, estimates and assumptions that are difficult to predict. Any or all forward-looking statements that we make may turn out to be wrong (due to inaccurate assumptions that we make or otherwise), and our actual outcomes and results may differ materially from those expressed in these forward-looking statements. Potential risks and uncertainties that could cause actual results to differ materially include, but are not limited to, those set forth in Part I, Item 1A under the heading "Risk Factors", Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report and in any other documents incorporated by reference to this Annual Report. 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 update, and expressly disclaim any duty to update, our forward-looking statements, whether as a result of circumstances or events that arise after the date hereof, new information, 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," and "the Company" refer to the combined operations of Orthofix Medical Inc. and its consolidated subsidiaries and affiliates, unless the context requires otherwise.

Company Overview

We are a global medical device and biologics company with a spine and extremities focus. Our mission is to deliver innovative, quality-driven solutions as we partner with health care professionals to improve patients' lives. Headquartered in Lewisville, Texas, our spine and orthopedic extremities products are distributed in more than 70 countries via our sales representatives and distributors.

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

The Company originally was formed in 1987 in Curaçao as "Orthofix International N.V." In 2018, the Company completed a change in its jurisdiction of organization from Curaçao to the State of Delaware (the "Domestication") and changed its name to "Orthofix Medical Inc." As a result, it is now a corporation existing under the laws of the State of Delaware.

Available Information and Orthofix Website

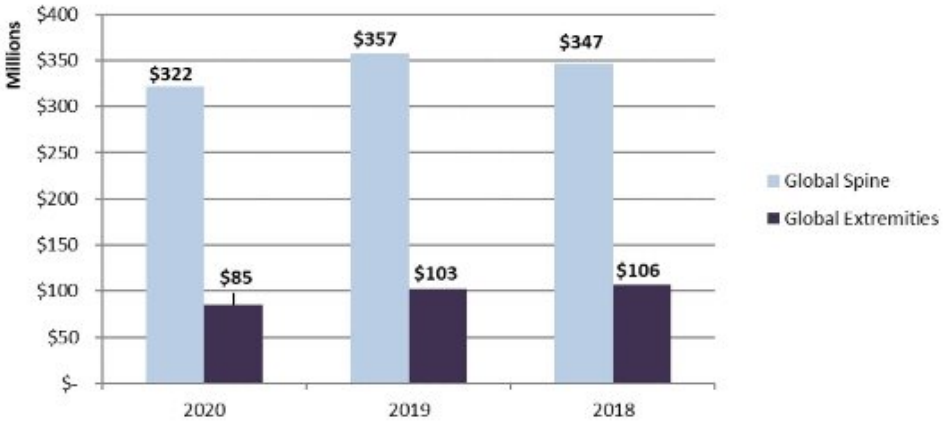
Our filings with the Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements for Meetings of Shareholders, any registration statements, and amendments to those reports, are available free of charge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

COVID-19 Update and Outlook

Refer to Part II, Item 7 of this Annual Report under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations," for a discussion of the effects of the global COVID-19 pandemic on our business in 2020 and of its expected impact in 2021 and beyond.

Business Segments

We manage our business by our two reporting segments, Global Spine and Global Extremities, which accounted for 79% and 21%, respectively, of our total net sales in 2020. 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, 2020, 2019, and 2018.



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.

Global Spine

Within the Global Spine segment, we provide implantable medical devices, biologics, and other regenerative solutions which aim to restore the quality of life of patients suffering from diseases and traumas of the spine. We offer a variety of treatment solutions which uniquely incorporate multiple treatment modalities, such as mechanical, biological, and electromagnetic modes, to achieve desired clinical outcomes.

Global Spine Strategy

Our strategy for the Global Spine segment is to drive business growth through organic and inorganic innovation, physician collaboration, global market expansion, and partnerships with dedicated and high-performing commercial sales channels. Growth initiatives include:

- Continued expansion of our presence in the U.S cervical disc replacement market through surgeon training, the publication of clinical evidence, patient education, and sales channel support
- A regular cadence or new product launches supporting our spine implant, biologics, and bone growth therapies portfolios
- Ongoing, global sales channel optimization
- Reinforcement of our bone growth stimulation business through the collection and dissemination of clinical evidence, and the delivery of new and novel value-added services
- Conducting clinical research to support and broaden our spine implant, biologics, and bone growth stimulation portfolios
- Acquiring or licensing products, technologies and companies to further expand the spine portfolio
- Attracting, developing and retaining key talent

Global Spine Principal Products

The Global Spine reporting segment is largely represented by three principal product categories, i) Bone Growth Therapies, ii) Spinal Implants, and iii) Biologics. Each of these product categories are further described below:

Bone Growth Therapies

Within the Bone Growth Therapies product category, we manufacture, distribute, and provide support services for market-leading bone growth stimulation devices that enhance bone fusion. These class III medical devices are indicated as an adjunctive, noninvasive treatment to improve fusion success rates in the cervical and lumbar spine as well as a therapeutic treatment for non-spinal, appendicular fractures that have not healed (nonunions). These devices utilize our 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. We sell these products almost exclusively in the U.S. using distributors and direct sales representatives to provide our devices to healthcare providers and their patients.

Spinal Implants

Within the Spinal Implants product category, we design, develop and market a portfolio of motion preservation and fixation implant products used in surgical procedures of the spine. We distribute these products globally through a network of distributors and sales representatives to sell spine products to facilities that conduct spine care to include hospitals, ambulatory surgery centers, out-patient facilities (“spine care facilities”) and to surgeons who treat patients in need.

Biologics

Within the Biologics product category, we offer a portfolio of regenerative products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. We market regeneration tissue forms and distribute tissues provided to us by MTF Biologics (“MTF”) to spine care facilities and surgeons, primarily in the U.S., through a network of independent distributors and sales representatives. Our partnership with MTF allows us to exclusively market the Trinity ELITE, Trinity Evolution, and fiberFUSE tissue forms for musculoskeletal defects to enhance bony fusion.

The following table and discussion identifies our principal Global Spine products by trade name and describes their primary applications:

Product	Primary Application
Bone Growth Therapies Products	
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 Implants Products	
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
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
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
FORZA PEEK / Titanium Composite (“PTC”) Spacer System	A posterior lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a polyetheretherketones (“PEEK”) core to maintain imaging characteristics
FORZA Spacer System	PEEK interbody devices for PLIF and TLIF procedures
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
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
CONSTRUX Mini PTC Spacer System	A cervical interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics
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
JANUS Midline Fixation Screw	An addition to the Firebird Spinal Fixation System designed to achieve more cortical bone purchase in the medial to lateral trajectory, when compared to traditional pedicle screws, and that provides surgeons with the option of a midline approach

Product	Primary Application
LONESTAR Cervical Stand Alone	A stand-alone spacer system designed to provide the biomechanical strength to a traditional or minimal invasive anterior cervical discectomy and fusion procedure with less disruption of patient anatomy and to preserve the anatomical profile
PILLAR SA PTC PEEK Spacer System	A standalone anterior lumbar interbody fusion lumbar interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics
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
FIREBIRD SI	A minimally invasive screw system that is intended for fixation of sacroiliac joint disruptions in skeletally mature patients
Biologics Technologies	
Trinity ELITE	A fully moldable allograft with viable cells used during surgery that is designed to aid in the success of a spinal fusion or bone fusion procedure
Trinity Evolution	An allograft with viable cells used during surgery that is designed to aid in the success of a spinal fusion or bone fusion procedure
AlloQuent Structural Allografts ("AlloQuent")	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	An osteoconductive scaffold and a bone graft substitute product comprised of beta tri-calcium phosphate and type 1 bovine collagen, available in both putty and strip formulations
fiberFUSE	An allograft comprised of a mixture of cancellous bone and demineralized cortical bone that creates a natural scaffold for revascularization, cellular ingrowth, and new bone formation
O-Genesis Graft Delivery	A complete bone graft delivery system designed to deliver allograft, autograft, or synthetic bone graft to all orthopedic sites, which is provided in a sterile, single-use form
VersaShield	A thin hydrophilic amniotic membrane designed to serve as a wound or tissue covering for a variety of surgical demands

Bone Growth Therapies — 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 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 SpinalStim and CervicalStim systems are accompanied by an application for mobile devices called STIM onTrack. The mobile app includes a first-to-market feature that enables physicians to remotely view patient adherence to prescribed treatment protocols and patient reported outcome measures. Designed for use with smartphones and other mobile devices, the STIM onTrack tool helps patients follow their prescription with daily treatment reminders and a device usage calendar. The app is free and available through the iTunes App Store.

Bone Growth Therapies — Orthopedic Therapy

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

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

Similar to our SpinalStim and CervicalStim systems, the PhysioStim device is also accompanied by the STIM onTrack mobile app, enabling physicians treating patients with nonunion fractures to remotely view and assess patient adherence to prescribed treatment protocols and patient reported outcome measures.

Spinal Implants — Motion Preservation Solutions

In 2018, we acquired Spinal Kinetics Inc., a privately held developer and manufacturer of artificial cervical and lumbar discs, namely the M6-C cervical and M6-L lumbar artificial discs, which are used to treat patients suffering from degenerative disc disease of the spine. The M6 discs are the only FDA-approved artificial discs that mimic the anatomic structure of a natural disc by incorporating an artificial viscoelastic nucleus and fiber annulus into their design. Like a natural disc, this unique construct allows for shock absorption at the implanted level, as well as provides a controlled range of motion when the spine transitions in its combined complex movements. Both discs have European Commission CE mark approval and prior to 2019, had historically been exclusively distributed outside the U.S. In February 2019, we received FDA approval of the M6-C artificial cervical disc to treat patients with cervical disc degeneration. We released the M6-C artificial cervical disc in the U.S. in 2019 through a controlled market launch accompanied by an extensive training and education curriculum for surgeons. In addition, we are planning to initiate a U.S. 2-level investigational device exemption ("IDE") study for the M6-C artificial cervical disc in 2021.

Spinal Implants — Spinal Repair Solutions

We provide a wide array of implants designed for use primarily in cervical, thoracic, and lumbar fusion surgeries. These implants are made of either metal or a thermoplastic compound called PEEK. The majority of the implants that we offer are made of titanium metal. The Firebird Spinal Fixation System, the Phoenix Minimally Invasive Spinal Fixation System, and the Centurion POCT Systems are sets of rods, cross connectors, and screws that are implanted during posterior fusion procedures. The Firebird Modular and pre-assembled Spinal Fixation Systems are designed to be used in either open or minimally-invasive posterior lumbar fusion procedures with our ProView MAP System. To complement our plates, rods, and screw fixation options, we offer an entire portfolio of cervical and thoracolumbar PEEK interbody devices within our Pillar and Forza product lines. This interbody portfolio includes two stand-alone devices, Lonestar and Pillar SA, as well as the Construx Mini PTC system, a novel titanium composite spacer, which offers a superior alternative to other plasma spray coated options currently available on the market. We also offer specialty plates and screws that are used in less common procedures, and as such, are not manufactured by many device makers.

Biologics — Regenerative Solutions

The premier biologics tissues we market include the Trinity ELITE and Trinity Evolution tissue forms, which are cortical cancellous allografts that retain the inherent growth factors and viable cells found in bone. They 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.

The fiberFUSE tissue is the newest biologics tissue form with handling characteristics analogous to Trinity ELITE without compromising bone content. It provides an advanced demineralized bone offering that leverages fiber technology with the advantages of ingrowth that cancellous bone provides and expands the offering to address a broader scope of surgical applications. This tissue offering was developed by MTF in close collaboration to expand the Orthofix portfolio and provides an opportunity to serve a great number of clinical indications addressed by surgeons.

We receive marketing fees through our collaboration with MTF for the Trinity ELITE, Trinity Evolution, fiberFUSE, AlloQuent, and VersaShield tissues. MTF processes the tissues, maintains inventory, and invoices hospitals, surgery centers, and other points of care for service fees, which are submitted by customers via purchase orders. We have exclusive worldwide rights to market the Trinity ELITE and Trinity Evolution tissue forms and exclusive rights to market the fiberFUSE and AlloQuent tissues in the U.S. 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.

Future Product Applications

We have sponsored research at the University of Pennsylvania, Cleveland Clinic, New York University, and University of California San Francisco, where scientists conducted animal and cellular studies to identify the mechanisms of action of our PEMF signals on bone and tendon and efficacy of healing. From these efforts, many studies have been published in peer-reviewed journals. Among other insights, the studies illustrate positive effects of PEMF on callus formation and bone strength as well as proliferation and differentiation of cells involved in regeneration and healing. Furthermore, we believe that the research work with Cleveland Clinic and the University of Pennsylvania, allowing for characterization and visualization of the Orthofix PEMF waveform, is paving the way for signal optimization for a variety of new applications and indications. This collection of pre-clinical data, along with additional clinical data, could represent new clinical indication opportunities for our regenerative stimulation solutions. In addition, we currently have research and a clinical study underway to identify potential clinical indications for treating rotator cuff tears and we also plan on initiating a U.S. 2-Level IDE study for the M6-C artificial cervical disc.

Global Extremities

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

Global Extremities Strategy

Our strategy for the Global Extremities reporting segment is to continue to offer pioneer solutions to the most complex reconstructive problems related to trauma, adult and pediatric limb reconstruction and extremities along the entire treatment pathway.

Our key strategies in this segment are:

- Geographic market & product focus on:
    - Adult and pediatric limb reconstruction worldwide
    - Complex foot & ankle reconstruction in the U.S.
    - Complex fracture reconstruction

- Securing our position as the company with the most complete portfolio in limb reconstruction, including both internal and external solutions, through a patient-centric approach and digital treatment journey
- Promote the advantages of our JuniOrtho pediatric products portfolio and support tools
- Leverage the market appeal and acceptance of our software platforms: HEX-ray and OrthoNext
- Leverage our historical position as a company highly focused on complex and challenging niche conditions to be at the forefront of innovation in helping surgeons and patients alike in the management of the Charcot foot and ankle
- Within the orthopedic trauma segment, focus on open and complex fracture management with additional attention to joint pathologies, like dislocations, of upper and lower limbs; we aim to develop new international business opportunities within trauma, becoming a trusted partner of Non-governmental Organizations ("NGOs") and Military Medicine Organizations
- Collaborate with physicians and healthcare partners to improve patients' live through technology, digital transformation, clinical evidence, and our industry-leading medical education programs, such as Orthofix Academy
- Continue the strong pace of new product launches
- Acquire or license products, technologies, and companies to support these market opportunities.

Global Extremities Focus Products

Global Extremities offers innovative and minimally invasive extremity solutions to help surgeons improve their patient's quality of life, which are designed to address the lifelong bone and joint health needs of patients of all ages. In addition, our well-rounded product lines offer comprehensive internal and external fixation solutions for pediatrics, limb reconstruction, trauma, and foot & ankle specialties.

Our fracture repair solutions comprise a wide range of devices designed for specific anatomical areas. The philosophy underlying these devices is to provide adequate stability and to allow for early functional recovery, thereby improving patients' quality of life. Our goal is to offer devices that enable a simple, standardized approach for reproducible results.

Our trauma products consist of a comprehensive portfolio of ready-to-use, sterile, dedicated implant kits designed for a wide range of anatomical sites.

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

Product	Primary Application
External Fixators	External fixation, including our limb-lengthening systems, ProCallus, XCaliber, Pennig, Radiolucent Wrist Fixators, and Calcaneal Fixator
JuniOrtho	A brand identity for extremity fixation pediatric products. JuniOrtho is a range of products and resources dedicated to pediatrics and young adults with bone fractures and deformities that brings together our expertise and products in the pediatric space. It consists of a 360° approach to the patient journey with dedicated tools to treat all stages of the healing process: collaterals, educational games, software applications, and patient apps for post-operative management Our JuniOtho portfolio includes, among the others: - A complete line of nailing systems for trauma and limb reconstruction, including our elastic nail, MJ-FLEX, and our rigid intramedullary nail for adolescents, Agile Nail; - The Galaxy Fixation Pediatric System; - The eight-Plate Guided Growth System ("eight-Plate") and the eight-Plate Guided Growth System+ ("eight-Plate Plus"); - The JuniOrtho Plating System

Product	Primary Application
eight-Plate and eight-Plate Plus	The first and a market-leading system for gradual correction of the growth plate in pediatric patients
TrueLok	A surgeon-designed, lightweight external fixation system for trauma, limb lengthening, and deformity correction, which 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
TrueLok Hexapod System ("TL-HEX")	A hexapod external fixation system for trauma and deformity correction with associated software, designed 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, which allows multi-planar adjustment of the external supports. The rings' positions are adjusted either rapidly or gradually in precise increments to perform bone segment repositioning in three-dimensional space
HEX-ray	An innovative software designed to facilitate pre-operative planning and post-operative monitoring with the TL-HEX software. It allows a unique and realistic representation of the case using x-rays and providing accurate and user-friendly management of the surgery
myHEXplan and mySuperheroAcademy	Mobile apps developed to support patients treated with TrueLok and TL-HEX, which are designed to improve communication and connection with hospital staff (myHEXplan) or to help patients learn by playing a virtual game (mySuperheroAcademy)
LRS advanced Limb Reconstruction System	An external fixation for limb lengthening and corrections of deformity, which 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
FITBONE Intramedullary Limb-Lengthening System	An intramedullary lengthening system intended for limb lengthening of the femur and tibia, surgically implanted in the bone through a minimally invasive procedure; it includes an external telemetry control set that manages the distraction process
Galaxy Fixation System	A pin-to-bar system for temporary and definitive fracture fixation, 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 shoulder, elbow and wrist
Galaxy Fixation Shoulder	A unique solution for the treatment of proximal humeral fractures
Chimaera Hip Fracture System ("Chimaera")	A strong, versatile hip nail that allows fixation to be adapted to the type of fracture being treated
Ankle Hindfoot Nail ("AHN")	A differentiated solution for hindfoot fusions
G-BEAM Fusion Beaming System	A system designed to address the specific demands of advanced deformity and trauma reconstructions of foot and ankle applications, such as Charcot, requiring fusion of the medial and/or lateral columns, with or without corrective osteotomies as well as for joint fusions within the mid- and hindfoot
OSCAR	An ultrasonic powered surgical system for revision arthroplasty

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 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 occurs. External fixation allows small degrees of micromotion (dynamization), which promotes blood flow at the fracture site, and accelerates the bone healing process. 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.

We offer most of our products in sterile packaging, which fulfills the need of a streamlined and ready-to-use set of products, particularly in trauma applications where timing is crucial.

Examples of our external fixation devices include the TrueLok, TL-HEX, the Galaxy Fixation System, and the LRS Advanced Limb Reconstruction System.

Internal Fixation

Internal fixation devices consist of either long rods, commonly referred to as nails, or plates that are attached to the bone with the use of screws. Nails and plates come in various sizes, depending on the bone that requires treatment. 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 Chimaera, AHN, and the G-BEAM Fusion Beaming System.

Acquired in March 2020, the FITBONE intramedullary lengthening nail provides an internal option for limb lengthening of the femur and tibia and provides Orthofix with the most complete limb reconstruction portfolio on the market. Over 3,500 cases have been performed with the FITBONE system in more than 15 countries.

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), degenerative diseases, and conditions resulting from a previous trauma. An example of a product offered in this area is the eight-Plate Plus.

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 2020, 2019, and 2018, we incurred research and development expenses of $39.1 million, $34.6 million, and $33.2 million, respectively.

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 possess 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. We do not believe that the expiration of any single patent is likely to significantly affect our intellectual property position. The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Our success will depend in part on our not infringing patents issued to others, including our competitors and potential competitors. While we make extensive efforts to ensure that our products do not infringe other parties' patents and proprietary rights, our

products and methods may be covered by patents held by our competitors. For a further discussion of these risks, please see Item 1A of this Annual Report under the heading “Risk Factors.”

We rely on confidentiality and non-disclosure agreements with employees, consultants, and other parties to protect, in part, trade secrets and other proprietary technology.

We obtain assignments or licenses of varying durations for certain of our products from third parties. We typically acquire rights under such assignments or licenses in exchange for lump-sum payments or arrangements under which we pay a percentage of sales to the licensor. However, while assignments or licenses to us generally are irrevocable, no assurance can be given that these arrangements will continue to be made available to us on terms that are acceptable to us, or at all. The terms of our license and assignment agreements vary in length from a specified number of years, to the life of product patents, or for 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 our fundamental policy to conduct business in accordance with the highest ethical and legal standards. We have a comprehensive compliance and ethics program, which is overseen by our Chief Ethics and Compliance Officer, who reports directly to our Chief Executive Officer and the Compliance Committee of the Board of Directors. The program is intended to promote lawful and ethical business practices throughout our domestic and international businesses. It is designed to prevent and detect violations of applicable federal, state, and local laws in accordance with the standards set forth in guidance issued by the U.S. Department of Justice (“U.S. DOJ”) (“Evaluation of Corporate Compliance Programs” (updated June 2020)), 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 the 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 a 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 to 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
- 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 to provide a reasonable assurance of safety and effectiveness, or devices deemed not substantially equivalent to a device that previously received 510(k) clearance (as described below), are placed in class III. Our Spinal Implants and Global Extremities products are, for the most part, class II devices and the instruments used in conjunction with these products are generally class I. Our Bone Growth Therapies products and the M6-C artificial cervical disc are currently classified as class III by the FDA, and have been approved for commercial distribution in the U.S.

through the PMA process. However, an FDA panel recently recommended that bone growth stimulator devices be reclassified by the FDA from Class III to Class II devices with special controls. For additional discussion of this development, see Item 1A of this Annual Report under the heading “Risk Factors.”

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

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

In 2017, the E.U. adopted the E.U. Medical Device Regulation (Council Regulations 2017/745) which imposes stricter requirements for the marketing and sale of medical devices, including new quality system and post-market surveillance requirements. The regulation provides a transition period until May 2021 for currently-approved medical devices to meet the additional requirements and for certain devices this transition period can be extended until May 2024. After this transition period, all medical devices marketed in the E.U. will require certification according to these new requirements. Complying with this new regulation will require us to incur significant costs over the transition period and failure to meet the requirements of the regulation could adversely impact our business in the E.U. and other countries that utilize or rely on E.U. requirements for medical device registrations.

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

For a further description of some of these risks, see Item 1A of this Annual Report under the heading “Risk Factors.”

Certain Other Product and Manufacturing Regulations

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

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

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

Accreditation Requirements

Our subsidiary, Orthofix US LLC, 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 US LLC 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 ("HHS"), the U.S. DOJ, 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 or for 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 HHS promulgates health information privacy and security rules under HIPAA. These rules protect health information by regulating its use and disclosure, including for research and other purposes. Failure of a HIPAA "covered entity" to comply with HIPAA regarding such "protected health information" could constitute a violation of federal law, subject to civil and criminal penalties. Covered entities include healthcare providers (including certain of those that sell devices or equipment) that engage in particular electronic

transactions, including, as we do, the transmission of claims to health plans. Consequently, health information that we access, collect, analyze, and otherwise use and/or disclose includes protected health information that is subject to HIPAA. As noted above, many state laws also pertain to the confidentiality of health information. Such laws are not necessarily preempted by HIPAA, in particular those state laws that afford greater privacy protection to the individual than HIPAA. These state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

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

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

Physician Payments Sunshine Provision of the Affordable Care Act

The Physician Payments Sunshine Provision of the Affordable Care Act (Section 6002) (the "Sunshine Act"), requires public disclosure to the U.S. government of payments to physicians and teaching hospitals, including in-kind transfers of value, such as gifts or meals. The Sunshine Act also provides penalties for non-compliance. The Sunshine Act requires that we file an annual report on March 31st of a calendar year for the transfers of value incurred for the prior calendar year.

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

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

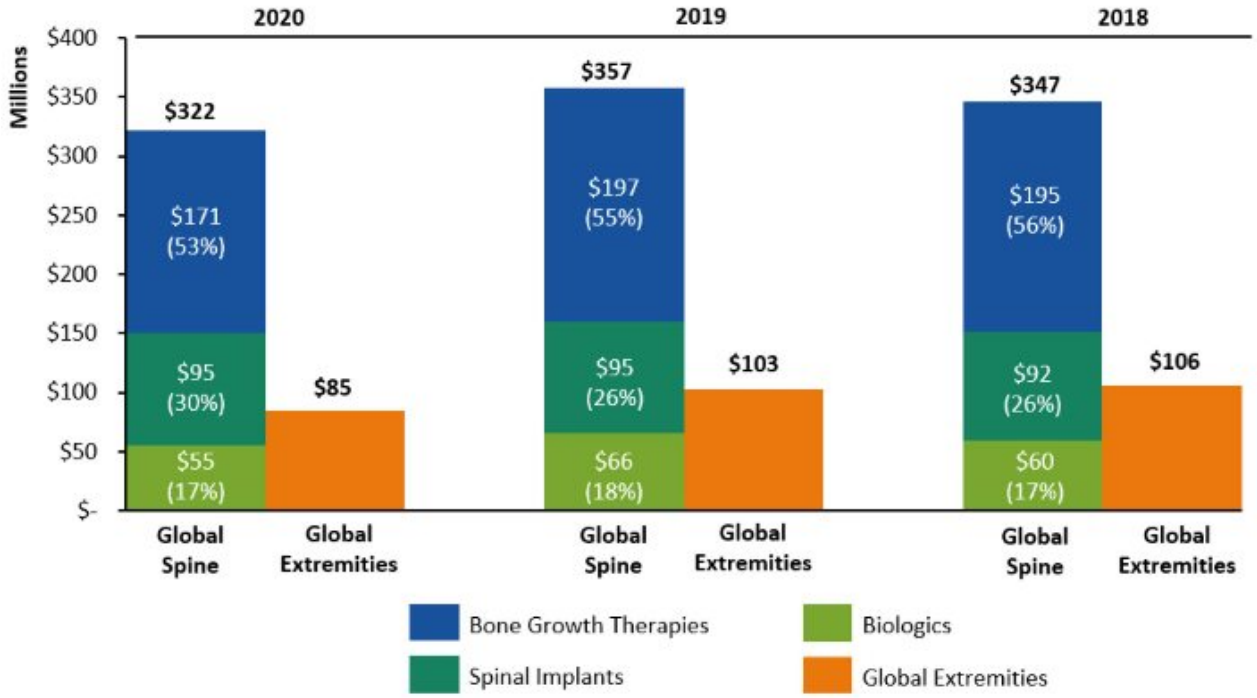
Sales, Marketing and Distribution

General Trends

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

Reporting Segments and Product Categories

Our revenues are generated from the sales of products in our two reporting segments, Global Spine and Global Extremities. Further, our Global Spine reporting segment is comprised of three primary product categories: Bone Growth Therapies, Spinal Implants, and Biologics. See the following chart for the distribution of sales between each of our reporting segments and product categories for each of the years ended December 31, 2020, 2019, and 2018.



Sales Network

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

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

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

Marketing and Product Education

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

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

To provide additional advanced training for physicians, consistent with the AdvaMed Code of Ethics (“AdvaMed Code”) and the MedTech Europe Code of Ethical Business Practice (“MedTech Code”), we organize regular multilingual teaching seminars in multiple locations and also virtually. In person training locations include our facility in Verona, Italy, various locations in Latin America, and our corporate headquarters in Lewisville, Texas. In recent years, thousands of surgeons from around the world have attended these

in person and virtual product education seminars, which have included a variety of lectures from specialists, as well as demonstrations and hands-on workshops. In response to the COVID-19 pandemic, our sales and training teams have focused on offering virtual training opportunities and we have participated in numerous virtual sales conferences. We plan to continue to utilize these virtual training platforms into the future.

Competition

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

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

Manufacturing and Sources of Supply

We generally design, develop, assemble, test and package our stimulation, motion preservation, orthopedic, and spinal implant products, and subcontract the manufacture of a substantial portion of the component parts and instruments. 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.

We partner with MTF Biologics to provide our customers allograft solutions (HCT/Ps) for various spine, orthopedic and other bone repair needs. Our partnership with MTF Biologics provides donor screening, processing, and quality standards that are expected by our customers. We are the exclusive marketing representative for the Trinity ELITE, Trinity Evolution, fiberFUSE, and AlloQuent HCT/Ps.

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, 2020, we had 1,036 employees worldwide. Of these, 741 were employed in the U.S. and 295 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 208 at December 31, 2020, are governed by the provisions of a National Collective Labor Agreement setting forth mandatory minimum standards for labor relations in the metal mechanic workers industry. We are not a party to any other collective bargaining agreement. We believe we have good relations with our employees.

Item 1A. Risk Factors

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

Risks Related to our Legal and Regulatory Environment

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

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

We are subject to the Foreign Corrupt Practices Act (the "FCPA") and other similar anti-bribery laws and any violations of such laws could subject us to adverse consequences.

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 U.S. are with governmental entities and are therefore subject to such anti-bribery laws.

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

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

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

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

Due to the breadth of some of these laws, there can be no assurance that we will not be found to be in violation of any such laws, and as a result we may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring

of our operations, or the exclusion from participation in federal, non-U.S., or state healthcare programs. Any penalties could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against them, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

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

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

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

CMS, in its ongoing implementation of the Medicare program, periodically reviews medical study literature to determine how the literature addresses certain procedures and therapies in the Medicare population. The impact that this information could have on Medicare coverage policy for our products is currently unknown, but we cannot provide assurances that the resulting actions will not restrict Medicare coverage for our products. There can be no assurance that we or our distributors will not experience significant reimbursement problems in the future related to these or other proceedings. Globally, our products are sold in many countries, such as the U.K., Germany, France, and Italy, which have publicly funded healthcare systems. The ability of hospitals supported by such systems to purchase our products is dependent, in part, upon public budgetary constraints. Any increase in such constraints may have a material adverse effect on our sales and collection of accounts receivable from such sales.

As required by law, CMS has continued efforts to implement a competitive bidding program for selected 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.

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 E.U. 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 E.U. We have received certification for all currently existing manufacturing facilities.

An FDA panel recently recommended that bone growth stimulator devices be reclassified by the FDA from Class III to Class II devices, which could increase future competition for us in this product category and negatively affect our future sales of such products.

We have the market-leading bone growth stimulation platform with the only cervical spinal spine indication granted by the FDA, and the only mobile device app accessory designed to help patients adhere to their prescriptions and improve their clinical outcomes, STIM onTrack 2.1. We also are investing in IDE studies to expand indications for use in areas such as rotator cuff tears. Our bone growth therapy products currently are designated as Class III devices. Class III devices are subject to the FDA's most rigorous pathway to approval for medical devices in the U.S. The FDA may change classification of a device only if the proposed new class has sufficient regulatory controls to provide reasonable assurances of safety and effectiveness.

In September 2020, the FDA's Orthopaedic and Rehabilitation Devices Panel recommended that bone growth stimulator devices be reclassified from Class III to Class II devices with "special controls" to ensure patient safety and therapy efficacy. These proposed special controls include the condition that such devices be subject to rigorous clinical studies and post market surveillance for any new products. This would be in addition to other special controls and the Class II general requirement that any new products show "substantial equivalence" to already-cleared or approved devices.

We believe that the panel's recommendation correctly recognizes the importance of PMA-like clinical data for these devices, so that manufacturers continue to be required to submit robust clinical data under the approval or clearance process to ensure the safety and efficacy of these devices for patients. We, along with other bone growth stimulation manufacturers, submitted comments in response to the FDA's proposed rulemaking to underscore the panel's recommendation of the need for robust clinical data prior to approval or clearance of bone growth stimulator products, together with post market surveillance requirements.

In the long-term, the recommended reclassification could enhance the ability of competitors to enter the market if they are able to create technologies with comparable efficacy to our devices, which could result in our products facing additional competition, thereby negatively affecting our future sales of these products.

We continue to be affected by U.S. healthcare reform initiatives.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (or collectively the "ACA"), has caused a number of substantial changes to occur in recent years 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:

- Established a 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

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

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

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

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

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

Risks Related to our Business and Industry

The novel coronavirus pandemic has materially affected our business and may cause further unpredictable effects in the future.

The novel coronavirus discovered in late 2019, and the disease it causes, known as COVID-19, has negatively affected our business since March 2020 and may cause continuing negative effects in 2021 and beyond. For Orthofix, the most significant effect to date on our business has been a significant reduction in elective surgery procedure volumes, which represent the majority of procedures in which our products are used. This reduction in procedure volumes began suddenly in March 2020 when shelter in place and social distancing instructions were instituted in the U.S. and many of our other sales markets, which caused a pronounced reduction in revenue during April 2020 and May 2020, when a significant number of hospitals were either closed for elective procedures or otherwise operating at significantly reduced volumes. Generally, this reduction in procedure volumes dissipated during June 2020 and July 2020, as many regions were able to reopen for elective procedures, with an existing patient backlog. At the present time, volumes have fluctuated as infection rates and hospitalizations have increased, and we may continue to experience significant decreases in procedure volumes if hospitals and other healthcare providers take similar precautionary measures in the future.

The future trajectory of the COVID-19 pandemic remains uncertain, both in the U.S. and in other markets. Following the recent winter increase of cases, case counts have been declining in most markets in the weeks preceding this filing. In addition, several

vaccines have been approved, and the number of people being vaccinated has been steadily increasing in recent weeks. However, new variants of the virus have emerged recently, and it is unclear the extent to which approved vaccines will work on these new variants, or how soon vaccines can be updated to account for such variants.

Given these various uncertainties, it is unclear the extent to which lingering slowdowns in elective procedures will continue to affect our business in 2021 and beyond. We expect that the effects of COVID-19 on our business will depend on various factors including (i) the magnitude and length of additional case waves, (ii) the distribution, efficacy, and public acceptance of COVID-19 vaccines, (iii) the comfort level of patients in returning to clinics and hospitals, (iv) the extent to which localized elective surgery shutdowns occur, (v) the unemployment rate's effect on potential patients lacking medical insurance coverage, and (vi) general hospital capacity constraints occurring because of the need to treat COVID-19 patients.

Throughout 2020 we have focused on making our facilities safe given updated COVID-19 public health guidelines, and we believe that our employee workforce has done excellent work in adapting to the new environment. In particular, we have been able to continue our manufacturing activities to keep pace with customer orders. However, given the potential for further shelter in place orders in our largest manufacturing and operational centers (particularly, Lewisville, Texas and Verona, Italy), there remains a risk that a significant localized surge in the virus could cause disruption to our manufacturing, distribution, administrative, and other business operations (including downtime at our manufacturing facilities and the interruption of the production of our products).

In addition, while we have not seen such effects to date, risk remains that COVID-19 could have material negative effects on contractual counterparties, leading to supply chain disruptions or counterparty payment defaults and bankruptcies (including bankruptcies to hospital systems that significantly rely on revenue from elective surgeries).

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described herein, such as our need to generate sufficient cash flows to service indebtedness and our ability to protect our information technology networks and infrastructure from unauthorized access, misuse, malware, phishing and other events that could have a security impact as a result of our remote working environment or otherwise.

All of these factors, collectively, could materially adversely affect our business, financial condition and results of operations.

Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if a group purchasing organization ("GPO") 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 GPOs, independent delivery networks, and large single accounts continue to use their market power to consolidate purchasing decisions and as larger manufacturers use their broad offerings to secure exclusive arrangements. If a GPO were to exclude us from their supplier list, our net sales could be adversely impacted. We expect that market demand, government regulation, third-party reimbursement policies, and societal pressures will continue to change the worldwide healthcare industry, which may exert further downward pressure on the prices of our products.

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

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

In addition, the orthopedic medical device industry in which we compete is undergoing, and is characterized by, rapid and significant technological change. We expect competition to intensify as technological advances are made. New technologies and products

developed by other companies are regularly introduced into the market, which may render our products or technologies non-competitive or obsolete.

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

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

Our allograft and cellular bone allografts could expose us to certain risks that could disrupt our business.

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

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

We plan to continue to make improvements in our products, to develop new products, and to introduce our products into new markets. Despite our planning, the process of developing and introducing new products (including product enhancements) is inherently complex and uncertain, and involves risks, including the ability of such new products to satisfy customer needs, gain broad market acceptance (including by physicians), and obtain regulatory approvals. These events can depend on the product achieving broad clinical acceptance, the level of third-party reimbursement, and the introduction of competing technologies, among other things. In addition, these risks make it inherently difficult to forecast and predict the future net sales of our products. If the market opportunities that we expect to develop for our products, including new products, are not as large as we expect, it could adversely affect our ability to grow our business.

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

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

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

Our operations are dependent upon our information technology systems, which encompass all of our major business functions. We rely upon such information technology systems to manage and replenish inventory, to fill and ship customer orders on a timely basis, to coordinate our sales activities across all of our products and services, and to coordinate our administrative activities. A

substantial disruption in our information technology systems for any prolonged time period (arising from, for example, system capacity limits from unexpected increases in our volume of business, outages, or delays in our service) could result in delays in receiving inventory and supplies or filling customer orders and adversely affect our customer service and relationships. Our systems might be damaged or interrupted by natural or man-made events, or by computer viruses, physical or electronic break-ins, and similar disruptions affecting the global internet. There can be no assurance that such delays, problems, or costs will not have a material adverse effect on our cash flows, operating results, and financial condition.

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

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

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

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

For example, third parties may attempt to hack into our products to obtain data relating to patients, to 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 E.U. and, the GDPR may impose fines of up to four percent of our global revenue in the event of violations. Internationally, some countries have also passed laws that require individually identifiable data on their citizens to be maintained on local servers and that may restrict transfer or processing of that data. We believe that we meet the expectations of applicable regulations and that the ongoing costs of compliance with such rules are not material to our business but could become material due to new regulations. There is no guarantee that we will be able to comply with these regulations, or otherwise avoid the negative reputational and other affects that might ensue from a significant data breach or failure to comply with applicable data privacy regulations, each of which could have significant adverse effects on our business, financial condition, or results of operations.

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

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

We contract with third-party manufacturers to produce many of our products like many other companies in the medical device industry. If we or any such manufacturer fail to meet production and delivery schedules, it can have an adverse impact on our ability to sell such products. Further, whether we directly manufacture a product or utilize a third-party manufacturer, shortages and spoilage of materials, labor stoppages, product recalls, manufacturing defects, and other similar events can delay production and inhibit our ability to bring a new product to market in timely fashion. For example, the supply of the Trinity ELITE and Trinity Evolution allografts are derived from human cadaveric donors, and our ability to market the tissues depends on MTF continuing to have access to donated human cadaveric tissue and their continued maintenance of high standards in their 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. Frequently, 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 standard distribution agreements, each party has the right to terminate in the event of a material breach by the other party and we generally have the right to terminate if the distributor does not meet agreed sales targets or fails to make payments on time. Any termination of our existing relationships with independent sales representatives or distributors could have an adverse effect on our business unless and until commercially acceptable alternative distribution arrangements are put in place. In addition, we operate in areas of the world that have been or may be disproportionately affected by recessions or disasters and we bear risk that existing or future accounts receivable may be uncollected if these distributors or hospitals experience disruptions to their business that cause them to discontinue paying ongoing accounts payable or become insolvent.

We depend on our senior management team.

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

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

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

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

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

- Changes in a specific country’s or region’s political or economic conditions;
- Trade protection measures and import or export licensing requirements or other restrictive actions by foreign governments;
- Tariff increases and import or export restrictions

- Consequences from changes in tax or customs laws;
- Difficulty in staffing and managing widespread operations;
- Differing labor regulations;
- Differing protection of intellectual property;
- Unexpected changes in regulatory requirements; and
- Violation by our independent agents of the FCPA or other anti-bribery or anti-corruption laws.

Risks Related to our Intellectual Property

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

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 that are similar to, or that compete directly with, our products. 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, Investments, 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 that 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 have provided $10.0 million in investments and loans to a privately-held company in Switzerland and may not be able to recoup our investment.

In October 2020, we entered into agreements with Neo Medical SA, a privately-held Swiss-based medical technology company developing a new generation of products for spinal surgery ("Neo Medical"). Our collaboration with Neo Medical focuses on co-developing with them a cervical platform and deploying single-use, sterile-packed procedure solutions designed to increase operating room efficiencies, reduce procedural times and costs, improve patient outcomes through novel device designs and techniques, and reduce infection rates. These instruments are designed for surgical settings including acute care hospitals, outpatient hospitals and also ambulatory surgery centers. Under our agreements with Neo Medical, we will also exclusively distribute Neo Medical's thoracolumbar procedure solutions to certain U.S. accounts.

In connection with these arrangements, we purchased $5.0 million of Neo Medical's preferred stock, and loaned CHF 4.6 million ($5.0 million as of the issuance date) to Neo Medical pursuant to a convertible loan agreement. The loan accrues interest at an

annual rate of 8% and is convertible by either party into additional shares of Neo Medical's preferred stock. If not otherwise converted to preferred stock in the interim, the loan and all accrued interest become due and payable in October 2024.

Neo Medical is using the proceeds of our preferred stock purchase and loan to fund its ongoing operations. However, no assurance can be made that Neo Medical's business ultimately will be successful. As such, we could ultimately be unable to recoup any value for the preferred stock that we purchased and/or unable to recoup the amount of our loan.

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

We may from time to time sell, license, assign, or otherwise dispose of or divest assets, the stock of subsidiaries, or individual products, product lines or technologies, which we determine are no longer desirable for us to own, some of which may be material. Any such activity could result in us incurring costs and expenses from these efforts, some of which could be significant. This may also result in us retaining liabilities related to the assets or properties disposed of even though, for instance, the income-generating assets have been disposed. 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 and/or establish our sales and distribution networks in certain domestic and international markets, the timing and level of reimbursement for our products by third-party payors, the extent to which we are subject to government regulation or enforcement, the valuation of certain assets and liabilities, and other factors, many of which are outside our control.

We face risks related to foreign currency exchange rates.

Because some of our revenue, operating expenses, assets, and liabilities are denominated in foreign currencies, we are subject to foreign exchange risks that could adversely affect our operations and reported results. To the extent that we incur expenses or recognize net sales 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 2020 had a favorable impact of $1.0 million on net sales outside of the U.S. Although we seek to manage our foreign currency exposure by matching non-dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we may enter into currency hedges from time to time.

Our global operations may expose us to tax risks

We are subject to taxes in the U.S. and numerous foreign jurisdictions. Significant judgment and interpretation of tax laws are required to estimate our tax liabilities. Tax laws and rates in various jurisdictions may be subject to significant change as a result of political and economic conditions. Our effective income tax rate could be adversely affected by changes in those tax laws, changes in the mix of earnings among tax jurisdictions, changes in the valuation of our deferred tax assets and liabilities, and the resolution of matters arising from tax audits.

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

We maintain a $300.0 million secured revolving credit facility secured by a pledge of substantially all of our property.

In October 2019, we and certain of our wholly-owned subsidiaries (collectively, the "Borrowers") entered into a Second Amended and Restated Credit Agreement (the "Amended Credit Agreement"). The Amended Credit Agreement provides for a $300.0 million secured revolving credit facility maturing on October 25, 2024, and amends and restates the previous $125.0 million secured revolving credit facility. No amount is currently outstanding on the credit facility as of December 31, 2020 or as of the date hereof, but the Company may draw on this facility in the future.

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

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

We believe that we are in compliance with the covenants, and there were no events of default, at December 31, 2020 (and in prior periods). However, there can be no assurance that we will be able to meet such financial covenants in future fiscal quarters. The failure to do so could result in an event of default under such agreement, which could have a material adverse effect on our financial position in the event that we have significant amounts drawn under the facility at such time.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our principal facilities as of December 31, 2020 are as follows:

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

Item 3. Legal Proceedings

For a description of 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, 2021, we had 290 holders of record of our common stock. The closing price of our common stock on February 22, 2021 was $44.98. 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
2019		
First Quarter	$ 74.44	$ 47.79
Second Quarter	57.85	48.02
Third Quarter	55.17	48.77
Fourth Quarter	54.02	39.75
2020		
First Quarter	$ 47.91	$ 22.11
Second Quarter	39.70	25.23
Third Quarter	36.00	28.03
Fourth Quarter	44.30	30.56

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 our ability to pay dividends in certain circumstances pursuant to our Amended Credit Agreement. We currently intend to retain all of our consolidated earnings to finance the continued growth of our business.

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

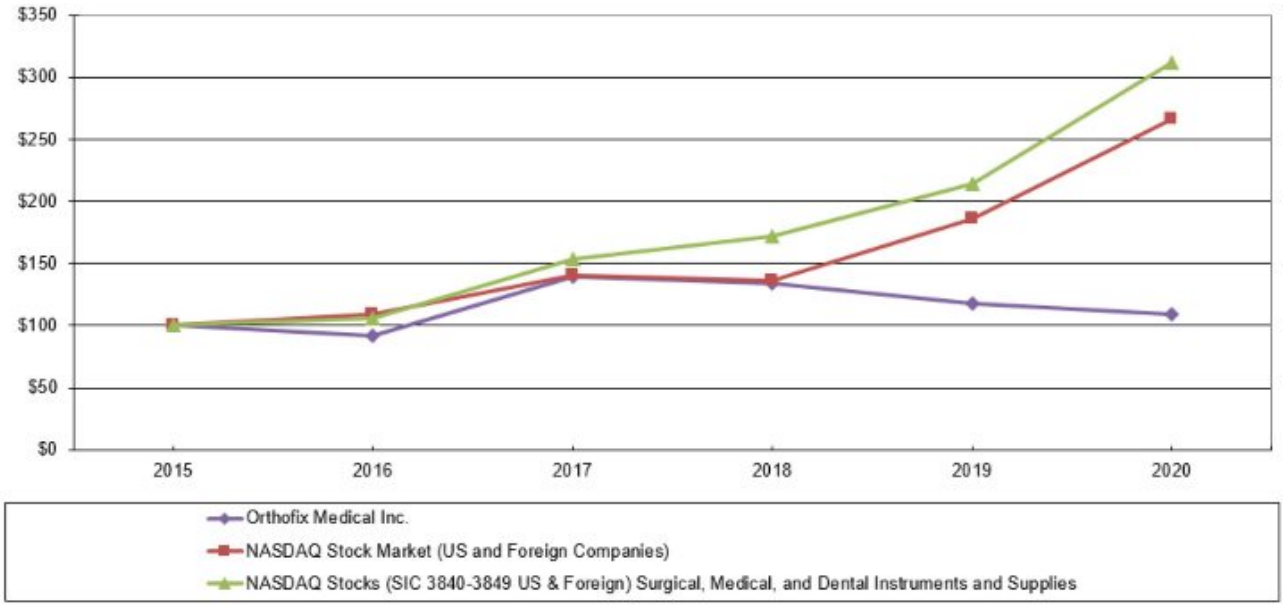
Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of 2020.

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 $100 was invested in Orthofix Common Stock and in each of the indexes on December 31, 2015. Points on the graph represent the performance as of the last business day of each of the years indicated.



Item 6. Selected Financial Data

No longer required under Item 301 of Regulation S-K.

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

The following discussion and analysis of our financial condition and result of operations should be read in conjunction with "Forward-Looking Statements" and our consolidated financial statements and notes thereto appearing elsewhere in this Annual Report. The discussion and analysis below is focused on our 2020 and 2019 financial results, including comparisons of our year-over-year performance between these years. Discussion and analysis of our 2018 fiscal year specifically, as well as the year-over-year comparison of our 2019 financial performance to 2018, is located in Part II, Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on February 24, 2020, which is available on our website at www.orthofix.com and the SEC's website at www.sec.gov.

Executive Summary

We are a global medical device and biologics company with a spine and extremities focus. Headquartered in Lewisville, Texas, we have two reporting segments: Global Spine and Global Extremities. Our spine and orthopedic extremities products are distributed in over 70 countries via our sales representatives and distributors.

Notable financial results in 2020 include the following:

- Net sales were $406.6 million, a decrease of 11.6% on a reported basis and 11.8% on a constant currency basis
- U.S. Spinal Implants net sales of $77.8 million, an increase $4.9 million, or 6.7%, on a reported basis
- U.S. Motion Preservation net sales of $18.4 million, an increase of $14.3 million, or 344.3% on a reported basis
- Net cash from operating activities of $74.3 million, an increase of $42.2 million or 131.9%

COVID-19 Update and Outlook

The global Coronavirus Disease 2019 ("COVID-19") pandemic has significantly affected our patients, communities, employees and business operations. The pandemic has led to the cancellation or deferral of elective surgeries and procedures within certain hospitals, ambulatory surgery centers, and other medical facilities; restrictions on travel; the implementation of physical distancing measures; and the temporary or permanent closure of businesses. In addition, broad economic factors resulting from the pandemic, including increased unemployment rates and reduced consumer spending, are affecting our patients and partners. These circumstances have negatively affected the sales of our products, particularly during the period from March 2020 through May 2020 when elective surgery restrictions were most pronounced, though these effects remain ongoing in certain geographical areas. However, we remain focused on protecting the health and wellbeing of our employees, partners, patients, and the communities in which we operate while assuring the continuity of our business operations.

At this time, the future trajectory of the COVID-19 pandemic remains uncertain, both in the U.S. and in other markets. Although we anticipate that there will be vaccines widely distributed in the future, the timing and efficacy of such vaccines are uncertain.

Given these various uncertainties, it is unclear the extent to which lingering slowdowns in elective procedures will affect our business into 2021 and beyond. We expect that the effects of COVID-19 on our business will depend on various factors including (i) the magnitude and length of any additional in case waves, (ii) the distribution, efficacy, and public acceptance of COVID-19 vaccines (iii) the comfort level of patients in returning to clinics and hospitals, (iv) the extent to which localized elective surgery shutdowns occur, (v) the unemployment rate's effect on potential patients lacking medical insurance coverage, and (vi) general hospital capacity constraints occurring because of the need to treat COVID-19 patients.

In addition, while we have not seen such effects to date, risk remains that COVID-19 could have material negative effects on contractual counterparties, leading to supply chain disruptions or counterparty payment defaults and bankruptcies (including bankruptcies to hospital systems that significantly rely on revenue from elective surgeries).

Results of Operations

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

	Year ended December 31,		
	2020 (%)	2019 (%)	2018 (%)
Net sales	100.0	100.0	100.0
Cost of sales	25.1	21.9	21.3
Gross profit	74.9	78.1	78.7
Sales and marketing	50.3	48.6	45.4
General and administrative	16.7	18.6	18.4
Research and development	9.6	7.5	7.3
Acquisition-related amortization and remeasurement	(0.2)	7.5	1.0
Operating income (loss)	(1.5)	(4.1)	6.6
Net income (loss)	0.6	(6.2)	3.0

Net Sales by Reporting Segment

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

				Percentage Change			
				2020/2019	2020/2019	2019/2018	2019/2018
(U.S. Dollars, in thousands)	2020	2019	2018	Reported	Constant Currency	Reported	Constant Currency
Bone Growth Therapies	$ 171,396	$ 197,181	$ 195,252	-13.1%	-13.1%	1.0%	1.0%
Spinal Implants	94,857	94,544	91,658	0.3%	0.2%	3.1%	3.8%
Biologics	55,482	65,496	59,684	-15.3%	-15.3%	9.7%	9.7%
Global Spine	321,735	357,221	346,594	-9.9%	-10.0%	3.1%	3.2%
Global Extremities	84,827	102,734	106,448	-17.4%	-18.2%	-3.5%	0.3%
Net sales	$ 406,562	$ 459,955	$ 453,042	-11.6%	-11.8%	1.5%	2.6%

Global Spine

Global Spine offers the following products categories:

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

2020 Compared to 2019

Net sales decreased $35.5 million or 9.9%

- Bone Growth Therapies net sales decreased $25.8 million or 13.1%, primarily driven by the disruption caused by COVID-19, which has led to lower order volumes

- Spinal Implants net sales increased $0.3 million or 0.3%, in spite of the disruption caused by COVID-19, as Motion Preservation net sales increased $11.7 million as a result of increases in case volumes and active surgeons, as the U.S. market continues to adopt our M6-C artificial cervical disc
- Biologics net sales decreased $10.0 million or 15.3%, primarily driven by lower procedure volumes as a result of the disruption caused by COVID-19 and continued pricing pressure observed within this market

Global Extremities

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

2020 Compared to 2019

Net sales decreased $17.9 million, or 17.4%

- Decrease of $18.7 million, primarily a result of the impact of COVID-19 on procedure volumes, particularly with our international stocking distributors
- Partially offset by an increase of $0.8 million due to changes in foreign currency exchange rates, which had a positive impact on net sales for 2020

Gross Profit

				Percentage Change	
(U.S. Dollars, in thousands)	**2020**	**2019**	**2018**	**2020/2019**	**2019/2018**
Net sales	$ 406,562	$ 459,955	$ 453,042	-11.6%	1.5%
Cost of sales	101,889	100,607	96,628	1.3%	4.1%
Gross profit	$ 304,673	$ 359,348	$ 356,414	-15.2%	0.8%
Gross margin	74.9%	78.1%	78.7%	-3.2%	-0.6%

2020 Compared to 2019

Gross profit decreased $54.7 million, or 15.2%

- Decrease primarily due to the decline in net sales and lower fixed cost absorption, primarily attributable to COVID-19 and its negative effect on elective procedure volumes
- Decrease also partially due to the recognition of non-cash inventory charges on products due to lower procedure volumes, largely as a result of COVID-19

Sales and Marketing Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2020**	**2019**	**2018**	**2020/2019**	**2019/2018**
Sales and marketing	$ 204,434	$ 223,676	$ 205,527	-8.6%	8.8%
As a percentage of net sales	50.3%	48.6%	45.4%	1.7%	3.2%

2020 Compared to 2019

Sales and marketing expense decreased $19.2 million

- Decrease largely attributable to reduced commissions as a result of the decline in net sales, partially offset by commission support provided to our direct sales representatives during the second quarter of 2020
- Decrease in travel, entertainment, and marketing expenses related to the cancellation of several sales events and conferences in 2020 and the leveraging of virtual trainings and events in response to the COVID-19 pandemic

General and Administrative Expense

(U.S. Dollars, in thousands)	2020	2019	2018	Percentage Change 2020/2019	Percentage Change 2019/2018
General and administrative	$ 67,948	$ 85,607	$ 83,251	-20.6%	2.8%
As a percentage of net sales	16.7%	18.6%	18.4%	-1.9%	0.2%

2020 Compared to 2019

General and administrative expense decreased $17.7 million

- Decrease of $9.0 million attributable to lower succession and transition charges, including acceleration of certain share-based compensation expense, relating to the retirement, transition, or termination of certain executive officers and from targeted restructuring activities
- Decrease of $6.3 million in expenses associated with lower strategic investments, largely due to diligence and integration costs associated with strategic initiatives
- Decrease of $2.6 million attributable to lower legal judgments and settlements

Research and Development Expense

(U.S. Dollars, in thousands)	2020	2019	2018	Percentage Change 2020/2019	Percentage Change 2019/2018
Research and development	$ 39,056	$ 34,637	$ 33,218	12.8%	4.3%
As a percentage of net sales	9.6%	7.5%	7.3%	2.1%	0.2%

2020 Compared to 2019

Research and development expense increased $4.4 million

- Increase of $2.8 million related to costs to comply with recent medical device reporting regulations
- Remaining increase primarily the result of our efforts to build out our internal team to support the acceleration of our new product innovation initiative

Acquisition-related Amortization and Remeasurement

(U.S. Dollars, in thousands)	2020	2019	2018	Percentage Change 2020/2019	Percentage Change 2019/2018
Acquisition-related amortization and remeasurement	$ (499)	$ 34,212	$ 4,324	-101.5%	691.2%
As a percentage of net sales	-0.2%	7.5%	1.0%	-7.7%	6.5%

2020 ***Compared to 2019***

Acquisition-related amortization and remeasurement decreased $34.7 million

- Decrease of $36.4 million primarily related to the remeasurement of potential future revenue-based milestone payments associated with the Spinal Kinetics acquisition that become due upon achievement of certain revenue targets, primarily attributable to the effects and uncertainty of COVID-19 as it relates to the estimated likelihood and timing of potential milestone payments
- Partially offset by an increase of $1.7 million related to the amortization of intangible assets acquired through business combinations or asset acquisitions

Non-operating Expense

(U.S. Dollars, in thousands)	2020	2019	2018	Percentage Change 2020/2019	Percentage Change 2019/2018
Interest expense, net	$ (2,483)	$ (122)	$ (828)	1935.2%	-85.3%
Other income (expense)	8,381	(8,143)	(6,381)	-202.9%	27.6%

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 certain privately-held companies, and credit losses recognized on certain convertible debt investments. 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.

2020 Compared to 2019

Interest expense, net, increased $2.4 million

- Decrease of $1.5 million attributable interest income recognized on our investment in eNeura in 2019
- Increase of $0.8 million associated with interest expense incurred on our outstanding indebtedness under our secured revolving credit facility

Other income (expense), net, increased $16.5 million

- Increase of $6.5 million associated with an other-than-temporary impairment on the eNeura debt security in 2019, prior to its settlement
- Increase of $5.3 million associated with changes in foreign currency exchange rates, as we recorded a non-cash remeasurement gain of $3.9 million in 2020 compared to a loss of $1.4 million in 2019
- Increase of $4.7 million attributable to funds received from the U.S. Department of Health and Human Services as part of the Provider Relief Fund included within the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act")

Income Taxes

				Percentage Change	
(U.S. Dollars, in thousands)	**2020**	**2019**	**2018**	**2020/2019**	**2019/2018**
Income tax expense (benefit)	$ (2,885)	$ 1,413	$ 9,074	-304.2%	-84.4%
Effective tax rate	784.0%	-5.2%	39.7%	789.2%	-44.9%

2020 Effective Tax Rate

The increase in the effective tax rate during the year was primarily a result of the statute expirations of uncertain tax positions and the reduction in contingent consideration, offset by the increase in income before income taxes, increases in valuation allowance, and non-deductible executive compensation. The primary factors affecting our tax rate for 2020 are as follows:

- Statute expirations and effective settlement of uncertain tax positions
- Valuation allowance recognized on certain foreign deferred tax assets
- Non-taxable decreases in the fair value of contingent consideration
- Executive compensation that is not deductible as a result of the Tax Act
- State tax and foreign income taxed at differing rates

2019 Effective Tax Rate

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

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

Segment Review

Our business is managed through two reporting segments: Global Spine and Global Extremities. The primary metric used in managing the business by segment is EBITDA (which is described further in Note 16 to the Notes to the Consolidated Financial Statements contained in Item 8 of this Annual Report).

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

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2020**	**2019**	**2018**
Global Spine	$ 63,036	$ 39,528	$ 76,545
Global Extremities	(4,993)	7,496	9,453
Corporate	(25,382)	(49,252)	(43,626)
Total EBITDA	32,661	(2,228)	42,372
Depreciation and amortization	(30,546)	(24,699)	(18,659)
Interest expense, net	(2,483)	(122)	(828)
Income (loss) before income taxes	$ (368)	$ (27,049)	$ 22,885

Liquidity and Capital Resources

Cash, cash equivalents, and restricted cash at December 31, 2020 was $96.8 million compared to $70.4 million at December 31, 2019.

	Year Ended December, 31,		
(U.S. Dollars, in thousands)	**2020**	**2019**	**Change**
Net cash from operating activities	$ 74,272	$ 32,033	$ 42,239
Net cash from investing activities	(52,334)	(22,924)	(29,410)
Net cash from financing activities	3,245	(10,688)	13,933
Effect of exchange rate changes on cash and restricted cash	1,235	(207)	1,442
Net change in cash, cash equivalents, and restricted cash	$ 26,418	$ (1,786)	$ 28,204

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)	**2020**	**2019**	**Change**
Net cash from operating activities	$ 74,272	$ 32,033	$ 42,239
Capital expenditures	(17,094)	(20,524)	3,430
Free cash flow	$ 57,178	$ 11,509	$ 45,669

Operating Activities

Cash flows from operating activities increased $42.2 million

- Increase in net income (loss) of $31.0 million
- Net decrease of $37.8 million in non-cash gains and losses, largely related to changes in fair value of contingent consideration, share-based compensation expense, and interest and loss on valuation of investment securities
- Net increase of $49.1 million relating to changes in working capital accounts, primarily attributable to changes in accounts receivable, a $13.9 million prepayment received under the Medicare & Medicaid Services (“CMS”) Accelerated and Advance Payment Program, inventories, and other current and long-term assets and liabilities, which included the expiration of statute of limitations related to certain unrecognized tax benefits.

Two of our primary working capital accounts are accounts receivable and inventory. Day’s sales in receivables were 57 days at December 31, 2020 compared to 66 days at December 31, 2019 (calculated using fourth quarter net sales and ending accounts receivable), largely due to strong collection efforts on accounts receivable, coupled with a slight decrease in net sales for the quarter. Inventory turns remained consistent at 1.2 times as of December 31, 2020 and 2019.

Investing Activities

Cash flows from investing activities decreased $29.4 million

- Decrease of $18.0 million associated with cash paid in 2020 to acquire assets associated with the FITBONE intramedullary lengthening system for limb lengthening of the femur and tibia bones
- Decrease of $10.0 million associated with our investments in Neo Medical SA, in the form of preferred stock and a convertible loan agreement

Financing Activities

Cash flows from financing activities increased $13.9 million

- Increase of $13.7 million associated with the payment of the Spinal Kinetics FDA Milestone in 2019, which represented the acquisition-date fair value attributable to the FDA Milestone liability originally recognized

Credit Facilities

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

Borrowings under the Amended Credit Agreement may be used for, among other things, working capital and other general corporate purposes (including share repurchases, permitted acquisitions and permitted payments of dividends and other distributions). Borrowings under the Amended Credit Agreement may be limited based upon EBITDA levels recognized over the preceding 12 months.

In April 2020, as a precautionary measure to increase our cash position and preserve financial flexibility in response to the uncertainty resulting from the COVID-19 pandemic, we completed a borrowing of $100.0 million under our secured revolving credit facility. We repaid the $100.0 million in borrowings in the third quarter of 2020. As of December 31, 2020, we have no outstanding borrowings under the Amended Credit Agreement. For additional information regarding the credit facility, see Note 11 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

In addition, we have no borrowings outstanding on our €5.5 million ($6.7 million) available line of credit in Italy as of December 31, 2020. 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.

Impact of COVID-19 and the CARES Act on Liquidity and Capital Resources

In April 2020, as precautionary measures to increase our cash position and preserve financial flexibility in response to the uncertainty from the COVID-19 pandemic, we (i) completed a borrowing of $100.0 million under our secured revolving credit facility (which was subsequently repaid in full in the third quarter of 2020), (ii) instituted temporary salary reductions for U.S. employees and the Board of Directors, which were in effect for two months during the second quarter of 2020, (iii) suspended the 401(k) match program through the remainder of fiscal year 2020, and (iv) initiated organizational travel restrictions and a temporary reduction in new hiring.

On March 27, 2020, the CARES Act was signed into U.S. federal law, which provided emergency assistance and health care for individuals, families, and businesses affected by the COVID-19 pandemic.

In April 2020, we received $13.9 million in funds from the CMS Accelerated and Advance Payment Program to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic. On October 1, 2020, the President of the United States signed the "Continuing Appropriations Act, 2021 and Other Extensions Act," which relaxed previously existing recoupment terms for providers and suppliers that received funds from the program. Under these new terms, recoupment will be delayed until one year after payment was issued. After that first year, Medicare will automatically recoup 25% of Medicare payments otherwise owed to the provider or supplier for 11 months. At the end of the 11-month period, recoupment will increase to 50% for another 6 months.

Thus, during these time periods, rather than receiving the full amount of payment for newly submitted claims, our outstanding accelerated / advance payment balance will be reduced by the recoupment amount until the full balance has been repaid.

In addition, in April 2020, we automatically received, without request, $4.7 million in funds from the U.S. Department of Health and Human Services as part of the Provider Relief Fund. Upon review of the qualifying criteria required to retain the funding, which primarily relate to lost revenues or the incurrence of expenses attributable to COVID-19, it was determined that we met the criteria to retain the funds received.

Further, as part of the CARES Act, we were permitted to defer all employer social security payroll tax payments for the remainder of the 2020 calendar year, such that 50% of the taxes are deferred until December 31, 2021, with the remaining 50% deferred until December 31, 2022. As of December 31, 2020, we have deferred $0.6 million associated with this program. This deferred balance was subsequently repaid in the first quarter of 2021.

Given the various uncertainties attributable to the COVID-19 pandemic that remain, both in the U.S. and in other markets, our liquidity may be impacted in the future by the potential of continued decreases in elective surgical procedures, delays in payments from customers, facility closures, or other reasons related to the COVID-19 pandemic. As of the date of issuance of these consolidated financial statements, the extent to which COVID-19 is likely to materially impact our liquidity in the future remains uncertain.

Spinal Kinetics Acquisition and Contingent Consideration

As part of the consideration for the Spinal Kinetics acquisition, we agreed to milestone payments in the future of up to $60.0 million in cash. One milestone payment, which was for $15.0 million, became due upon FDA approval of Spinal Kinetics' M6-C artificial cervical disc (the "FDA Milestone"). The FDA Milestone was achieved and paid in 2019.

The remaining milestone payments are comprised of revenue-based milestone payments of up to $45.0 million in connection with future sales of the acquired artificial discs. The fair value of the contingent consideration arrangement as of December 31, 2020 was $35.4 million; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration (though not greater than $45.0 million). As of December 31, 2020, we classified $14.9 million of the liability attributable to the revenue-based milestone within other current liabilities, as we expect to pay one of the revenue-based milestones in the next twelve months, and the remaining $20.5 million within other long-term liabilities. For additional discussion of this matter, see Note 12 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

FITBONE Asset Acquisition

On February 3, 2020, we entered into an Asset Purchase Agreement (the "Purchase Agreement") with Wittenstein SE ("Wittenstein"), a privately-held German-based company, to acquire assets associated with the FITBONE intramedullary lengthening system for limb lengthening of the femur and tibia bones. Under the terms of the Purchase Agreement, as consideration for the acquired assets, we paid $18.0 million in cash consideration and entered into a Contract Manufacturing and Supply Agreement ("CMSA") with Wittenstein. The acquisition was completed on March 26, 2020 and was treated as a business combination.

Neo Medical Investment and Convertible Loan

On October 1, 2020, we entered into a partnership with Neo Medical SA, a privately held Swiss-based medtech company ("Neo Medical"), that includes a co-development agreement covering the parties' joint development of single use instruments for cervical spine procedures, and a distribution agreement under which Orthofix will exclusively distribute Neo Medical's thoracolumbar procedure solutions to certain U.S. customer accounts.

Separately, we also purchased shares of Neo Medical's preferred stock for consideration of $5.0 million and entered into a Convertible Loan Agreement, whereby we loaned CHF 4.6 million to Neo Medical (the "Convertible Loan"), which had a value of approximately $5.0 million at the date of issuance. The loan bears interest at 8.0%, with interest due semi-annually. The Convertible Loan matures in October 2024, provided that if a change in control of Neo Medical occurs prior to maturity, the Convertible Loan shall become immediately due upon such event. Both of these investments are recorded within other long-term assets.

The Convertible Loan may be convertible by either party into shares of Neo Medical's preferred stock. The price per share at which the loan converts is dependent upon i) the party electing conversion and ii) Neo Medical's price per share in its most recent fundraising activities at the time of conversion, as specified within the agreement.

Brazil

In September 2019, in relation to an ongoing legal dispute with a former Brazilian distributor, approximately $0.5 million (based upon foreign exchange rates as of December 31, 2020) of our cash in Brazil was frozen upon request to satisfy a judgment. Although we are appealing the judgment, this cash has been reclassified to restricted cash. For additional discussion regarding this matter, see Note 13 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Related Party Transaction

On February 2, 2021, we entered into a technology assignment and royalty agreement with a medical device technology company partially owned and controlled by the wife of President and Chief Executive Officer, Jon Serbousek, whereby we acquired the intellectual property rights to certain assets for consideration of up to $10.0 million. Consideration is comprised of $1.0 million, which was paid at signing, and $9.0 million in contingent consideration, dependent upon multiple milestones, such as receipt of 510(k) clearance or the attainment of certain net sales targets. In addition, we will pay a royalty of 2% to 4% on net sales, commencing upon commercialization of the acquired assets. The transaction was approved by our Audit and Finance Committee, with the Audit and Finance Committee directly supervising and directing the negotiation of the transaction by our employees who reported directly to the committee in connection with such negotiations. Mr. Serbousek was excluded from such discussions and did not participate in the negotiation or evaluation of the transaction. Mr. Serbousek is also being excluded from the administration and implementation of the agreements and the transactions contemplated thereby, all discussions or disputes with the counterparty in connection with the agreement, the transactions contemplated thereby, or the administration or implementation thereof, oversight of our development and commercialization activities in relation to the acquired technology, and all other matters relating to the relationship between us and the counterparty.

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 increased from $49.2 million at December 31, 2019 to $53.7 million at December 31, 2020, due to currency translation. As a result of the 2017 Tax Act, current year earnings have been deemed to be repatriated. Our investment in foreign subsidiaries continues to be indefinite in nature, however, we may periodically repatriate a portion of these earnings to the extent that we do not incur significant additional tax liability.

Contractual Obligations

As a result of our operations, we are subject to certain contractual obligations with material cash requirements. Our material contractual obligations include, but are not limited to i) our contingent consideration arrangement associated with the Spinal Kinetics acquisition, ii) operating lease and finance lease obligations, and iii) uncertain tax positions.

For a description of our contingent consideration arrangements, lease obligations, and uncertain tax positions, refer to Notes 12, 9, and 20, respectively, of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Off-balance Sheet Arrangements

As of December 31, 2020, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, cash flows, liquidity, capital expenditures or capital resources that are material to investors. In addition, we do not consider the backlog of firm orders to be material.

Critical Accounting Estimates

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

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

Revenue Recognition

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

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

For revenue derived from third-party payors, including commercial insurance carriers, health maintenance organizations, preferred provider organizations and governmental payors, such as Medicare, in connection with the sale of our stimulation products, we recognize revenue when the stimulation product is fitted to and accepted by the patient and all applicable documents that are required by the third-party payor have been obtained. Amounts paid by these third-party payors are generally based on fixed or allowable reimbursement rates. These revenues are recorded at the expected or preauthorized reimbursement rates, net of any contractual allowances or adjustments. Certain billings are subject to review by the third-party payors and may be subject to adjustment.

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

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

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

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

Stocking distributors purchase our products and then re-sell them directly to customers, such as hospitals. Revenue derived from stocking distributor arrangements is recognized 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 Expected Credit Losses and Contractual Allowances

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. The determination of the contractual life of accounts receivable, the aging of outstanding receivables, as well as the historical collections, write-offs, and payor reimbursement experience over the estimated contractual lives of such receivables, are integral parts of the estimation process related to reserves for expected credit losses and the establishment of contractual allowances. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for expected credit losses and contractual allowances. Revisions in allowances for expected credit loss 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. These estimates are periodically tested against actual collection experience. In addition, we analyze our receivables by geography and by customer type, where appropriate, in developing estimates for expected credit losses.

We believe our allowance for credit losses is sufficient to cover customer credit risks; however, a 10% change in our allowance for credit losses as of December 31, 2020 would result in an increase or decrease to sales and marketing expense of $0.5 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, 2020 would result in an increase or decrease to net sales of

$0.5 million. Our allowance for credit losses and estimation of contractual allowances are “critical accounting estimates” because changes in the assumptions used to develop the estimates could materially affect key financial measures, including net sales, gross margin, operating income, EBITDA, net income, and accounts receivable.

Inventory Allowances

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

Valuation of Intangible Assets

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

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

Goodwill

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

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

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

In the fourth quarters of 2020 and 2019, we performed 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. As part of our qualitative assessment, we included quantitative factors to assess the likelihood of an impairment and concluded it more likely that not that an impairment hasn’t occurred.

Fair Value Measurements

Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The two most significant items that are or were recorded at fair value include (i) contingent consideration attributable to the Spinal Kinetics acquisition, (ii) our convertible loan agreement with Neo Medical and (iii) our eNeura debt security (prior to its restructuring and settlement in 2019).
The contingent consideration consists of potential future milestone payments of up to $60.0 million in cash associated with the Spinal Kinetics acquisition, which must be achieved within five years of the acquisition date to be paid. The milestone payments include (i) up to $15.0 million for meeting the FDA Milestone and (ii) revenue-based milestone payments of up to $45.0 million in connection with future sales of the M6-C artificial cervical disc and the M6-L artificial lumbar disc. The FDA milestone was achieved and paid in February of 2019.

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

We estimate the fair value of the remaining 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 net sales of Motion Preservation products, discount rates 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 $1.9 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 $2.0 million.

We estimate the fair value of our convertible loan agreement with Neo Medical using Monte Carlo simulations, option-pricing models, and a probability-weighted discounted cash flow model. The fair value measurement is based on significant inputs that are unobservable in the market, with significant unobservable inputs including applicable discount rates, implied volatility, the likelihood and projected timing of repayment or conversion, and projected cash flows in support of the estimated enterprise value of Neo Medical. Significant changes in these assumptions could result in a significantly higher or lower fair value. Holding other inputs constant, an increase in the assumed cost of equity discount rate by 2% would have resulted in a decrease in the fair value of the convertible loan of $0.9 million, whereas a decrease the cost of equity discount rate by 2% would have resulted in an increase in the fair value of the convertible loan by $1.1 million.

Prior to its restructuring and settlement in 2019 for $4.0 million, the fair value of the eNeura debt security was based upon significant unobservable inputs, including the use of a discounted cash flows model, requiring us to develop our own assumptions. Some of the more significant unobservable inputs used in the fair value measurement of the eNeura debt security were our estimates related to the timing and likelihood of conversion as a result of a change in control event, the timing and likelihood of repayment, and the applicable discount rate. Further, we were required to determine whether any decline in the fair value of the debt security below its basis was other-than-temporary, as the debt security was settled prior to our adoption of ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* . In making this determination, we considered our intentions to hold or sell the security, whether it more likely than not that we would be required to sell the security before the recovery of its amortized cost basis, and our best estimate of the amount that we ultimately expected to collect from the security. The estimated amount we expected to collect was based upon significant unobservable inputs, requiring us to develop our own assumptions.

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

Litigation and Contingent Liabilities

From time to time, we are parties to or targets of lawsuits, investigations and proceedings, including product liability, personal injury, patent and intellectual property, health and safety and employment and healthcare regulatory matters, which are handled and defended in the ordinary course of business. These lawsuits, investigations or proceedings could involve a substantial number of

claims and could also have an adverse impact on our reputation and customer base. Although we maintain various liability insurance programs for liabilities that could result from such lawsuits, investigations or proceedings, we are self-insured for a significant portion of such liabilities.

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

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

Tax Matters

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

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

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

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

Share-based compensation

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.

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

Non-GAAP Financial Measures

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

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

Constant Currency

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

EBITDA

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

Free Cash Flow

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

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

We are exposed to interest rate risk in connection with our Revolving Credit Facility, which bears interest at floating rates based on LIBOR, or possibly an alternative reference rate to be used in place of LIBOR upon the occurrence of a benchmark transition event, plus an applicable borrowing margin or at a base rate (as defined in the Amended Credit Agreement) plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant. As we do not have any balance outstanding associated with the Amended Credit Agreement as of December 31, 2020, this risk is currently minimal.

We believe that a concentration of credit risk related to our 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, 2020, we recorded a foreign currency gain of $3.9 million on the statement of operations and comprehensive income (loss) resulting from gains and losses in foreign currency transactions.

We also are subject to currency exposure from translating the results of our global operations into the U.S. Dollar at exchange rates that fluctuate during the period. The U.S. Dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the year ended December 31, 2020 and unfavorably impacted during the year ended December 31, 2019 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 $7.1 million and a decrease in operating income of $0.9 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 $7.1 million and an increase in operating income of $0.9 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, 2020, 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, 2020, the Company's internal control over financial reporting is effective based on the specified criteria.

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

Changes in Internal Control over Financial Reporting

There have not been any changes in our internal control over financial reporting during the fourth quarter of 2020 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, 2020, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Orthofix Medical Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive income (loss), changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2020, and the related notes and our report dated February 25, 2021 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 26, 2021

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 January 28, 2021 and incorporated herein by reference).
4.1	Form of Stock Certificate (filed as an exhibit to the Company's Current Report on Form 8-K dated August 1, 2018 and incorporated herein by reference).
4.2	Description of the Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and incorporated herein by reference).
10.1	Second Amended and Restated Credit Agreement, dated October 25, 2019, among Orthofix Medical Inc., Orthofix Inc., Orthofix Spinal Implants Inc., Orthofix International B.V., Orthofix III B.V., and certain subsidiaries of Orthofix Medical Inc. as guarantors, the several banks and other financial institutions as may from time to time become parties thereunder as lenders, and JPMorgan Chase, N.A., as administrative agent (filed as an exhibit to the Company's Current Report on Form 8-K filed on November 1, 2019 and incorporated herein by reference).
10.2†	Matrix Commercialization Collaboration Agreement, entered into July 24, 2008, by and between Orthofix Holdings, Inc. and Musculoskeletal Transplant Foundation (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and incorporated herein by reference).
10.3	Amendment No. 1 to Matrix Commercialization Collaboration Agreement, dated as of December 15, 2010, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and incorporated herein by reference).
10.4†	Amendment No. 2 to Matrix Commercialization Collaboration Agreement, dated as of January 9, 2012, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to amendment no. 1 to the Company's Annual Report on Form 10-K/A for the year ended December 31, 2011 and incorporated herein by reference).
10.5†	Amendment No. 3 to Matrix Commercialization Collaboration Agreement, entered into on July 1, 2013 and effective as of June 25, 2013, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2013 and incorporated herein by reference).

Exhibit Number	Description
10.6	Amendment No. 4 to Matrix Commercialization Collaboration Agreement, entered into on April 1, 2014, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed April 7, 2014 and incorporated herein by reference).
10.7†	Amendment No. 5 to Matrix Commercialization Collaboration Agreement, entered into on March 10, 2016, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Current Report on Form 8-K filed March 14, 2016 and incorporated herein by reference).
10.8†	Amendment No. 6 to Matrix Commercialization Collaboration Agreement, entered into on December 29, 2017, by and between Musculoskeletal Transplant Foundation, Inc. and Orthofix Holdings, Inc. (filed as an exhibit to the Company's Annual Report on Form 10-K filed February 26, 2018 and incorporated herein by reference).
10.9*	Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as Amended.
10.10	Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and incorporated herein by reference).
10.11	Amendment No. 1 to Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K dated June 8, 2020 and incorporated herein by reference).
10.12	Form of Employee Performance Stock Unit Agreement under the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and incorporated herein by reference).
10.13	Form of Time-Based Vesting Employee Restricted Stock Unit Grant Agreement (2019 Executive Retention Grants) under the Orthofix Medical Inc. Amended and Restated 202 Long-Term Incentive Plan (filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and incorporated herein by reference).
10.14	Form of Time-Based Vesting Employee Restricted Stock Grant Agreement under the Orthofix International N.V. 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed July 8, 2016 and incorporated here by reference).
10.15	Form of 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).
10.16	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).
10.17	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).
10.18	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).
10.19	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).
10.20	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).
10.21	Employee Inducement Restricted Stock Unit Agreement for Paul Gonsalves (filed as an exhibit to the Company's Form S-8 filed on September 14, 2020 and incorporated herein by reference).

Exhibit Number	Description
10.22	Employee Inducement Non-Qualified Stock Option Agreement for Paul Gonsalves (filed as an exhibit to the Company's Form S-8 filed on September 14, 2020 and incorporated herein by reference).
10.23	Employee Inducement Restricted Stock Unit Agreement for Jon Serbousek (filed as an exhibit to the Company's Form S-8 filed on August 5, 2019 and incorporated herein by reference).
10.24	Employee Inducement Non-Qualified Stock Option Agreement for Jon Serbousek (filed as an exhibit to the Company's Form S-8 filed on August 5, 2019 and incorporated herein by reference).
10.25	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 Restricted Stock Agreement (filed as an exhibit to the Company's Form S-8 filed on April 30, 2018 and incorporated herein by reference).
10.27	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).
10.28	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).
10.29	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).
10.30	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).
10.31	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).
10.32	Transition and Retirement Agreement, dated February 25, 2019, between Bradley R. Mason and Orthofix Medical Inc. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 and incorporated herein by reference).
10.33	Consulting Agreement, dated November 1, 2019, between Orthofix Medical Inc. and Bradley R. Mason (filed as an Exhibit to the Company's Current Report on Form 8-K filed November 1, 2019 and incorporated herein by reference).
10.34	Change in Control and Severance Agreement, dated November 1, 2019, between Orthofix Medical Inc. and Jon Serbousek (filed as an Exhibit to the Company's Current Report on Form 8-K filed November 1, 2019 and incorporated herein by reference).
10.35	Letter agreement, dated December 4, 2019, between the Company and Kevin Kenny (filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and incorporated herein by reference).
10.36	Change in Control and Severance Agreement, dated November 1, 2019, between Orthofix Medical Inc. and Kevin Kenny (filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2019 and incorporated herein by reference).
10.37*	Letter agreement, dated August 21, 2020, between the Company and Paul Gonsalves.
10.38	Change in Control and Severance Agreement, dated September 11, 2020, between Orthofix Medical Inc. and Paul Gonsalves (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 and incorporated herein by reference).

Exhibit Number	Description
10.39	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Doug Rice (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.40	Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Kimberley Elting (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.41	Amended Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Michael M. Finegan (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.42	Consulting Agreement, dated July 4, 2020, between Orthofix Medical Inc. and Michael Finegan (filed as an Exhibit to the Company's Quarterly Report on Form 10-Q filed August 6, 2020 and incorporated herein by reference).
10.43	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).
10.44	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).
10.45*	Termination Agreement, dated May 4, 2020 between Orthofix AG and Davide Bianchi.
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, 2020 filed on February 26, 2021, formatted in Inline XBRL (Inline Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss), (iii) Consolidated Statements of Changes in Shareholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to the Consolidated Financial Statements.
104	The cover page from Orthofix Medical Inc.'s Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL and contained in Exhibit 101.

* Filed with this Form 10-K.

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

Item 16. Form 10-K Summary

None

SIGNATURES

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

ORTHOFIX MEDICAL INC.

Dated: February 26, 2021

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

Dated: February 26, 2021

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

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

Name	Title	Date
/s/ JON SERBOUSEK **Jon Serbousek**	President and Chief Executive Officer, Director (Principal Executive Officer)	February 26, 2021
/s/ DOUG RICE **Doug Rice**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 26, 2021
/s/ RONALD A. MATRICARIA **Ronald A. Matricaria**	Chairman of the Board of Directors	February 26, 2021
/s/ JASON HANNON **Jason Hannon**	Director	February 26, 2021
/s/ JAMES HINRICHS **James Hinrichs**	Director	February 26, 2021
Alexis V. Lukianov	Director	February 26, 2021
/s/ LILLY MARKS **Lilly Marks**	Director	February 26, 2021
/s/ MICHAEL E. PAOLUCCI **Michael E. Paolucci**	Director	February 26, 2021
/s/ MARIA SAINZ **Maria Sainz**	Director	February 26, 2021
/s/ JOHN SICARD **John Sicard**	Director	February 26, 2021

ORTHOFIX MEDICAL INC.

Statement of Management's Responsibility for Financial Statements

To the Shareholders of Orthofix Medical Inc.:

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

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

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

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

James Hinrichs
Chairman of the Audit Committee

Jon Serbousek
President and Chief Executive Officer, Director

Doug Rice
Chief Financial Officer

ORTHOFIX MEDICAL INC.

Index to Consolidated Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Orthofix Medical Inc. (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive income (loss), changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020, 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, 2020, 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, 2021 expressed an unqualified opinion thereon.

Adoption of New Accounting Standards

As discussed in Notes 3, 9 and 15 to the consolidated financial statements, the Company changed its methods of accounting for 1) leases in 2019 due to the adoption of ASU No. 2016-02, *Leases (Topic 842)*, 2) recognition of revenue from contracts with customers in 2018 due to the adoption of ASU No. 2014-09, *Revenue from Contracts with Customers*, and 3) measurement of equity investments at fair value and the recognition of any changes in fair value in 2018 due to the adoption of ASU No. 2016-01, *Financial Instruments* and ASU 2018-03, *Technical Connections and Improvements to Financial Instruments*.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

Contingent Consideration – Spinal Kinetics

Description of the Matter

As described in Note 12 to the consolidated financial statements, the Company's contingent consideration at the acquisition date of Spinal Kinetics, Inc. consisted of potential milestone payments of $15.0 million for achieving FDA approval and up to $45 million in connection with certain future product sales. At December 31, 2020, the fair value of contingent consideration was $35.4 million.

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

How We Addressed the Matter in Our Audit

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

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

Inventory Excess and Obsolescence Reserves

Description of the Matter

At December 31, 2020, the Company's inventory balance is $84.6 million, which is net of management's estimate of inventory excess and obsolescence reserves. As described in Note 5 to the consolidated financial statements, management adjusts the value of its inventory to net realizable value to the extent it determines inventory cost cannot be recovered due to obsolescence or other factors. In order to make these determinations, management estimates future demand and sales prices to determine the appropriate inventory reserves and to make corresponding adjustments to the carrying value of these inventories to reflect the lower of cost or net realizable value.

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

How We Addressed the Matter in Our Audit

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

To test the inventory excess and obsolescence reserve balance, we performed audit procedures that included, among others, evaluating the significant assumptions and qualitative adjustments described above and the underlying data used by the Company in its analysis. Our audit procedures included testing the completeness and accuracy of the underlying data used in the model and evaluating whether such data was representative of current circumstances. We assessed the historical accuracy of management's estimates and performed sensitivity analyses of significant assumptions to evaluate the changes in the inventory excess and obsolescence reserves that would result from changes in the assumptions.

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

Description of the Matter	As described in Note 15 to the consolidated financial statements, the Company recognizes revenue from stocking distributors ("distributor revenue") upon shipment and receipt of a confirming purchase order, which is when the distributor obtains control of the promised goods. Those revenues are based on the Company's historical collection experience, which considers the potential for, among other things, the return of previously sold products. Auditing the Company's measurement of any potential variable consideration under the distributor contracts is especially challenging due to the potential of side agreements that may allow for the return of previously sold products.
How We Addressed the Matter in Our Audit	We obtained an understanding, evaluated the design and tested the operating effectiveness of controls over the Company's process to (i) review and approve new distributor agreements; (ii) review and approve all changes made to existing arrangements; (iii) review and approve product returns; and (iv) identify and report potential distributor side agreements by inspecting source documentation used during management's review. Our audit procedures included, among others, confirmation of the terms and conditions of material distributor agreements. In addition, we evaluated whether the Company's actual returns of product from distributors were appropriately approved and considered in management's application of its revenue recognition policy for distributor revenue.

/s/ Ernst & Young LLP

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

Dallas, Texas
February 26, 2021

ORTHOFIX MEDICAL INC.

Consolidated Balance Sheets as of December 31, 2020 and 2019

(U.S. Dollars, in thousands except share and per share data)	2020	2019
Assets		
Current assets		
Cash and cash equivalents	$ 96,291	$ 69,719
Restricted cash	530	684
Accounts receivable, net of allowances of $4,848 and $3,987, respectively	72,423	86,805
Inventories	84,635	82,397
Prepaid expenses and other current assets	16,500	20,948
Total current assets	270,379	260,553
Property, plant and equipment, net	63,613	62,727
Intangible assets, net	60,517	54,139
Goodwill	84,018	71,177
Deferred income taxes	25,042	35,117
Other long-term assets	22,292	11,907
Total assets	**$ 525,861**	**$ 495,620**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 23,118	$ 19,886
Current portion of finance lease liability	510	323
Other current liabilities	80,271	64,674
Total current liabilities	103,899	84,883
Long-term portion of finance lease liability	22,338	20,648
Other long-term liabilities	42,760	62,458
Total liabilities	168,997	167,989
Contingencies (Note 13)		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 19,423,874 and 19,022,619 issued and outstanding as of December 31, 2020 and 2019, respectively	1,942	1,902
Additional paid-in capital	292,291	271,019
Retained earnings	59,379	57,749
Accumulated other comprehensive income (loss)	3,252	(3,039)
Total shareholders' equity	356,864	327,631
Total liabilities and shareholders' equity	**$ 525,861**	**$ 495,620**

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

ORTHOFIX MEDICAL INC.

Consolidated Statements of Operations and Comprehensive Income (Loss)
For the years ended December 31, 2020, 2019, and 2018

(U.S. Dollars, in thousands, except share and per share data)	2020	2019	2018
Net sales	$ 406,562	$ 459,955	$ 453,042
Cost of sales	101,889	100,607	96,628
Gross profit	304,673	359,348	356,414
Sales and marketing	204,434	223,676	205,527
General and administrative	67,948	85,607	83,251
Research and development	39,056	34,637	33,218
Acquisition-related amortization and remeasurement	(499)	34,212	4,324
Operating income (loss)	(6,266)	(18,784)	30,094
Interest expense, net	(2,483)	(122)	(828)
Other income (expense), net	8,381	(8,143)	(6,381)
Income (loss) before income taxes	(368)	(27,049)	22,885
Income tax benefit (expense)	2,885	(1,413)	(9,074)
Net income (loss)	**$ 2,517**	**$ (28,462)**	**$ 13,811**
Net income (loss) per common share:			
Basic	$ 0.13	$ (1.51)	$ 0.73
Diluted	0.13	(1.51)	0.72
Weighted average number of common shares:			
Basic	19,267,920	18,903,289	18,494,002
Diluted	19,391,718	18,903,289	18,911,610
Other comprehensive income (loss), before tax			
Unrealized gain (loss) on debt securities	1,881	(2,593)	1,770
Reclassification adjustment for amortization of historical unrealized gains on debt security	—	(1,034)	—
Reclassification adjustment for loss on debt security in net income	—	(5,193)	—
Currency translation adjustment	4,872	(653)	(1,823)
Other comprehensive income (loss), before tax	6,753	(9,473)	(53)
Income tax benefit (expense) related to items of other comprehensive income (loss)	(462)	2,201	(438)
Other comprehensive income (loss), net of tax	6,291	(7,272)	(491)
Comprehensive income (loss)	$ 8,808	$ (35,734)	$ 13,320

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, 2020, 2019, and 2018

(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, 2017	18,278,833	$ 1,828	$ 220,591	$ 70,402	$ 3,787	$ 296,608
Cumulative effect adjustment from adoption of ASU 2014-09	—	—	—	4,761	—	4,761
Cumulative effect adjustment from adoption of ASU 2016-16	—	—	—	(1,896)	—	(1,896)
Net income	—	—	—	13,811	—	13,811
Other comprehensive loss, net of tax	—	—	—	—	(491)	(491)
Share-based compensation	—	—	18,930	—	—	18,930
Common shares issued	300,855	30	3,644	—	—	3,674
At December 31, 2018	**18,579,688**	**$ 1,858**	**$ 243,165**	**$ 87,078**	**$ 3,296**	**$ 335,397**
Cumulative effect adjustment from adoption of ASU 2016-02	—	—	—	70	—	70
Cumulative effect adjustment from adoption of ASU 2018-02	—	—	—	(937)	937	—
Net loss	—	—	—	(28,462)	—	(28,462)
Other comprehensive loss, net of tax	—	—	—	—	(7,272)	(7,272)
Share-based compensation	—	—	21,540	—	—	21,540
Common shares issued	442,931	44	6,314	—	—	6,358
At December 31, 2019	**19,022,619**	**$ 1,902**	**$ 271,019**	**$ 57,749**	**$ (3,039)**	**$ 327,631**
Cumulative effect adjustment from adoption of ASU 2016-13	—	—	—	(887)	—	(887)
Net income	—	—	—	2,517	—	2,517
Other comprehensive income, net of tax	—	—	—	—	6,291	6,291
Share-based compensation	—	—	16,207	—	—	16,207
Common shares issued	401,255	40	5,065	—	—	5,105
At December 31, 2020	**19,423,874**	**$ 1,942**	**$ 292,291**	**$ 59,379**	**$ 3,252**	**$ 356,864**

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, 2020, 2019, and 2018

(U.S. Dollars, in thousands)	2020	2019	2018
Cash flows from operating activities			
Net income (loss)	$ 2,517	$ (28,462)	$ 13,811
Adjustments to reconcile net income to net cash from operating activities			
Depreciation and amortization	30,546	24,699	18,659
Amortization of operating lease assets, debt costs, and other assets	3,730	3,778	1,024
Provision for expected credit losses	199	1,891	(599)
Deferred income taxes	10,787	1,393	(2,661)
Share-based compensation	16,207	21,540	18,930
Interest and loss on the valuation of investment securities	116	5,000	3,050
Change in fair value of contingent consideration	(7,300)	29,140	3,069
Other	(2,228)	2,433	1,633
Changes in operating assets and liabilities, net of effects of acquisitions			
Accounts receivable	13,283	(11,037)	(3,706)
Inventories	(873)	(5,712)	9,698
Prepaid expenses and other current assets	4,526	(3,698)	(1,127)
Accounts payable	2,532	2,138	(170)
Other current liabilities	5,975	(7,716)	(7,563)
Contract liability (Note 15)	13,851	—	—
Payment of contingent consideration	—	(1,340)	—
Other long-term assets and liabilities	(19,596)	(2,014)	(4,130)
Net cash from operating activities	**74,272**	**32,033**	**49,918**
Cash flows from investing activities			
Acquisition of a business	(18,000)	—	(44,294)
Capital expenditures for property, plant and equipment	(15,485)	(18,997)	(13,592)
Capital expenditures for intangible assets	(1,609)	(1,527)	(1,664)
Purchase of investment securities	(10,000)	—	—
Asset acquisitions and other investments	(7,240)	(2,400)	(1,448)
Net cash from investing activities	**(52,334)**	**(22,924)**	**(60,998)**
Cash flows from financing activities			
Proceeds from revolving credit facility	100,000	—	—
Repayment of revolving credit facility	(100,000)	—	—
Proceeds from issuance of common shares	7,598	11,551	7,100
Payments related to withholdings for share-based compensation	(2,493)	(5,193)	(3,425)
Payment of contingent consideration	—	(13,660)	—
Payments related to finance lease obligation	(323)	(365)	—
Payment of debt issuance costs and other financing activities	(1,537)	(3,021)	(682)
Net cash from financing activities	**3,245**	**(10,688)**	**2,993**
Effect of exchange rate changes on cash and restricted cash	1,235	(207)	(881)
Net change in cash, cash equivalents, and restricted cash	26,418	(1,786)	(8,968)
Cash, cash equivalents, and restricted cash at the beginning of the year	70,403	72,189	81,157
Cash, cash equivalents, and restricted cash at the end of the year	**$ 96,821**	**$ 70,403**	**$ 72,189**
Components of cash, cash equivalents, and restricted cash at the end of the year			
Cash and cash equivalents	$ 96,291	$ 69,719	$ 69,623
Restricted cash	530	684	2,566
Cash, cash equivalents, and restricted cash at the end of the year	**$ 96,821**	**$ 70,403**	**$ 72,189**

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

ORTHOFIX MEDICAL INC.

Notes to the Consolidated Financial Statements

1. Business, basis of presentation, COVID-19 update, and CARES Act

Description of the Business

Orthofix Medical Inc. and its subsidiaries (the "Company") is a global medical device and biologics company with a spine and extremities focus. The Company's mission is to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patients' lives. Headquartered in Lewisville, Texas, the Company has two reporting segments: Global Spine and Global Extremities. Orthofix spine and orthopedic extremities products are distributed in over 70 countries via the Company's sales representatives and distributors.

Basis of Presentation

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.

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

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COVID-19 Update

The global Coronavirus Disease 2019 ("COVID-19") pandemic has significantly affected the Company's patients, communities, employees and business operations. The pandemic has led to the cancellation or deferral of elective surgeries and procedures within certain hospitals, ambulatory surgery centers, and other medical facilities; restrictions on travel; the implementation of physical distancing measures; and the temporary or permanent closure of certain businesses. In addition, broad economic factors resulting from the pandemic, including increased unemployment rates and reduced consumer spending, are affecting the Company's patients and partners. These circumstances have negatively affected the Company's net sales, particularly during the period from March 2020 through May 2020, when elective surgery restrictions were most pronounced, though these effects remain ongoing in certain

geographical areas. However, the Company remains focused on protecting the health and wellbeing of its employees, partners, patients, and the communities in which it operates while assuring the continuity of its business operations.

The Company's consolidated financial statements reflect estimates and assumptions made by management that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and reported amounts of revenue and expenses during the reporting periods presented. At this time, the future trajectory of the COVID-19 pandemic remains uncertain, both in the U.S. and in other markets. Although the Company anticipates that vaccines will be widely distributed in the future, the timing and efficacy of such vaccines are uncertain.

Given these various uncertainties, it is unclear the extent to which lingering slowdowns in elective procedures will affect the Company's business into 2021 and beyond. The expected effects of COVID-19 on the Company's business will depend on various factors including (i) the magnitude and length of additional case waves, (ii) the distribution, efficacy, and public acceptance of COVID-19 vaccines (iii) the comfort level of patients in returning to clinics and hospitals, (iv) the extent to which localized elective surgery shutdowns occur, (v) the unemployment rate's effect on potential patients lacking medical insurance coverage, and (vi) general hospital capacity constraints occurring because of the need to treat COVID-19 patients.

In addition, while the Company has not seen such effects to date, risk remains that COVID-19 could have material negative effects on contractual counterparties, leading to supply chain disruptions or counterparty payment defaults and bankruptcies (including bankruptcies to hospital systems that significantly rely on revenue from elective surgeries).

These matters are also described in Part I, Item 1A of this Form 10-K under the heading *Risk Factors*.

Coronavirus Aid, Relief, and Economic Security Act ("CARES Act")

On March 27, 2020, the President of the United States signed the CARES Act into federal law, which was aimed at providing emergency assistance and health care for individuals, families, and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. The CARES Act, among other things, included provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act had no impact to the Company's income tax benefit reported within the consolidated statements of operations for the year ended December 31, 2020.

The CARES Act has provided financial relief to the Company through other various programs, which are each described in further detail below.

In April 2020, the Company received $13.9 million in funds from the Centers for Medicare & Medicaid Services ("CMS") Accelerated and Advance Payment Program. For discussion of the Company's accounting for these funds, see Note 15.

The Company also automatically received, as a durable medical equipment provider, without request, $4.7 million in funds from the U.S. Department of Health and Human Services in April 2020 as part of the Provider Relief Fund. Upon review of the qualifying criteria required to retain the funding, which primarily relate to lost revenues or the incurrence of expenses attributable to COVID-19, it was determined that the Company met the criteria to retain the funds received. As such, the Company recognized other income of $4.7 million related to this in-substance grant for the year ended December 31, 2020.

In addition, as part of the CARES Act, the Company was permitted to defer all employer social security payroll tax payments for the remainder of the 2020 calendar year, such that 50% of the taxes are deferred until December 31, 2021, with the remaining 50% deferred until December 31, 2022. As of December 31, 2020, the Company has deferred $0.6 million associated with this program, all of which is classified within other current liabilities. This deferred balance was subsequently repaid in the first quarter of 2021.

2. 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, allowances for expected credit losses, inventories, valuation of intangible assets, 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.

The following is a discussion of accounting policies and methods used in our consolidated financial statements that are not presented within other footnotes.

Prior period reclassifications

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

Market risk

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

The financial statements for operations outside the United States are generally maintained in their local currency. All foreign currency denominated balance sheet accounts, except shareholders' equity, are translated to U.S. Dollars at year end exchange rates and revenue and expense items are translated at average rates of exchange prevailing during the year. Gains and losses resulting from the translation of foreign currency are recorded in the accumulated other comprehensive income (loss) component of shareholders' equity. Transactional foreign currency gains and losses, including those generated from intercompany operations, are included in other expense, net and were a gain of $3.9 million, loss of $1.4 million, and a loss of $3.3 million for the years ended December 31, 2020, 2019 and 2018, 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.

Net sales to our customers based in Europe were approximately $57.7 million in 2020, which represents a substantial portion of our accounts receivable balance as of December 31, 2020. It is at least reasonably possible that changes in global economic conditions and/or local operating and economic conditions in the regions, or other factors, could affect the future realization of these accounts receivable balances.

Cash, cash equivalents and restricted cash

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

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

In September 2019, approximately $0.5 million (based upon foreign exchange rates as of December 31, 2020) of the Company's cash in Brazil was frozen upon request to satisfy a judgment related to an ongoing legal dispute with a former Brazilian distributor. Although the Company is appealing this judgment, this cash has been reclassified to restricted cash. Refer to Note 13 for further discussion of this matter.

Investing activities that did not result in cash receipts or cash payments during the years ended December 31, 2020, 2019, and 2018 consisted of the following, which were not included within cash from investing activities in the Company's consolidated statements of cash flows:

(U.S. Dollars, in thousands)	2020	2019	2018
Supplemental disclosure of cash flow information:			
Noncash investing activities:			
Intangible assets acquired in asset acquisitions	$ 1,575	$ 1,600	$ 2,015
Contingent consideration recognized at acquisition date	375	—	25,491

Advertising costs

Advertising costs are expensed as incurred. Advertising costs are included within sales and marketing expense and totaled $0.9 million, $0.8 million, and $0.6 million for the years ended December 31, 2020, 2019, and 2018, respectively.

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

Expenditures for research and development are expensed as incurred. Expenditures related to the Company's collaborative arrangement with MTF Biologics ("MTF") are expensed based on the terms of the related agreement. The Company recognized $0.8 million in research and development expense for the year ended December 31, 2020 under the collaborative arrangement with MTF and did not recognize any such expenditures for the year ended December 31, 2019.

On October 1, 2020, the Company and Neo Medical SA, a privately held Swiss-based company developing a new generation of products for spinal surgery ("Neo Medical"), entered into a partnership that includes a co-development agreement covering the parties' joint development of single use instruments for cervical spine procedures, and a distribution agreement under which the Company will exclusively distribute Neo Medical's thoracolumbar procedure solutions to certain U.S. customer accounts. In connection with this agreement, the Company is responsible for the payment of variable costs associated with the development of the specified products. Research and development expenses incurred under this collaborative arrangement for the year ended December 31, 2020 totaled less than $0.1 million.

In connection with the Spinal Kinetics Inc. acquisition in 2018, the Company recognized $26.8 million of IPR&D costs within intangible assets, net and recorded additional research and development costs to further develop this acquired IPR&D. See Note 7 for further details.

Acquired IPR&D represents the fair value assigned to acquired research and development assets that have not reached technological feasibility. The fair value assigned to acquired IPR&D is determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting revenues from the projects, and discounting the net cash flows to present value. The revenue and cost projections used to value acquired IPR&D are, as applicable, reduced based on the probability of success of developing the asset. Additionally, estimated revenues consider the relevant market sizes and growth factors, expected trends in technology, and the nature and expected timing of new product introductions by the Company and its competitors. The rates utilized to discount the net cash flows to their present value are commensurate with the stage of development of the project and uncertainties in the economic estimates used in the projections. Any future costs to further develop the IPR&D subsequent to acquisition are recorded to research and development expense as incurred. See Note 7 for additional policy discussion related to amortization and impairment testing for IPR&D.

3. Recently adopted accounting standards and recently issued accounting pronouncements

Adoption of Accounting Standards Update ("ASU") 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments and Subsequent Amendments

In June 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-13 (which was then further clarified in subsequent ASUs), which requires that credit losses for certain types of financial instruments, including accounts receivable, be estimated based on expected credit losses among other changes. Effective January 1, 2020, the Company adopted ASU 2016-13 using a modified retrospective approach. Therefore, results for reporting periods after January 1, 2020 are presented under Topic 326, while prior period amounts are not adjusted and continue to be reported in accordance with the historical accounting guidance. See Note 15 for additional discussion of the Company's adoption of Topic 326 and its resulting accounting policies.

Adoption of ASU 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment

In January 2017, the FASB issued ASU 2017-04, which eliminates Step 2 of the previous goodwill impairment test, which required a hypothetical purchase price allocation to measure goodwill impairment. Under ASU 2017-04, a goodwill impairment loss will now be measured as the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the recorded amount of

goodwill. The Company adopted this ASU effective January 1, 2020 on a prospective basis. Adoption of this ASU did not impact the Company's condensed consolidated balance sheet, statements of operations, or cash flows, but is expected to impact the measurement of any future goodwill impairment.

Adoption of ASU 2018-13, Fair Value Measurement (Topic 820): Disclosure Framework—Changes to the Disclosure Requirements for Fair Value Measurement

In August 2018, the FASB issued ASU 2018-13, which eliminates certain disclosures, such as the amount and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, and adds new disclosure requirements for Level 3 measurements. The Company adopted this ASU effective January 1, 2020, with certain provisions of the ASU applied retrospectively and other provisions provided prospectively. Adoption of this ASU did not impact the Company's condensed consolidated balance sheet, statements of operations, or cash flows; however, adoption of the ASU did result in modified disclosures in Note 12.

Adoption of ASU 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract

In August 2018, the FASB issued ASU 2018-15, which 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 was not affected by the amendments in this update. The Company adopted this ASU effective January 1, 2020 on a prospective basis. Adoption of this ASU did not have a material impact to the Company's condensed consolidated balance sheet, statements of operations, or cash flows, but is expected to impact future cloud computing arrangements.

Adoption of ASU 2020-04, Reference Rate Reform (Topic 848)

In March 2020, the FASB issued ASU 2020-04, which provides temporary optional guidance to ease the potential financial reporting burden of the expected market transition away from LIBOR. The new guidance provides optional expedients and exceptions for applying U.S. GAAP to contract modifications, hedge accounting, and other transactions affected by reference rate reform if certain criteria are met through December 31, 2022. The Company adopted this ASU effective March 12, 2020, the effective date of the ASU, on a prospective basis. Adoption of this ASU did not have a material impact to the Company's condensed consolidated balance sheet, statements of operations, or cash flows, but is expected to impact the future borrowing rate used for the Company's secured revolving credit facility.

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

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU 2016-02, which changes how lessees account for leases. For most leases, the standard requires a liability to be recorded on the balance sheet based on the present value of future lease obligations with a corresponding right-of-use asset. For leases classified as operating leases, the Company is now required to recognize lease costs on a straight-line basis based on the combined amortization of the lease obligation and the right-of-use asset. Similar to capital leases under the previous accounting standard, leases are accounted for as finance leases when the relevant criteria is met. Effective January 1, 2019, the Company adopted ASU 2016-02 using a modified retrospective approach. Upon adoption, the Company elected a package of practical expedients permitted within the new standard. The elected practical expedients allow the Company to carry forward its historical lease classification and to not separate and allocate the consideration paid between lease and non-lease components included within a contract. The Company also elected an optional transition method that waives the requirement to apply the ASU to the comparative periods presented within the financial statements in the year of adoption. Therefore, results for reporting periods beginning after January 1, 2019 are presented under Topic 842, while prior period amounts are not adjusted and continue to be reported in accordance with the Company's historic accounting policies under Topic 840. See Note 9 for additional discussion of the Company's adoption of Topic 842 and its lease accounting policies.

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

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

Recently issued accounting pronouncements

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Simplifying the accounting for income taxes (ASU 2019-12)	Reduces the complexity of accounting for income taxes by eliminating certain exceptions to the general principles in Accounting Standards Codification ("ASC") 740, *Income Taxes.* Additionally, the ASU simplifies GAAP by amending the requirements related to the accounting for "hybrid" tax regimes and also adding the requirement to evaluate when a step up in the tax basis of goodwill should be considered part of the business combination and when it should be considered a separate transaction. Certain of the provisions are to be applied retrospectively with other provisions applied prospectively.	January 1, 2021	The Company will adopt this new ASU effective January 1, 2021. Provisions related to general intra-period tax allocations, the calculation of income taxes for interim periods, and the effects of changes in tax laws or tax rates will be adopted on a prospective basis. The provision applicable to exceptions to the recognition of deferred taxes for investment ownership changes will be adopted using a modified retrospective approach, with a cumulative adjustment to retained earnings, and the provision for changes in accounting for franchise taxes will be applied either on a retrospective basis or using a modified retrospective approach. The Company does not expect this change in guidance to have a material impact to its consolidated financial statements.

4. Acquisitions

FITBONE Asset Purchase Agreement

On February 3, 2020, the Company, through a wholly owned subsidiary, entered into an Asset Purchase Agreement (the "Purchase Agreement") with Wittenstein SE ("Wittenstein"), a privately-held German-based company, to acquire assets associated with the FITBONE intramedullary lengthening system for limb lengthening of the femur and tibia bones. Under the terms of the Purchase Agreement, as consideration for the acquired assets, the Company paid $18.0 million in cash consideration and entered into a Contract Manufacturing and Supply Agreement ("CMSA") with Wittenstein. The Company has accounted for this acquisition as a business combination. The acquisition was completed on March 26, 2020.

The following table summarizes the final fair values of assets acquired and liabilities assumed at the acquisition date. The Company's purchase accounting was completed in the fourth quarter of 2020.

(U.S. Dollars, in thousands)	Acquisition Date Fair Value	Balance Sheet Classification	Assigned Useful Life
Assets acquired			
Inventories	$ 528	Inventories	
Developed technology	4,500	Intangible assets, net	8 years
Customer relationships	800	Intangible assets, net	15 years
Trade name	600	Intangible assets, net	15 years
In-process research and development ("IPR&D")	300	Intangible assets, net	Indefinite
Total identifiable assets acquired	6,728		
Goodwill	11,272		
Total fair value of consideration transferred	$ 18,000		

The Company recorded goodwill of $11.3 million in connection with the acquisition, of which $11.1 million was assigned to the Global Extremities reporting segment and $0.2 million was assigned to the Global Spine reporting segment. Specifically, goodwill includes synergies associated with the purchase of the acquired assets and is expected to be deductible for tax purposes.

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, the Company will determine the useful life of the asset and begin amortization.

The Company also entered into a CMSA with Wittenstein for an initial term of up to two years to manufacture the FITBONE product line. The Company is accounting for the CMSA as a finance lease. See Note 9 for further discussion of the recognized finance lease.
The Company recorded $0.4 million and $0.6 million of acquisition related costs during the years ended December 31, 2020 and 2019, respectively. These costs are included in the consolidated statements of operations within general and administrative expenses. Additionally, The Company's results of operations included net sales of $1.9 million related to the FITBONE product line for the year ended December 31, 2020. The Company did not recognize any revenues related to the FITBONE product line for the year ended December 31, 2019.

Distributor Acquisition

In July 2020, the Company, through a wholly owned subsidiary, entered into an agreement to acquire certain assets of a medical device distributor. The Company agreed to pay consideration of up to $7.6 million in accordance with the parties' agreement.
The following table summarizes the fair values of assets acquired and of consideration paid:

(U.S. Dollars, in thousands)		Fair Value	Balance Sheet Classification	Assigned Useful Life
Fair Value of Consideration Transferred				
Cash paid or payable	$	7,200		
Contingent consideration		375		
Total fair value of consideration transferred	$	7,575		
Fair value of assets acquired				
Customer relationships	$	7,340	Intangible assets, net	5 years
Assembled workforce		235	Intangible assets, net	5 years
Total fair value of assets acquired	$	7,575		

Spinal Kinetics Inc. Acquisition

In April 2018, the Company completed the acquisition of Spinal Kinetics Inc. ("Spinal Kinetics"), a privately held developer and manufacturer of artificial cervical and lumbar discs for $45.0 million in net cash, plus potential milestone payments of up to $60.0 million in cash. The total fair value of consideration transferred was $76.6 million. Goodwill attributable to the Spinal Kinetics acquisitions was assigned to the Global Spine reporting segment and is not deductible for tax purposes.

Options Medical, LLC Asset Acquisition

In January 2019, the Company acquired certain assets of Options Medical, LLC ("Options Medical"), a medical device distributor based in Florida. Under the terms of the acquisition, the parties agreed to terminate an existing exclusive sales representative agreement, employees of Options Medical became employees of the Company, and the Company acquired all customer lists and customer information related to the sale of the Company's products. As consideration for the assets acquired, the Company paid $6.4 million.

Purchase Price Allocations for Acquisitions Completed in 2019 and 2018

(U.S. Dollars, in thousands)	Spinal Kinetics	Assigned Useful Life	Options Medical	Assigned Useful Life
Assets acquired				
Cash and cash equivalents	$ 6,785		$ —	
Restricted cash	30		—	
Accounts receivable	1,705		—	
Inventories	8,175		—	
Prepaid expenses and other current assets	315		—	
Property, plant and equipment	2,285		—	
Other long-term assets	320		175	
Intangible assets				
Customer relationships	—	N/A	5,832	10 years
Developed technology	12,400	10 years	—	N/A
In-process research and development	26,800	Indefinite	—	N/A
Tradename	100	2 years	—	N/A
Assembled workforce	—	N/A	568	5 years
Deferred income taxes	3,594		—	
Total identifiable assets acquired	$ 62,509		$ 6,575	
Liabilities assumed				
Accounts payable	$ 351		$ —	
Other current liabilities	2,869		69	
Other long-term liabilities	301		106	
Total liabilities assumed	3,521		175	
Goodwill	17,612		—	
Total fair value of consideration transferred	$ 76,600		$ 6,400	

5. Inventories

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

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

	December 31,	
(U.S. Dollars, in thousands)	2020	2019
Raw materials	$ 8,442	$ 9,587
Work-in-process	12,149	14,027
Finished products	29,142	20,712
Field/consignment	34,902	38,071
Inventories	$ 84,635	$ 82,397

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 estimated net realizable value.

6. Property, plant and equipment

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

The useful lives of these assets are generally as follows:

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

The Company evaluates the useful lives of these assets on an annual basis. Depreciation is computed on a straight-line basis over the useful lives of the assets. Depreciation of leasehold improvements is computed over the shorter of the lease term or the useful life of the asset. Total depreciation expense was $19.3 million, $17.7 million and $15.9 million for the years ended December 31, 2020, 2019 and 2018, respectively.

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

	December 31,	
(U.S. Dollars, in thousands)	**2020**	**2019**
Cost		
Buildings	$ 4,096	$ 3,731
Plant and equipment	50,159	46,470
Instrumentation	93,252	82,327
Computer software	52,565	49,696
Furniture and fixtures	8,024	7,328
Construction in progress	1,628	2,201
Finance lease assets	23,337	21,179
Property, plant, and equipment, gross	233,061	212,932
Accumulated depreciation	(169,448)	(150,205)
Property, plant, and equipment, net	$ 63,613	$ 62,727

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

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

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

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

7. Intangible assets

Intangible assets are recorded at cost, or when acquired as a part of a business combination, at estimated fair value. These assets are amortized on a straight-line basis over the useful lives of the assets, which the Company believes is materially consistent with the pattern of economic benefit provided by these assets.

		December 31,	
(U.S. Dollars, in thousands)	Weighted Average Amortization Period	2020	2019
Cost			
Patents	10 years	$ 50,326	$ 42,034
Developed technology	10 years	44,334	39,200
IPR&D	Indefinite	300	—
Customer relationships	7 years	15,685	7,430
License and other	8 years	16,941	15,960
Trademarks—finite lived	10 years	1,812	942
	9 years	129,398	105,566
Accumulated amortization			
Patents		$ (46,272)	$ (38,246)
Developed technology		(8,925)	(4,523)
Customer relationships		(2,095)	(535)
License and other		(11,006)	(7,701)
Trademarks—finite lived		(583)	(422)
		(68,881)	(51,427)
Intangible assets, net		$ 60,517	$ 54,139

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

Amortization expense for intangible assets was $11.2 million, $7.0 million and $2.7 million for the years ended December 31, 2020, December 31, 2019 and 2018, respectively. Future amortization expense for intangible assets is estimated as follows:

(U.S. Dollars, in thousands)	Amortization
2021	$ 9,292
2022	9,143
2023	8,488
2024	8,020
2025	7,001
Thereafter	18,273
Total finite-lived intangible assets, net	$ 60,217
Indefinite-lived intangible assets, net	300
Intangible assets, net	$ 60,517

8. Goodwill

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

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

At the beginning of the fourth quarters of 2020 and 2019, 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, 2019, by reportable segment:

(U.S. Dollars, in thousands)	December 31, 2019	Acquisition	Currency Translation Adjustment	December 31, 2020
Global Spine	$ 71,177	$ 140	$ -	$ 71,317
Global Extremities	—	11,132	1,569	12,701
Goodwill	$ 71,177	$ 11,272	$ 1,569	$ 84,018

There have been no impairments related to the Company's goodwill since the change in reporting segments in 2019.

9. Leases

As discussed in Note 3, the Company adopted ASU No. 2016-02—*Leases* (Topic 842), as of January 1, 2019, using the modified retrospective approach. Adoption of the new standard resulted in the recognition of operating lease assets and lease liabilities of $20.2 million and $20.5 million, respectively, as of January 1, 2019. The difference between the lease assets and lease liabilities, net of the deferred tax impact, and the elimination of historical prepaid or deferred rent, was recorded as an adjustment to retained earnings. The standard did not have a material impact to the Company's consolidated statements of operations and comprehensive income (loss) or cash flows.

The Company determines if an arrangement is a lease at inception. The Company's leases primarily relate to facilities, vehicles, and equipment. Lease assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent

the obligation to make lease payments arising from the lease. Lease assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company's incremental borrowing rate is used as a discount rate, based on the information available at the commencement date, in determining the present value of lease payments. Lease assets also include the impact of any prepayments made and are reduced by impact of any lease incentives.

The Company does not recognize lease liabilities or lease assets on the balance sheet for short-term (leases with a lease term of twelve months or less as of the commencement date). Rather, any short-term lease payments are recognized as an expense on a straight-line basis over the lease term. The current period short-term lease expense reasonably reflects our short-term lease commitments.

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

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

A summary of the Company's lease portfolio as of December 31, 2020 and 2019 is presented in the table below:

(U.S. Dollars, in thousands, except lease term and discount rate)	Classification	December 31, 2020	December 31, 2019
Assets			
Operating leases	Other long-term assets	$ 4,840	$ 5,798
Finance leases	Property, plant and equipment, net	20,552	20,207
Total lease assets		$ 25,392	$ 26,005
Liabilities			
Current			
Operating leases	Other current liabilities	$ 2,092	$ 1,875
Finance leases	Current portion of finance lease liability	510	323
Long-term			
Operating leases	Other long-term liabilities	2,946	4,084
Finance leases	Long-term portion of finance lease liability	22,338	20,648
Total lease liabilities		$ 27,886	$ 26,930
Weighted Average Remaining Lease Term			
Operating leases		3.6 years	4.2 years
Finance leases		18.1 years	20.7 years
Weighted Average Discount Rate			
Operating leases		2.4%	2.3%
Finance leases		4.2%	4.4%

The components of lease costs were as follows:

(U.S. Dollars, in thousands)	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Finance lease costs:		
Amortization of right-of-use assets	$ 1,766	$ 972
Interest on finance lease liabilities	940	919
Operating lease costs	2,235	2,161
Short-term lease costs	230	255
Variable lease costs	673	749
Total lease costs	$ 5,844	$ 5,056

Rent expense for operating leases in 2018 totaled $4.5 million, which were accounted for under Topic 840.

Supplemental cash flow information related to leases was as follows:

(U.S. Dollars, in thousands)	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows from operating leases	$ 4,299	$ 4,075
Operating cash flows from finance leases	689	919
Financing cash flows from finance leases	323	365
Right-of-use assets obtained in exchange for lease obligations		
Operating leases	959	878
Finance leases	1,949	21,179

Wittenstein Contract Manufacturing and Supply Agreement

In March 2020, the Company entered into a CMSA with Wittenstein for an initial term of two years to manufacture the FITBONE product line. As consideration, the Company will pay $2.0 million to Wittenstein at the conclusion of the CMSA if certain conditions are met in relation to the prompt delivery of manufactured products. The Company is accounting for the CMSA as a finance lease as the Company has the right to direct the use of and to obtain substantially all of the economic benefits of the dedicated equipment used to manufacture the products and has the option to obtain title and possession of the equipment at the conclusion of the CMSA. As a result, the Company recognized both a finance lease liability and a related ROU asset of $1.9 million as of the commencement date of the CMSA.

A summary of the Company's remaining lease liabilities as of December 31, 2020 is included below:

(U.S. Dollars, in thousands)	Operating Leases	Finance Leases
2021	$ 2,197	$ 1,414
2022	1,773	3,442
2023	467	1,471
2024	161	1,501
2025	195	1,531
Thereafter	524	24,175
Total undiscounted value of lease liabilities	5,317	33,534
Less: Interest	(279)	(10,686)
Present value of lease liabilities	$ 5,038	$ 22,848
Current portion of lease liabilities	$ 2,092	$ 510
Long-term portion of lease liabilities	2,946	22,338
Total lease liabilities	$ 5,038	$ 22,848

10. Other current liabilities

(U.S. Dollars, in thousands)	December 31, 2020	2019
Accrued expenses	$ 6,090	$ 5,571
Salaries, bonuses, commissions and related taxes payable	22,362	14,008
Accrued distributor commissions	9,331	12,286
Accrued legal and settlement expenses	5,422	9,227
Contingent consideration liability	14,900	14,700
Short-term operating lease liability	2,092	1,875
Non-income taxes payable	5,509	4,021
Accelerated and advance payment program	9,834	—
Other payables	4,731	2,986
Other current liabilities	$ 80,271	$ 64,674

In December 2019, the Company approved and initiated a targeted restructuring plan in the U.S. to streamline costs and to better align talent with the Company's strategic initiatives. The plan consists primarily of the realignment of certain personnel, representing a limited number of positions. As of December 31, 2019, the Company recorded a liability of $3.2 million in connection with this activity, all of which was recognized in 2019 within general and administrative expenses. During 2020, the Company recorded additional accruals of $2.5 million associated with these activities and made payments totaling $4.4 million, resulting in an ending liability of $1.3 million as of December 31, 2020 associated with the restructuring plan.

11. Long-term debt

On October 25, 2019, the Company, and certain of its wholly-owned subsidiaries (collectively with the Company, the "Borrowers"), as borrowers, and certain material subsidiaries of the Company as guarantors, entered into a Second Amended and Restated Credit Agreement (the "Amended Credit Agreement") with JPMorgan Chase Bank, N.A. ("JPMorgan"), as Administrative Agent, and certain lender parties thereto. The Amended Credit Agreement provides for a $300 million secured revolving credit facility (the "Facility") amending and restating the $125 million secured revolving credit facility that previously existed with such lenders. The Credit Agreement has a maturity date of October 25, 2024.

In April 2020, as a precautionary measure to increase the Company's cash position and to preserve financial flexibility during the uncertainty resulting from the COVID-19 pandemic, the Company completed a borrowing of $100.0 million under the Facility. The Company made payments totaling $100.0 million in the third quarter of 2020 to fully pay down the outstanding balance. The Company had no borrowings outstanding under the Facility at December 31, 2020 and 2019, respectively.

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

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

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

The Amended Credit Agreement contains customary affirmative and negative covenants, including limitations on the Company's and its subsidiaries ability to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, pay subordinated indebtedness and enter into affiliate transactions. In addition, the Amended Credit Agreement contains financial covenants requiring the Company on a consolidated basis to maintain, as of the last day of any fiscal quarter, a total net leverage ratio of not more than 3.5 to 1.0 (which ratio can be permitted to increase to 4.0 to 1.0 for no more than 4 fiscal quarters following a material acquisition) and an interest coverage ratio of at least 3.0 to 1.0. The Amended Credit Agreement also includes events of default customary for facilities of this type and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Facility may be accelerated and/or the lenders' commitments terminated. The Credit Agreement also includes events of default customary for facilities of this type, and upon the occurrence of such events of default, subject to customary cure rights, all outstanding loans under the Facility may be accelerated and/or the lenders' commitments terminated. The Company is in compliance with all required financial covenants as of December 31, 2020.

In conjunction with obtaining the Facility, the Company has paid $1.5 million in debt issuance costs and has capitalized a total of $1.8 million associated with the Facility. These costs are being amortized over the life of the Facility. The debt issuance costs are included in other long-term assets, net of accumulated amortization. As of December 31, 2020 and December 31, 2019, debt issuance costs, net of accumulated amortization, were $1.4 million and $1.7 million, respectively. Debt issuance costs amortized or expensed totaled $0.4 million, $0.4 million, and $0.4 million for the years ended December 31, 2020, 2019, and 2018, respectively.

The Company has an unused available line of credit of €5.5 million ($6.7 million and $6.2 million) at December 31, 2020 and 2019, 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 $1.9 million, $0.8 million, and $0.8 million for the years ended December 31, 2020, 2019, and 2018, respectively.

12. Fair value measurements and investments

Fair value is defined as the price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Non-financial assets and liabilities of the Company measured at fair value include any long-lived assets that are impaired in a currently reported period or equity securities measured at observable prices in orderly transactions. The authoritative guidance also describes three levels of inputs that may be used to measure fair value:

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

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

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

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

The Company's available for sale debt securities, equity securities, 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, 2020	Level 1	Level 2	Level 3
Assets				
Neo Medical convertible loan agreement	$ 7,160	$ —	$ —	$ 7,160
Neo Medical preferred equity securities	5,000	—	5,000	—
Bone Biologics equity securities	—	—	—	—
Total	$ 12,160	$ —	$ 5,000	$ 7,160
Liabilities				
Spinal Kinetics contingent consideration	$ (35,400)	$ —	$ —	$ (35,400)
Other contingent consideration	(375)	—	—	(375)
Deferred compensation plan	(1,441)	—	(1,441)	—
Total	$ (37,216)	$ —	$ (1,441)	$ (35,775)

(U.S. Dollars, in thousands)	Balance December 31, 2019	Level 1	Level 2	Level 3
Assets				
Bone Biologics equity securities	$ 219	$ —	$ 219	$ —
Total	$ 219	$ -	$ 219	$ -
Liabilities				
Spinal Kinetics contingent consideration	$ (42,700)	$ —	$ —	$ (42,700)
Deferred compensation plan	(1,255)	—	(1,255)	—
Total	$ (43,955)	$ —	$ (1,255)	$ (42,700)

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

Neo Medical Convertible Loan Agreement and Equity Investment

On October 1, 2020, the Company purchased shares of Neo Medical's preferred stock for consideration of $5.0 million and entered into a Convertible Loan Agreement pursuant to which Orthofix loaned Neo Medical CHF 4.6 million (the "Convertible Loan"). The loan bears interest at 8.0%, with interest due semi-annually. At each interest payment date, the borrower may elect to capitalize any interest due to the then outstanding principal balance of the loan. The Convertible Loan matures on October 1, 2024, provided that if a change in control of Neo Medical occurs prior to the maturity date, the Convertible Loan shall become immediately due upon such event. The Convertible Loan may be convertible by either party into shares of Neo Medical's preferred stock. The Company may convert the loan at its own election at any time prior to the full repayment or settlement of the Convertible Loan. Neo Medical may elect to convert the loan only in the event of a qualified financing event, as defined within the agreement. The price per share at which the loan converts is dependent upon i) the party electing conversion and ii) Neo Medical's price per share in its most recent fundraising activities at the time of conversion, as specified within the agreement.

The equity securities are recorded in other long-term assets and are considered an investment that does not have a readily determinable fair value. As such, the Company measures this investment at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. As such, the carrying value of this investment as of December 31, 2020, was $5.0 million.

The Convertible Loan is recorded in other long-term assets as an available for sale debt security at fair value, with applicable interest recorded in interest income. The fair value of the Convertible Loan, including accrued interest, is based upon significant unobservable inputs, including the use of Monte Carlo simulations, option-pricing models, and a probability-weighted 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 Convertible Loan include applicable discount rates, implied volatility, the likelihood and projected timing of repayment or conversion, and projected cash flows in support of the estimated enterprise value of Neo Medical. Holding other inputs constant, changes in these assumptions could result in a significant change in the fair value of the Convertible Loan. If the amortized cost of the Convertible Loan exceeds its estimated

fair value, security is deemed to be impaired, and must be evaluated for the recognition of credit losses. Impairment resulting from credit losses is recognized within the statement of income, while impairment resulting from other factors is recognized within other comprehensive income. As of December 31, 2020, the Company has not recognized any credit losses related to the Convertible Loan.

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

(U.S. Dollars, in thousands)	2020	2019
Fair value of Neo Medical Convertible Loan at January 1	$ —	$ —
Issuance date	5,000	—
Interest recognized in interest income, net	103	—
Foreign currency remeasurement recognized in other income (expense), net	176	—
Unrealized gain (loss) recognized in other comprehensive income (loss)	1,881	—
Fair value of Neo Medical Convertible Loan at December 31	7,160	—
Amortized cost basis of Neo Medical Convertible Loan at December 31	5,279	—

The following table provides quantitative information related to certain key assumptions utilized within the valuation as of December 31, 2020:

(U.S. Dollars, in thousands)	Fair Value as of December 31, 2020	Unobservable inputs	Estimate
Neo Medical Convertible Loan	$ 7,160	Cost of equity discount rate	21.1%
		Implied volatility	108.1%

Bone Biologics Equity Securities

The Company holds an investment in common stock of Bone Biologics Inc. (“Bone Biologics”), a privately-held developer of orthobiologic products. The equity securities are considered investments that do not have readily determinable fair values. As such, the Company measures these investments at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer.

In 2018, Bone Biologics completed a series of equity financing activities, which provided a new observable price change in an orderly transaction. As a result, the Company determined its investment was impaired and recorded a charge of $4.4 million in other expense, net. An additional impairment of $0.2 million was recognized in 2020 as a result of concerns over Bone Biologics’ ability to continue as a going concern.

The changes in valuation of these securities for the years ended December 31, 2020, 2019, and 2018 are shown below:

(U.S. Dollars, in thousands)	2020	2019	2018
Bone Biologics equity securities at January 1	$ 219	$ 219	$ 2,768
Impact of adoption of ASU 2016-01 recognized in other income	—	—	1,629
Purchase of additional common stock	—	—	500
Fair value adjustments and impairments recognized in other expense	(219)	—	(4,678)
Bone Biologics equity securities at December 31	$ —	$ 219	$ 219

Contingent Consideration

The Company recognized a contingent consideration obligation in connection with the acquisition of Spinal Kinetics in 2018. The Spinal Kinetics contingent consideration consists of potential future milestone payments of up to $60.0 million in cash. The milestone payments included (i) $15.0 million upon U.S. Food and Drug Administration (“FDA”) approval of the M6-C artificial cervical disc (the “FDA Milestone”) and (ii) revenue-based milestone payments of up to $45.0 million in connection with future sales of the acquired artificial discs. Milestones must be achieved within five years of April 30, 2018 to trigger applicable payments. In February 2019, the FDA Milestone was achieved and paid.

The estimated fair value of the remaining Spinal Kinetics contingent consideration was $35.4 million as of December 31, 2020. The estimated fair value reflects assumptions made by management as of December 31, 2020, including the estimated impact of COVID-19 on significant unobservable assumptions, such as the expected timing and volume of elective procedures and the impact of these procedures on future revenues. However, the impact of COVID-19 on the Company's business remains uncertain and difficult to predict. As information surrounding the pandemic is continuing to evolve, the actual amount ultimately paid could be higher or lower than the fair value of the remaining contingent consideration.

As of December 31, 2020, the Company has classified $14.9 million of the remaining liability within other current liabilities, as the Company currently expects to pay one of the revenue-based milestones in the next twelve months, and the remaining $20.5 million within other long-term liabilities. Any changes in fair value are recorded as an operating expense within acquisition-related amortization and remeasurement.

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

(U.S. Dollars, in thousands)	2020	2019
Spinal Kinetics contingent consideration at January 1	$ 42,700	$ 28,560
Increase (decrease) in fair value recognized in acquisition-related amortization and remeasurement	(7,300)	29,140
Payment made	—	(15,000)
Spinal Kinetics contingent consideration at December 31	$ 35,400	$ 42,700

The Company estimated the fair value of the remaining potential future revenue-based milestone payments using a Monte Carlo simulation and a discounted cash flow model. 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 valuation model include the Company's forecasted future revenues for Spinal Kinetics products, the expected timing of payment, applicable discount rates 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 range of key assumptions used within the valuation as of December 31, 2020:

(U.S. Dollars, in thousands)	Fair Value as of December 31, 2020	Valuation Technique	Unobservable inputs	Range
Spinal Kinetics contingent consideration	$ 35,400	Discounted cash flow	Revenue discount rate	8.09% - 8.12%
			Payment discount rate	3.83% - 3.90%
			Projected year of payment	2021 - 2022

Other contingent consideration is attributable to an agreement closed in the third quarter of 2020 to acquire certain assets of a medical device distributor as a portion of the consideration is based upon meeting certain revenue-based targets. This contingent liability is measured using a probability-weighted cash flow analysis.

eNeura Debt Security

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

Prior to the restructuring, the debt security was accounted for as an available for sale debt security at fair value and included within other long-term assets. The fair value was based upon significant unobservable inputs, including the use of a discounted cash flow model and assumptions regarding the expected payback period for the debt security, requiring the Company to develop its own

assumptions; therefore, the Company had categorized this asset as a Level 3 financial asset. The Company evaluated any declines in fair value, if any, each quarter to determine if impairments are other-than-temporary. The debt security had an amortized cost basis of $9.0 million at the time of the restructuring and as of December 31, 2018.

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

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

The following table provides a reconciliation of the beginning and ending balances for the eNeura debt security, when it was measured at fair value as an available for sale debt security (prior to its change in classification):

(U.S. Dollars, in thousands)	2020	2019	2018
Balance at January 1	$ —	$ 17,820	$ 16,050
Gains (losses) recorded for the period			
Recognized in other expense, net	—	—	—
Recognized in other comprehensive income (loss)	—	(2,593)	1,770
Change in classification of debt security to held to maturity	—	(15,227)	—
Issuance of Warrant as consideration for extension	—	491	—
Impairment of Warrant	—	(491)	—
Balance at December 31	$ —	$ —	$ 17,820

13. Commitments and Contingencies

Contingencies policy

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

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

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 medical device companies in Italy to make payments to the Italian government if medical device expenditures exceed regional maximum ceilings. Companies are required to make payments equal to a percentage of expenditures exceeding maximum regional caps. There is considerable uncertainty about how the law will operate and what the exact timeline is for finalization. The Company's current assessment of the IMDP involves significant judgment regarding the expected scope and actual implementation terms of the measure as the latter

have not been clarified to date by Italian authorities. The Company accounts for the estimated cost of the IMDP as sales and marketing expense and recorded expense of $1.5 million, $1.3 million, and $1.0 million for the years ended December 31, 2020, 2019, and 2018, respectively. As of December 31, 2020, the Company has accrued $7.0 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 September 2019, in relation to an ongoing legal dispute with a former Brazilian distributor, approximately $0.5 million (based upon foreign exchange rates as of December 31, 2020) of the Company's cash in Brazil was frozen upon request to satisfy a judgment. Although the Company is appealing the judgment, this cash has been reclassified to restricted cash. As of December 31, 2020, the Company has an accrual of $1.5 million related to this matter.

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.

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) is comprised of foreign currency translation adjustments, the unrealized gains (losses) on the eNeura debt security, which was settled in 2019, and unrealized gains (losses) on the Neo Medical Convertible Loan. The Company's policy is to release income tax effects related to items recognized within accumulated other comprehensive income (loss) using a portfolio approach. The components of and changes in accumulated other comprehensive income (loss) are as follows:

(U.S. Dollars, in thousands)	Currency Translation Adjustments	eNeura Debt Security	Neo Medical Convertible Loan	Accumulated Other Comprehensive Income (Loss)
Balance at December 31, 2018	$ (2,386)	$ 5,682	$ —	$ 3,296
Cumulative effect adjustment from adoption of ASU 2018-02	—	937	—	937
Other comprehensive loss	(653)	(2,593)	—	(3,246)
Income taxes	—	642	—	642
Reclassification adjustment to:				—
Interest income (expense), net	—	(1,034)	—	(1,034)
Other expense, net	—	(5,193)	—	(5,193)
Income taxes	—	1,559	—	1,559
Balance at December 31, 2019	$ (3,039)	$ —	$ —	$ (3,039)
Other comprehensive income	4,872	—	1,881	6,753
Income taxes	—	—	(462)	(462)
Balance at December 31, 2020	$ 1,833	$ —	$ 1,419	$ 3,252

15. Revenue recognition and accounts receivable

Revenue Recognition

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

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

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

Bone Growth Therapies

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

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

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

Biologics

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

Spinal Implants and Global Extremities

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

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

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

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, 2020, 2019, and 2018.

	For the year ended December 31,		
(U.S. Dollars, in thousands)	**2020**	**2019**	**2018**
Product sales	$ 353,087	$ 397,064	$ 395,589
Marketing service fees	53,475	62,891	57,453
Net sales	$ 406,562	$ 459,955	$ 453,042

Product sales primarily consists of the sale of Bone Growth Therapies, Spinal Implants, and Global Extremities products. Marketing service fees are received from MTF based on total sales of biologics tissues and relates solely to the Biologics product category within the Global Spine reporting segment. Marketing service fees received from MTF were $53.5 million, or approximately 96% of total Biologics revenues, for the year ended December 31, 2020. As MTF is the Company's single supplier for the Trinity Evolution and Trinity ELITE tissue forms, which are derived from human cadaveric donors, any event or circumstance that would impact MTF's continued access to donated human cadaveric tissue or the Company's ability to market these tissues may adversely impact the Company's financial results.

Revenues exclude any value added or other local taxes, intercompany sales and trade discounts. Shipping and handling costs for products shipped to customers are included in cost of sales, and were $2.4 million, $2.8 million and $2.7 million for the years ended December 31, 2020, 2019, and 2018, respectively.

Adoption of ASU 2016-13

As discussed in Note 3, the Company adopted ASU No. 2016-13 - *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* and subsequent amendments, using a modified retrospective approach. Adoption of the new standard resulted in an increase to the Company's allowance for expected credit losses of $1.1 million, an increase in deferred income tax assets of $0.2 million, and a decrease in retained earnings of $0.9 million as of January 1, 2020. The net impact of adoption to the Company's balance sheet as of January 1, 2020 is presented in the table below. The standard did not have a material impact to the Company's condensed consolidated statements of operations or cash flows.

(U.S. Dollars, in thousands)	**December 31, 2019**	**Impact of Adoption of ASC 326**	**January 1, 2020**
Assets			
Current assets			
Cash, cash equivalents, and restricted cash	$ 70,403	$ —	$ 70,403
Accounts receivable, net	86,805	(1,120)	85,685
Inventories	82,397	—	82,397
Prepaid expenses and other current assets	20,948	—	20,948
Total current assets	260,553	(1,120)	259,433
Deferred income taxes	35,117	233	35,350
Other long-term assets	199,950	—	199,950
Total assets	**$ 495,620**	**$ (887)**	**$ 494,733**
Liabilities and shareholders' equity			
Total liabilities	$ 167,989	$ —	$ 167,989
Shareholders' equity			
Common shares	$ 1,902	$ —	$ 1,902
Additional paid-in capital	271,019	—	271,019
Retained earnings	57,749	(887)	56,862
Accumulated other comprehensive loss	(3,039)	—	(3,039)
Total shareholders' equity	327,631	(887)	326,744
Total liabilities and shareholders' equity	**$ 495,620**	**$ (887)**	**$ 494,733**

Accounts receivable and related 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. Subsequent to the adoption of ASU 2016-13, the Company's allowance for expected credit losses represents the portion of the receivable's amortized cost basis that an entity does not expect to collect over the receivable's contractual life, considering past events, current conditions, and reasonable and supportable forecasts of future economic conditions.

The process for estimating the ultimate collection of accounts receivable involves significant assumptions and judgments. The determination of the contractual life of accounts receivable, the aging of outstanding receivables, as well as the historical collections, write-offs, and payor reimbursement experience over the estimated contractual lives of such receivables, are integral parts of the estimation process related to reserves for expected credit losses and the establishment of contractual allowances. Accounts receivable are analyzed on a quarterly basis to assess the adequacy of both reserves for expected credit losses and contractual allowances. Revisions in allowances for expected credit loss 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. These estimates are periodically tested against actual collection experience. In addition, the Company analyzes its receivables by geography and by customer type, where appropriate, in developing estimates for expected credit losses.

The following table provides a detail of changes in the Company's allowance for expected credit losses for the year ended December 31, 2020:

(U.S. Dollars, in thousands)	**Year Ended December 31, 2020**
Allowance for expected credit losses beginning balance	$ 3,987
Impact of adoption of ASU 2016-13	1,120
Current period provision for expected credit losses	199
Writeoffs charged against the allowance and other	(714)
Effect of changes in foreign exchange rates	256
Allowance for expected credit losses ending balance	$ 4,848

The Company will generally sell receivables from certain Italian hospitals each year to accelerate cash collections. During 2020, 2019, and 2018 the Company sold €8.3 million, €9.8 million, and €9.8 million ($9.6 million, $10.9 million, and $11.5 million) of receivables, respectively. The estimated related fees for 2020, 2019, and 2018 were $0.3 million, $0.3 million and $0.3 million, respectively, which is recorded as interest expense. Accounts receivables sold without recourse are removed from the balance sheet at the time of sale.

Puerto Rico Settlement

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

Contract Liabilities

The Company's contract liabilities largely relate to a prepayment of $13.9 million received in April 2020 from the CMS as part of the Accelerated and Advance Payment Program of the CARES Act intended to increase cash flow to providers of services and suppliers impacted by the COVID-19 pandemic.

On October 1, 2020, the President of the United States signed the "Continuing Appropriations Act, 2021 and Other Extensions Act," which relaxed a number of the Medicare Accelerated and Advance Payment Programs recoupment terms for providers and suppliers that received funds from the program. Under these new terms, recoupment will be delayed until one year after payment was issued. After that first year, Medicare will automatically recoup 25% of Medicare payments otherwise owed to the provider or supplier for 11 months. At the end of the 11-month period, recoupment will increase to 50% for another 6 months. Thus, during these time periods, rather than receiving the full amount of payment for newly submitted claims, the Company's outstanding accelerated / advance payment balance will be reduced by the recoupment amount until the full balance has been repaid.

As of December 31, 2020, the Company has classified $9.8 million of this contract liability within other current liabilities and $4.0 million within other long-term liabilities based upon the Company's estimates of when such funds will be recouped. The Company did not recognize any net sales during the year ended December 31, 2020, respectively, attributable to the satisfaction of performance obligations related to the CMS prepayment.

Other Contract Assets

The Company's contract assets, excluding 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 $2.0 million and $3.7 million as of December 31, 2020 and 2019, respectively.

Other contract assets are amortized on a straight-line basis over the term of the related contract. No impairments were incurred for other contract assets in 2020 or 2019. Further, the Company applies the practical expedient to expense sales commissions when incurred, as the applicable amortization period would be for one year or less.

16. Business segment information

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

Global Spine

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

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

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

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

Global Extremities

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

Corporate

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

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

	Year Ended December 31,					
	2020		2019		2018	
(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	$ 171,396	42.2%	$ 197,181	42.9%	$ 195,252	43.1%
Spinal Implants	94,857	23.3%	94,544	20.6%	91,658	20.2%
Biologics	55,482	13.6%	65,496	14.2%	59,684	13.2%
Global Spine	321,735	79.1%	357,221	77.7%	346,594	76.5%
Global Extremities	84,827	20.9%	102,734	22.3%	106,448	23.5%
Net sales	$ 406,562	100.0%	$ 459,955	100.0%	$ 453,042	100.0%

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

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2020	2019	2018
Global Spine	$ 63,036	$ 39,528	$ 76,545
Global Extremities	(4,993)	7,496	9,453
Corporate	(25,382)	(49,252)	(43,626)
Total EBITDA	32,661	(2,228)	42,372
Depreciation and amortization	(30,546)	(24,699)	(18,659)
Interest expense, net	(2,483)	(122)	(828)
Income (loss) before income taxes	$ (368)	$ (27,049)	$ 22,885

The following table presents depreciation and amortization by reporting segment:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2020	2019	2018
Global Spine	$ 18,362	$ 14,329	$ 9,512
Global Extremities	7,896	5,575	5,342
Corporate	4,288	4,795	3,805
Total	$ 30,546	$ 24,699	$ 18,659

Geographical information

The following data includes net sales by geographic destination:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2020	2019	2018
U.S.	$ 327,280	$ 361,939	$ 355,353
Italy	18,733	19,560	19,331
Germany	11,940	12,688	11,606
United Kingdom	7,147	10,090	8,731
Brazil	2,347	7,685	7,120
Others	39,115	47,993	50,901
Net sales	$ 406,562	$ 459,955	$ 453,042

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

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2020**	**2019**	**2018**
Global Spine			
U.S.	$ 304,595	$ 335,410	$ 326,994
International	17,140	21,811	19,600
Total Global Spine	321,735	357,221	346,594
Global Extremities			
U.S.	$ 22,685	26,529	28,359
International	62,142	76,205	78,089
Total Global Extremities	84,827	102,734	106,448
Consolidated			
U.S.	327,280	361,939	355,353
International	79,282	98,016	97,689
Net sales	$ 406,562	$ 459,955	$ 453,042

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

(U.S. Dollars, in thousands)	**2020**	**2019**
U.S.	$ 47,646	$ 51,278
Italy	10,503	7,937
Germany	2,516	849
United Kingdom	1,540	1,082
Brazil	163	141
Others	1,245	1,440
Total	$ 63,613	$ 62,727

17. Acquisition-related amortization and remeasurement

Acquisition-related amortization and remeasurement consists of amortization related to intangible assets acquired through business combinations or asset acquisitions and the remeasurement of any related contingent consideration arrangement. Components of acquisition-related amortization and remeasurement for the twelve months ended December 31, 2020, 2019, and 2018, respectively, are as follows:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2020**	**2019**	**2018**
Changes in fair value of contingent consideration	$ (7,300)	$ 29,140	$ 3,069
Amortization of acquired intangibles	6,801	5,072	1,255
Total	$ (499)	$ 34,212	$ 4,324

18. Share-based compensation

At December 31, 2020 and 2019, 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 23, 2018, which was subsequently provided by shareholder ratification. The 2012 LTIP provides for the grant of options to purchase shares of the

Company's common stock, stock awards (including restricted stock, unrestricted stock, and stock units), stock appreciation rights, performance-based awards and other equity-based awards. All of the Company's employees and the employees of the Company's subsidiaries and affiliates are eligible and may receive awards under the 2012 LTIP. In addition, the Company's non-employee directors, consultants, and advisors who perform services for the Company and its subsidiaries and affiliates may receive awards under the 2012 LTIP. Awards granted under the 2012 LTIP expire no later than ten years after the date of grant. At December 31, 2020, the Company reserves a total of 5,850,000 shares of common stock for issuance pursuant to the 2012 LTIP, subject to certain adjustments set forth in the 2012 LTIP. At December 31, 2020, there were 1,244,863 options outstanding under the 2012 LTIP, of which 732,865 were exercisable. In addition, there were 46,619 shares of unvested restricted stock outstanding and 697,495 restricted stock units outstanding, some of which contain market-based vesting, conditions, under the 2012 LTIP as of December 31, 2020.

2004 Long Term Incentive Plan

The 2004 Long Term Incentive Plan (the "2004 LTIP") reserved 3,100,000 shares for issuance, subject to certain adjustments set forth in the 2004 LTIP. At December 31, 2020, there were 12,500 options outstanding under the 2004 LTIP, all of which were exercisable.

Inducement Plans

The Inducement Plan for Spinal Kinetics Employees (the "Spinal Kinetics Inducement Plan") reserved 51,705 shares for issuance to employees of Spinal Kinetics as an inducement to continue employment with the Company. At December 31, 2020, there were no remaining options outstanding under the Spinal Kinetics Inducement Plan and 2,669 shares of unvested restricted stock outstanding.

In August 2019, the Company appointed a new President of Global Spine, who was then subsequently promoted to President and Chief Executive Officer. As an inducement to accept employment with the Company, the individual was awarded a grant of stock options to acquire up to 50,711 shares of common stock and an award of 14,743 restricted stock units. As of December 31, 2020, there were 50,711 options outstanding under this inducement, 12,677 of which were exercisable, and 11,058 shares of unvested restricted stock outstanding.

In September 2020, the Company appointed a new President of Global Extremities. As an inducement to accept employment with the Company, the individual was awarded a grant of stock options to acquire up to 32,945 shares of common stock and an award of 10,624 restricted stock units. As of December 31, 2020, there were 32,945 options outstanding under this inducement, none of which were exercisable, and 10,624 shares of unvested restricted stock outstanding.

Stock Purchase Plan

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

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

Due to the compensatory nature of such plan, the Company records the related share-based compensation in the consolidated statement of operations. Compensation expense is estimated using the Black-Scholes valuation model, with such value recognized as expense over the plan period. As of December 31, 2020, the aggregate number of shares reserved for issuance under the Stock Purchase Plan is 2,350,000. As of December 31, 2020, 1,991,738 shares had been issued.

Share-Based Compensation Expense

Share-based compensation expense is recorded in the same line of the consolidated statements of operations as the employee's cash compensation. The following tables present the detail of share-based compensation by line item in the consolidated statements of income as well as by award type, for the years ended December 31, 2020, 2019, and 2018:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2020**	**2019**	**2018**
Cost of sales	$ 705	$ 715	$ 522
Sales and marketing	3,620	2,512	1,802
General and administrative	10,624	16,872	15,197
Research and development	1,258	1,441	1,409
Total	$ 16,207	$ 21,540	$ 18,930

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2020**	**2019**	**2018**
Stock options	$ 2,571	$ 4,054	$ 3,061
Time-based restricted stock awards and stock units	8,485	11,084	7,265
Performance-based restricted stock awards and stock units	—	—	1,998
Market-based restricted stock units	3,509	4,733	5,256
Stock purchase plan	1,642	1,669	1,350
Total	$ 16,207	$ 21,540	$ 18,930

The income tax benefit related to this expense was $3.2 million, $3.5 million, and $3.2 million for the years ended December 31, 2020, 2019, and 2018, 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,		
	2020	**2019**	**2018**
Assumptions:			
Expected term (in years)	5.5	5.0	4.5
Expected volatility	30.2% – 35.1%	29.7% – 31.0%	28.7% – 30.1%
Risk free interest rate	0.28% – 1.65%	1.38% – 2.31%	2.55% – 2.79%
Dividend yield	—	—	—
Weighted average grant date fair value	$ 8.74	$ 14.64	$ 16.28

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

Summaries of the status of the Company's stock option plans as of December 31, 2020 and 2019 and changes during the year ended December 31, 2020 are presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at December 31, 2019	1,301,314	$ 42.92	
Granted	352,535	$ 27.86	
Exercised	(86,945)	$ 31.56	
Forfeited or expired	(75,885)	$ 52.11	
Outstanding at December 31, 2020	1,491,019	$ 39.56	5.74
Vested and expected to vest at December 31, 2020	1,491,019	$ 39.56	5.74
Exercisable at December 31, 2020	908,042	$ 41.56	3.71

As of December 31, 2020, the unamortized compensation expense relating to options granted and expected to be recognized was $3.6 million. This amount is expected to be recognized through September 2024 over a weighted average period of approximately 1.7 years. The total intrinsic value of options exercised was $0.9 million, $1.4 million and $3.2 million for the years ended December 31, 2020, 2019, and 2018, respectively. For the year ended December 31, 2020 we received $2.7 million in cash from stock option exercises, with the tax benefit realized for the tax deductions from these exercises of $0.1 million. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2020 is calculated as the difference between the exercise price of the underlying options and the market price of the Company's common stock for options that had exercise prices lower than $42.98, the closing price of the Company's stock on December 31, 2020. The aggregate intrinsic value of options outstanding was $9.1 million, $7.3 million, and $13.6 million for the years ended December 31, 2020, 2019, and 2018, respectively. The aggregate intrinsic value of options exercisable was $3.7 million, $6.7 million, and $11.0 million for the years ended December 31, 2020, 2019, and 2018, respectively.

Time-based Restricted Stock Awards and Stock Units

During the year ended December 31, 2020, the Company granted to employees and non-employee directors 250,459 shares of time- based restricted stock awards or stock units, which vest at various dates through December 2024. The compensation expense, which represents the fair value of the stock measured at the market price at the date of grant, is recognized on a straight-line basis over the vesting period, which is typically four years, net of actual forfeitures.

Since 2017, the annual grant to non-employee directors has been made in the form of one-year vesting restricted stock units with deferred delivery ("DSUs"), whereby shares are not settled until after the director ceases service as a director. As of December 31, 2020, there were 74,036 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, 2020, 2019, and 2018 was $6.5 million, $9.5 million and $8.0 million, respectively. Unamortized compensation expense related to time-based restricted stock awards and stock units amounted to $12.0 million at December 31, 2020, and is expected to be recognized over a weighted average period of approximately 2.5 years. The aggregate intrinsic value of time-based restricted stock awards and stock units outstanding was $21.2 million, $21.6 million and $18.8 million for the years ended December 31, 2020, 2019, and 2018, respectively.

Performance-based Restricted Stock Awards and Stock Units

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

The fair value of performance-based restricted stock awards and stock units is calculated based upon the closing stock price at the date of grant. Such value is recognized as expense over the derived requisite service period beginning in the period in which they are deemed probable to vest, net of actual forfeitures. Vesting probability is assessed based upon forecasted earnings and financial results. The Company did not grant any performance-based restricted stock awards or stock units to employees during the years ended December 31, 2020, 2019, and 2018.

During the year ended December 31, 2015, the Company granted to employees 110,660 shares of performance-based restricted stock awards, which vested based upon the achievement of certain earnings or return on invested capital targets. No compensation expense was recorded for these awards in 2020 or 2019 as the performance targets were obtained in prior years. Approximately $0.4 million of compensation expense was recorded for the year ended December 31, 2018 associated with these performance-based restricted stock awards. The fair value of performance-based restricted stock awards that vested during the years ended December 31, 2020, 2019, and 2018, were $0.0 million, $3.2 million, and $0.0 million, respectively. No unamortized compensation expense related to performance-based restricted stock awards remains as of December 31, 2020. The aggregate intrinsic value of performance-based restricted stock awards outstanding was $0.0 million, $0.0 million and $2.9 million for the years ended December 31, 2020, 2019, and 2018, respectively.

During the year ended December 31, 2015, the Company also granted 55,330 shares of performance-based restricted stock units to employees, which vested based upon the achievement of certain earnings or return on invested capital targets for the year ended December 31, 2018. The Company recognized compensation expense of $0.0 million, $0.0 million, and $1.6 million associated with these 2015 performance-based restricted stock units for the years ended December 31, 2020, 2019, and 2018, respectively. The fair value of performance-based restricted stock units that vested during the years ended December 31, 2020, 2019, and 2018, were $0.0 million, $2.7 million, and $0.0 million, respectively. No unamortized compensation expense remains as of December 31, 2020 related to these 2015 performance-based restricted stock units. The aggregate intrinsic value of performance-based restricted stock units outstanding was $0.0 million, $0.0 million, and $2.5 million for the years ended December 31, 2020, 2019, and 2018, respectively.

Market-based Restricted Stock Units

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

The fair value of market-based restricted stock units is determined at the date of the grant using the Monte Carlo valuation methodology, with any discounts for post-vesting restrictions estimated using the Chaffe Model. The Monte Carlo methodology incorporates into the valuation the possibility that the market condition may not be satisfied. Such value is recognized on a straight-line basis over the vesting period, net of actual forfeitures. The awards, if the market conditions are achieved, will be settled in shares of common stock, with one share of common stock issued per restricted stock unit if targets are achieved at the 100% level. Awards may be achieved at a minimum level of 50% and a maximum of 200%. The market conditions for the awards are based on the Company's stock achieving certain total shareholder return targets relative to specified index companies during a 3-year performance period beginning on each respective grant date. The fair value of market-based restricted stock units that vested and settled during the years ended December 31, 2020, 2019, and 2018, were $1.4 million, $0.0 million, and $0.0 million, respectively. Unamortized compensation expense for market-based restricted stock units amounted to $6.5 million at December 31, 2020, and is expected to be recognized over a weighted average period of approximately 1.6 years. The aggregate intrinsic value of market-based restricted stock units outstanding was $11.8 million, $11.9 million, and $14.2 million for the years ended December 31, 2020, 2019, and 2018, 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, 2020, and 2019 and changes during the year ended December 31, 2020 are presented below:

	Time-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
Outstanding at December 31, 2019	468,728	$ 51.96	257,162	$ 60.08
Granted	250,459	$ 29.93	158,238	$ 44.00
Vested and settled	(178,315)	$ 52.31	(45,178)	$ 49.53
Cancelled	(47,745)	$ 46.97	(94,884)	$ 54.64
Outstanding at December 31, 2020	493,127	$ 41.13	275,338	$ 54.45

Retirement of the Company's President and Chief Executive Officer

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

As part of the Retirement Agreement, certain time-based stock options and restricted stock awards were modified to vest on the Retirement Date. In addition, stock options were modified to extend the post-termination exercise period from 18 months under a standard qualified retirement to up to four years, dependent upon the remaining contractual terms of the options. For fiscal year 2019, in lieu of Mr. Mason's normal annual incentive awards under the 2012 LTIP, and in recognition of the ongoing transition assistance that he agreed to provide, Mr. Mason was granted an award of RSUs on April 1, 2019, with a grant date fair market value of $2.0 million that vested on the first anniversary of the date of grant, subject to his continued consulting services through his Retirement Date. The full fair value of the award was recorded as expense in 2019. The Company recognized no share-based compensation expense for the year ended December 31, 2020 and approximately $6.5 million during the year ended December 31, 2019 related to the Retirement Agreement, which was charged to general and administrative expense in the consolidated statements of operations and comprehensive income (loss).

19. Defined contribution plans and deferred compensation

Defined Contribution Plans

Orthofix US LLC 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, 2020, 2019, and 2018, expenses incurred relating to the 401(k) Plan, including matching contributions, were approximately $1.1 million, $2.7 million, and $2.3 million, respectively.

In April 2020, as a precautionary measure to increase the Company's cash position and preserve financial flexibility in response to the initial uncertainty of the COVID-19 pandemic, the Company temporarily suspended the 401(k) match program through the remainder of fiscal year 2020. The 401(k) match program was reinstated in January 2021.

The Company also operates defined contribution plans for its international employees meeting minimum service requirements. The Company's expenses for such contributions during each of the years ended December 31, 2020, 2019, and 2018 were $1.1 million, $1.0 million and $1.1 million, respectively.

Deferred Compensation Plans

Under Italian Law, our Italian subsidiary accrues, on behalf of its employees, deferred compensation, which is paid on termination of employment. The accrual for deferred compensation is based on a percentage of the employee's current annual remuneration plus an annual charge. Deferred compensation is also accrued for the leaving indemnity payable to agents in case of dismissal, which is regulated by a national contract and is equal to approximately 3.4% of total commissions earned from the Company. The Company's relations with its Italian employees, who represent 20.1% of total employees at December 31, 2020, are governed by the provisions of a National Collective Labor Agreement setting forth mandatory minimum standards for labor relations in the metal mechanic workers industry. The Company is not a party to any other collective bargaining agreement. The balance in other long-term liabilities as of December 31, 2020 and 2019 was $1.4 million and $1.3 million, respectively, and represents the amount which would be payable if all the employees and agents had terminated employment at that date.

20. 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)	2020	2019	2018
U.S.	$ 5,556	$ (24,890)	$ 28,642
Non-U.S.	(5,924)	(2,159)	(5,757)
Income (loss) before income taxes	$ (368)	$ (27,049)	$ 22,885

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

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2020	2019	2018
U.S.			
Current	$ (15,054)	$ (1,911)	$ 9,480
Deferred	(29)	2,008	(3,430)
	(15,083)	97	6,050
Non-U.S.			
Current	1,382	1,931	2,255
Deferred	10,816	(615)	769
	12,198	1,316	3,024
Income tax expense (benefit)	$ (2,885)	$ 1,413	$ 9,074

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, 2020, 2019, and 2018 consist of the following:

	2020		2019		2018	
(U.S. Dollars, in thousands, except percentages)	Amount	Percent	Amount	Percent	Amount	Percent
Statutory U.S. federal income tax rate	$ (77)	21.0%	$ (5,680)	21.0%	$ 4,806	21.0%
State taxes, net of U.S. federal benefit	1,151	(312.8)	1,043	(3.9)	1,038	4.5
Foreign rate differential, including withholding taxes	(147)	40.0	131	(0.5)	784	3.4
Valuation allowances, net	14,514	(3,944.0)	(165)	0.6	4,116	18.0
Research credits	(982)	266.8	(829)	3.1	(710)	(3.1)
Italian subsidiary intangible asset	—	—	—	—	(230)	(1.0)
Unrecognized tax benefits, net of settlements	(17,321)	4,706.8	(2,745)	10.1	81	0.4
Impact of the Tax Act	—	—	—	—	(560)	(2.4)
Equity compensation	1,657	(450.3)	626	(2.3)	(1,646)	(7.2)
Executive compensation	375	(101.9)	1,504	(5.6)	606	2.6
Contingent consideration	(1,460)	396.7	5,678	(21.0)	528	2.3
Other, net	(595)	161.7	1,850	(6.7)	261	1.2
Income tax expense (benefit) /effective rate	$ (2,885)	784.0%	$ 1,413	(5.2)%	$ 9,074	39.7%

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

On December 22, 2017, Staff Accounting Bulletin No. 118 ("SAB 118") was issued to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed (including computations) in reasonable detail to complete the accounting for certain income tax effects of the Tax Act. In accordance with SAB 118, we determined that the $8.6 million of the deferred tax expense recorded in connection with the remeasurement of certain deferred tax assets and liabilities and the zero transition tax on the mandatory deemed repatriation of foreign earnings was a provisional amount and a reasonable estimate at December 31, 2017. A more detailed analysis of the Company's deferred tax assets and liabilities and its historical foreign earnings as well as potential correlative adjustments was completed in 2018, which resulted in an

additional benefit of $0.6 million in the first quarter of 2018 and minimal adjustments in the fourth quarter of 2018. As of December 31, 2018, the Company has completed its accounting for the tax effects of enactment of the Tax Act.

The Company paid cash relating to taxes totaling less than $0.5 million, $8.1 million, and $15.6 million for the years ended December 31, 2020, 2019, and 2018, respectively. During 2020, the Company received federal income tax refunds from prior years of $3.5 million, which offset cash payments to other state and foreign jurisdictions of $4.0 million.

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

	December 31,	
(U.S. Dollars, in thousands)	**2020**	**2019**
Intangible assets and goodwill	$ 2,475	$ 1,390
Inventories and related reserves	17,585	13,216
Deferred revenue and cost of goods sold	4,035	4,652
Other accruals and reserves	4,061	4,337
Accrued compensation	8,734	9,221
Provision for expected credit losses	1,178	971
Net operating loss and tax credit carryforwards	42,569	44,230
Lease liabilities	6,033	6,268
Other, net	500	1,567
	87,170	85,852
Valuation allowance	(50,496)	(38,741)
Deferred tax asset	$ 36,674	$ 47,111
Withholding taxes	(40)	(40)
Property, plant and equipment	(5,975)	(5,881)
Right-of-use lease assets	(5,617)	(6,073)
Deferred tax liability	(11,632)	(11,994)
Net deferred tax assets	$ 25,042	$ 35,117

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 $11.8 million during the year principally relates to recognizing a full valuation allowance against the net deferred tax asset within the Company's European manufacturing subsidiary. The Company considered many factors when assessing the likelihood of future realization of these deferred tax assets, including recent cumulative losses experienced by the subsidiary, expectations of future taxable income or loss, the carryforward periods available to the Company for tax reporting purposes, and other relevant factors. That increase was partially offset by a decrease of valuation allowances on net operating loss carryforwards in other foreign jurisdictions due to expiration, statutory rate changes, and changes regarding the realizability of net deferred tax assets. It is reasonably possible that the valuation allowance will decrease in 2021 related to expiration of foreign net operating losses.

The Company has federal net operating loss carryforwards of $21.4 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 $33.6 million, of which $21.4 million relates to Spinal Kinetics and begins to expire in 2027. Additionally, the Company has net operating loss carryforwards in various foreign jurisdictions of approximately $140.2 million that begin to expire in 2021, the majority of which relate to the Company's Italy, Netherlands, and Brazil operations.

Prior to the Domestication, as an entity incorporated in Curaçao, "foreign earnings" referred to both U.S. and non-U.S. earnings. As a result of the Domestication, only income sourced outside of the U.S. is considered unremitted foreign earnings. Unremitted foreign earnings increased from $49.2 million at December 31, 2019 to $53.7 million at December 31, 2020. The increase is due to the impact of currency translation. As a result of the 2017 Tax Act, current year earnings have been deemed to be repatriated. Those foreign subsidiary earnings that are subject to U.S. taxation as a component of Global Intangible Low Taxed Income (GILTI) under the Tax Act are included as a component of current tax expense. The Company's investment in foreign subsidiaries continues to be indefinite in nature; however, the Company may periodically repatriate a portion of these earnings to the extent that it does not incur significant additional tax liability.

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

The Company's unrecognized tax benefit was $4.6 million and $16.9 million for the years ended December 31, 2020 and 2019, respectively. The Company recorded net interest and penalties expense (benefit) on unrecognized tax benefits of $(5.4) million, $(0.1) million, and $1.4 million for the years ended December 31, 2020, 2019, and 2018, respectively, and had approximately $1.2 million and $6.6 million accrued for payment of interest and penalties as of December 31, 2020 and 2019, respectively. The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company's effective tax rate if recognized. The Company believes it is reasonably possible that, in the next 12 months, the amount of unrecognized tax benefits, exclusive of interest and penalties, related to the resolution of federal, state and foreign matters could be reduced by $1.0 million to $1.5 million as audits close and statutes expire.

A reconciliation of the gross unrecognized tax benefits (excluding interest and penalties) for the years ended December 31, 2020, 2019, and 2018 follows:

(U.S. Dollars, in thousands)	2020	2019
Balance as of January 1,	$ 16,904	$ 21,351
Additions for current year tax positions	568	309
Increases for prior year tax positions	84	1,711
Settlements of prior year tax positions	(29)	(1,183)
Expiration of statutes	(12,898)	(5,284)
Balance as of December 31,	$ 4,629	$ 16,904

The Company and its subsidiaries file income tax returns in the U.S. federal jurisdiction and in certain state and foreign jurisdictions, including Italy, as well as other jurisdictions where the Company maintains operations. The statute of limitations with respect to federal and state tax filings is closed for years prior to 2016. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to 2015.

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

21. 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 18).

For each of the three years ended December 31, 2020, 2019, and 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,		
	2020	2019	2018
Weighted average common shares-basic	19,267,920	18,903,289	18,494,002
Effect of diluted securities:			
Unexercised stock options and employee stock purchase plan	51,951	—	313,648
Unvested time-based restricted stock awards	71,847	—	—
Unvested performance-based restricted stock awards	—	—	103,960
Weighted average common shares-diluted	19,391,718	18,903,289	18,911,610

There were 1,449,630; 1,704,708; and 349,930 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, 2020, 2019, and 2018, 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.

22. Subsequent events

On February 2, 2021, the Company entered into a technology assignment and royalty agreement with a medical device technology company partially owned and controlled by the wife of President and Chief Executive Officer, Jon Serbousek, whereby the Company acquired the intellectual property rights to certain assets for consideration of up to $10.0 million. Consideration is comprised of $1.0 million due at signing and $9.0 million in contingent consideration, dependent upon multiple milestones, such as receipt of 510(k) clearance or the attainment of certain net sales targets. In addition, the Company shall pay a royalty of 2% to 4% on net sales, commencing upon commercialization of the acquired assets. The transaction was approved by the Company's Audit and Finance Committee, with the Audit and Finance Committee directly supervising and directing the negotiation of the transaction by Company employees who reported directly to the committee in connection with such negotiations. Mr. Serbousek was excluded from such discussions and did not participate in the negotiation or evaluation of the transaction. Mr. Serbousek is also being excluded from the administration and implementation of the agreements and the transactions contemplated thereby, all discussions or disputes with the counterparty in connection with the agreement, the transactions contemplated thereby, or the administration or implementation thereof, oversight of the Company's development and commercialization activities in relation to the acquired technology, and all other matters relating to the relationship between the Company and the counterparty.

Exhibit 10.9

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 Period" means either of the consecutive six month periods beginning on November 1 or May 1, respectively, and ending on April 30 and October 31, respectively. In other words, the Plan Period will commence on November 1 and end on April 30, and will commence again on May 1 and end on October 31. However, pursuant to Section 7, the Committee may change the duration, frequency, start and end dates of future Plan Periods.

(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 Period, 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 Period 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 Period; 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 Period. 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 Period shall be made prior to the beginning of such Plan Period 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 Period 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 Period. A Director's election to participate in the Plan for any Plan Period shall be made prior to the beginning of such Plan Period 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 Period 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 Period equal to the total amount of the Director's annual or other compensation paid in cash for such Plan Period multiplied by the ratio of the number of days remaining in the Plan Period after such election is made over the total number of days in the Plan Period for which such Director receives annual director or other compensation.

(c) A Participant must complete a new election with respect to each Plan Period in order to participate in the Plan Period. During any Plan Period, a Participant may make a one-time election to decrease (including to zero) his or her rate of payroll deductions applicable to such Plan Period. 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 Period 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 Period, 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 by the 20th day of the last month of the applicable Plan Period, or the immediately preceding business day, if such day is a holiday or weekend. 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 Period 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 Period 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 Period.

(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 Period, 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 20th day of the last month of the applicable Plan Period, or the immediately preceding business day, if such day is a holiday or weekend, may again participate in the Plan for any subsequent Plan Periods, provided he or she satisfies the eligibility requirements of Section 4 and makes a timely election to contribute for such Plan Period.

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

(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 appropriate statutory rate, that the Participant incurs as a result of the Participant's participation in the Plan. To satisfy the statutory tax withholding requirements, the Company or its Subsidiary will irrevocably elect, 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 Periods;

(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 Period (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. Data Privacy

(a) In order to facilitate the administration of the Plan, it will be necessary for the Company (or its stock plan and payroll administrators) to collect, hold, and process certain personal information about Employees participating in the Plan (including without limitation, name, home address and date of birth.) By participating in the Plan, participating Employees consent to the Company (including its stock plan and payroll administrators) collecting, holding and processing personal data and transferring such data to third parties insofar as is reasonably necessary to implement, administer and manage the Employee's participation in the Plan and acknowledge that it may also be necessary to disclose information in order to comply with any legal obligations.

(b) The Company (including its stock plan and payroll administrators) will treat the participating Employees' personal data as private and confidential and will not disclose such data for purposes other than the management and administration of the Employees' participating in the Plan and will take reasonable measures to keep such personal data private, confidential, accurate and current.

(c) As the Company operates globally, it needs to share personal data with other related companies which are based abroad. Where the transfer is to a destination outside the Employee's country of domicile, the Company shall take reasonable steps to ensure that such personal data continue to be adequately protected and securely held. Nonetheless, by participating in the Plan, each participating Employee acknowledges that personal information about such Employee may be transferred to a country that does not offer the same level of data protection as the Employee's country of domicile.

14. 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.

15. 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.

Orthofix Medical Inc.

SECOND AMENDED AND RESTATED
STOCK PURCHASE PLAN, AS AMENDED

Amended and Restated Sub-Plan for the European Union and the United Kingdom

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In accordance with Section 12(a) of the Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as amended (the "Plan"), the Committee has adopted this amended and restated sub-plan of the Plan for purposes of offering participation to eligible Employees of the Company and any Subsidiary of the Company domiciled or resident of a member state of the European Union or the United Kingdom, and designated as a participating employer under the Plan. The Plan and this sub-plan are not intended to comply with the requirements of Code Section 423 (other than clauses (b)(3) and (b)(5) thereof). Unless otherwise provided herein, all defined terms in this sub-plan shall have the same definition and meaning as set forth in the Plan.

Definitions

"Eligible EU-Domiciled/Resident Employee" means each full-time or part-time employee of the Company or a Subsidiary who is domiciled or resident of a country in a member state of the European Union or the United Kingdom.

Participation

Notwithstanding any provision to the contrary in Section 5(a) of the Plan, the maximum contribution percentage for each Eligible EU-Domiciled/Resident Employee shall be established by the Committee prior to the commencement of each applicable Plan Period so as to ensure that the offering of participation to Eligible EU-Domiciled/Resident Employees shall comply with the exclusion for offerings set forth in either Article 1(3) of the EU Prospectus Regulation or Article 3(2) of the EU Prospectus Regulation (if this has been adopted into local law in the relevant jurisdiction) and any regulations applicable thereunder; provided, however, that the maximum contribution percentage for each Eligible EU-Domiciled/Resident Employee shall be no greater than the maximum contribution percentage permitted under the Plan (which, as of the date of the adoption of this sub-plan, is 25% of such Employee's annual compensation).

If the Company receives elections to contribute to the Plan from Eligible EU-Domiciled/Resident Employees which would, if accepted, mean that the value of the consideration under the Plan in a period of 12 months would exceed the limits for offerings set forth in Article 1(3) of the EU Prospectus Regulation and Article 3(2) of the EU Prospectus Regulation (if such Article 3(2) permitted limits have been adopted in the applicable jurisdiction), the Committee will adjust individual elections downwards on a proportionate basis or on any other basis which the Committee deems appropriate.

* * * * *

August 21, 2020

Paul Gonsalves

Offer Letter

Dear Paul,

It gives me great pleasure to present this offer of employment with Orthofix Medical, Inc. (with its subsidiaries and affiliates, "Orthofix").

Position: The position we are offering you is that of President of Global Extremities, reporting to Jon Serbousek, President and Chief Executive Officer.

Start Date: Your start date will be on September 14, 2020.

Base Salary: Your base salary will be $400,000 per year (the "Base Salary"), less applicable deductions and tax withholdings.

Annual Bonus: Subject to Orthofix policies and satisfaction of applicable performance criteria, you will be eligible to participate in the annual bonus program, with a target bonus opportunity of 70% of your Base Salary. Your 2020 annual bonus will be pro-rated based on your start date.

Sign-On Equity Award: As an inducement to and incentive for accepting this position, you will be eligible to receive a grant, effective as of your start date, under Orthofix's 2012 Long-Term Incentive Plan of (i) stock options to purchase shares of Orthofix common stock, valued at $300,000 (based on the Black-Scholes value of Orthofix common stock on the grant date, subject to rounding to the nearest whole share) and (ii) restricted stock units with respect to shares of Orthofix common stock, valued at $300,000 (based on the closing price of Orthofix common stock on the grant date, subject to rounding to the nearest whole share), in each case vesting in 25% increments on each of the first four anniversaries of your start date, subject to your continued service with Orthofix on each such vesting date. The sign-on equity awards are contingent upon and issued only upon approval by Orthofix's Board of Directors and will be subject to the terms and conditions of applicable award agreements, which will be made available to you shortly after approval of your awards by Orthofix's Board of Directors.

Equity Incentives: You will also be eligible to receive future, annual equity incentive awards. Any future equity incentive awards are contingent upon and issued only upon approval by Orthofix's Board of Directors (or Compensation Committee) and will be subject to the terms and conditions of applicable plan documents and award agreements. The

incentive value for the 2021 annual incentive award is anticipated to be approximately $600,000, but will be subject to Compensation Committee review and approval.

Benefits: Orthofix will offer you medical, dental, and vision insurance, effective the first of the month after your first 30 days of employment. You will also be eligible to participate in the Orthofix 401(k) retirement plan as of the first of the month after your first 30 days of employment. This plan currently provides an employer match of 100% for the first 2% contribution and 50% for the next 4% contribution. A more detailed explanation of these benefits and other benefits will be provided to you under separate cover. Orthofix defers to the provisions of its employee benefits plans, which plans shall govern to the extent of any conflict and which plans may be changed unilaterally by Orthofix.

Location and Residency: Your position will be based in Orthofix's Lewisville offices. As such, Orthofix will provide support in establishing residency in the Lewisville, Texas area and will provide reimbursement (upon submission of applicable supporting documentation) for a house-hunting trip with your spouse, for closing costs on the purchase of a home, for the move of household goods and two automobiles of up to $100,000. Relocation expenses will be grossed up for the value using the Company's standard gross-up formula for the expected tax liability of these expenses.

Third-Party Confidentiality/Non-Compete Obligations: Orthofix recognizes that, while you were employed with your prior employers, you may have been exposed to confidential, proprietary, and/or trade secret information ("Third-Party Confidential Information"). Moreover, Orthofix recognizes that you have a legal duty and may have a contractual duty not to use or disclose Third-Party Confidential Information outside of your employment with your former employers. Orthofix also recognizes that you may owe your former employers a contractual duty not to solicit certain customers ("Restricted Customers"). Orthofix has no intention of obtaining any Third-Party Confidential Information in any form. In fact, Orthofix's expectation is that you will abide by, and comply fully with, the terms of any agreements you may have with respect to such information. By signing below, you represent and warrant that you have complied, and will comply, with any such obligations, including, but not limited to, all confidentiality, non-solicitation, non-competition, and post-employment disclosure obligations. You further represent and warrant that you have not misappropriated any Third-Party Confidential Information and, to the extent you may have access to such information, you will not disclose or use it for any purpose contrary to the terms of any agreements you may have with respect to such information, or to benefit Orthofix in any way.

Orthofix also wishes to ensure that you are not placed in a position which might require you to solicit Restricted Customers or cause the disclosure or use of Third-Party Confidential Information, either intentionally or inadvertently. For this reason, this offer is contingent upon the legal department's review of any agreements you may have with a current or former employer or business partner, and Orthofix reserves the right to rescind the offer if it determines, in its sole discretion, that you have continuing obligations to a current or former employer or business partner that could restrict or interfere with the responsibilities Orthofix anticipates you performing on its behalf. If you are ever involved in any job situation which could require you to solicit Restricted Customers or cause you to use or disclose any Third-

Party Confidential Information, you agree to immediately notify Orthofix's Chief Legal Officer and advise Orthofix's Chief Legal Officer of your concerns. In the event it is determined that a risk of improper solicitation, disclosure, or use does exist, Orthofix will take appropriate measures.

Orthofix is also serious about protecting its own confidential, proprietary, and/or trade secret information. Accordingly, this offer of employment is contingent upon your execution of a confidentiality, non-competition, and inventions agreement (a "Restrictive Covenant Agreement").

Testing and Screening: This offer is contingent on the successful completion of a drug test and background screening. The drug screen must be completed within 48 hours of receipt of testing instructions. If the drug screen is not completed by the designated date, we reserve the right to rescind the offer.

Work Eligibility: Federal law requires all employees to provide their employers with verification of identity and eligibility to work in the United States within the first three (3) days of employment. All employees are required to show one or more forms of identification as a means of verification. This offer of employment is contingent upon your return of the necessary documentation to Orthofix within three days of your first day of employment with a copy of the acceptable identification you choose to present.

Employment-At-Will: You understand and acknowledge that, if you become employed by Orthofix, you will be an "at-will" employee at all times during your employment. As an at-will employee, both Orthofix and you will have the right to terminate your employment at any time, with or without cause, and with or without notice. At-will employment also means that your job duties, title, compensation, and benefits, as well as the company personnel policies and other procedures, may be changed or terminated at the sole discretion of Orthofix at any time. Please note that, while this offer letter summarizes your anticipated terms and conditions of employment with Orthofix, they may change, and it is ***not*** an employment contract.

Governing Law: This offer letter shall be governed by and construed in accordance with the laws of the State of Texas, without regard to its principles of conflicts of laws.

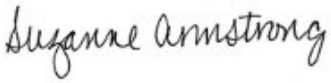
Other Agreements: Under separate cover, you will receive a Change in Control and Severance Agreement, and an Indemnity Agreement (the "Other Agreements"). Kindly return one signed copy of this offer letter and each Other Agreement.

Acceptance: Your signature at the end of this offer letter constitutes an acceptance of this offer and confirms that no promises, representations, or agreements that are inconsistent with any of the terms of this offer letter have been made to or with you by anyone at Orthofix. You also acknowledge and agree that no modification of the terms and conditions set forth in this offer letter can be made without the written authorization of Orthofix's President and Chief Executive Officer or Orthofix's Compensation Committee.

This offer of employment will remain open until August 24, 2020.

Paul, we look forward to working with you. Your experience, background and leadership will be a significant asset to Orthofix.

Sincerely,



Suzanne Armstrong
Vice President, Human Resources

ACKNOWLEDGED, ACCEPTED, AND AGREED:

/s/ Paul Gonsalves Date August 22, 2020

Paul Gonsalves

Exhibit 10.45

TERMINATION AGREEMENT

Between

Orthofix AG
c/o ALLconsult Services Armin L. Landtwing
Bundesstrasse 3
6302 Zug

(the "**Company**")

and

Davide Bianchi
[Address]
Switzerland

(the "**Employee**")
(each a "**Party**" and collectively the "**Parties**")

Preamble

This Agreement memorializes the Parties' recent discussions and mutual agreement regarding the Employee's departure as an employee of Orthofix AG, a company organized under the laws of Switzerland (the "Company"), and as an executive officer of Orthofix Medical Inc., a Delaware corporation that is the legal continuation of a Curacao company called Orthofix International N.V. ("Parent") and certain of its subsidiaries. With the intent to agree on the terms of termination of employment and to amicably settle all claims thereunder, the Parties agree as follows:

1. Definitions

For purposes of this Agreement, (i) "Orthofix Group" shall mean Parent and each of its direct and indirect US and non-US subsidiaries, (ii) "Employment Contract" shall mean that certain Amended and Restated Employment Contract, dated July 31, 2018, between the Parties, (iii) "Non-Competition Agreement" means that certain Non-Competition Agreement, signed by the Parties on November 18/26, 2013, between the Company and the Employee, and (iv) "Change in Control and Severance Agreement" means that certain Change in Control and Severance Agreement, dated September 7, 2016, between Parent and the Employee.

2. Termination of Employment, Salary, Bonus

The Employee approached the Company and Parent expressing his desire to have the Employment Contract terminated and cease his director and officer status with the Orthofix

Group. The Company hereby complies with the Employee's request and agrees to a mutual termination of the Employee's employment with the Company. The Employment Contract will therefore expire on, and the Employee's date of termination as an employee of the Company shall be, October 1, 2020 (the "**Termination Effective Date**")).

The termination of the Employee's Employment Contract constitutes a termination by mutual agreement (in accordance with Section 4.1 Employment Contract). However, as the Parties have agreed, for purposes of the notice period, the compensation the Employee is eligible to receive upon termination and Section 6.1(b)(iv) of the Employment Contract, the termination of the Employee's employment shall be deemed a termination without Cause in accordance with Section 4.5 of the Employment Contract.

During the period between today and the Termination Effective Date, the Employee will continue to receive his base salary and to be eligible for a pro-rated annual incentive plan bonus (to the extent applicable performance metrics are satisfied), but the Employee will not receive any further grants under Parent's Amended and Restated 2012 Long-Term Incentive Plan, as may be amended from time-to-time (the "2012 LTIP"). The Employee agrees that this compensation arrangement shall not provide him "Good Reason" to terminate the Employment Contract.

3. Garden Leave/ Resignation

The Employee is released from his duty to perform work (garden leave). Any remaining vacation entitlement and accrued working hours will be deemed compensated by the garden leave period.

The Employee shall resign (to the extent not otherwise removed), effective immediately, from all director and officer positions he holds with all members of the Orthofix Group (namely, as a director of each of Orthofix Srl and Orthofix S.A., and an officer of Orthofix Srl, Orthofix Medical Inc. and Orthofix Inc.). The Company shall provide the Employee with forms of resignation letters for him to sign, as applicable, in cases where the Employee has not otherwise been removed.

4. Return of Documents and Property

The Employee shall return by May 15, 2020 via Federal Express (or similar courier or delivery service) to Orthofix S.r.l., Via delle Nazioni 9, 37012 Bussolengo, Verona, Itally, Attn: Massimo Taurino, his keys, badges, smartphone, laptop and PC. The Employee shall further return to the Company (a) all documents and materials containing Confidential Information (including without limitation any "soft" copies or computerized or electronic versions thereof) or otherwise containing information relating to the business and affairs of any member of the Company Group (whether or not confidential) and (b) all other documents, materials and other property belonging

to any member of the Company Group that are in the possession or under the control of the Executive, in accordance with Section 6.5 of the Employment Contract.

5. Protective Covenants

5.1. Confidentiality, Non-Solicitation and Non-Competition Obligations

The Employee agrees and hereby confirms that he will continue to be bound by his confidentiality and non-competition obligations towards the Company and other members of the Orthofix Group (in compliance with Sections 6.1 and 6.3 of the Employment Contract) during the garden leave period (i.e. during the period from April 1, 2020 through the Termination Effective Date) and, in particular as regards business secrets, beyond the expiration of the Employment Contract.

The Employee also agrees and hereby confirms that he will continue to be bound by his non-solicitation obligations under Section 6.2 of the Employment Contract during the period through the Termination Effective Date and for a twelve-month period following the Termination Effective Date.

In accordance with Sections 6.1 and 6.7 of the Employment Contract, the Employee agrees and hereby confirms that he will further remain bound by the terms of the Non-Competition Agreement during the twelve-month period following the Termination Effective Date.

5.2. Consideration

As consideration for the Employee's obligations under the Non-Competition Agreement and other protective covenants towards the Company and other members of the Orthofix Group, the Employee shall receive the Accrued Amounts and Severance Amount (each, as defined in Section 3 of the Change in Control and Severance Agreement), in the amounts and timeline described in Exhibit A hereto. Hence, in accordance with Section 6.1(b)(iv) of the Employment Contract, the Company shall be deemed to have satisfied all payment and remuneration obligations referenced in Section 5 of the Non-Competition Agreement and the "Option" referenced in the Non-Competition Agreement are deemed to be exercised and fully paid-up thereunder.

5.3. Conditions

Any payments or benefits upon termination of the Employee's employment under Section V of the Employment Contract (including but not limited to the Accrued Amounts, the Severance Amount and any equity awards the Employee has received pursuant to the 2012 LTIP), are subject to a unilateral right of set-off by the Company and Parent, during and following the period of any breach or violation by the Employee of (i) the protective covenants under Sections

6.1 to 6.5 of the Employment Contract during and after expiration of the Employment Contract (i.e. covenants regarding non-competition, including but not limited to the terms of the Non-Competition Agreement, no solicitation or interference, confidential information, inventions, return of documents and property), (ii) Section 9 of the Change in Control and Severance Agreement, and (iii) the Employee's fiduciary obligations to members of the Orthofix Group under applicable law, including but not limited to the Employee's fiduciary duties under Delaware law pursuant to the Employee's status as an executive officer of Parent through the date of the Employee's resignation from such office.

In particular, the Employee further understands and agrees that payment to him of the Accrued Amounts and Severance Amount (each, as defined in Section 3 of the Change in Control and Severance Agreement, and in the amounts described in Exhibit A hereto) is conditioned upon and subject to, among other things, (i) the Employee's effective delivery and non-revocation of the Release (as defined in Section 5 of the Change in Control and Severance Agreement, and in the form of Exhibit B hereto) following the Termination Effective Date in accordance with the terms of the Change in Control and Severance Agreement, (ii) the Employee's full compliance with all the terms of the Non-Competition Agreement and all terms of Section 9 of the Change in Control and Severance Agreement, and (iii) the Employee's continued compliance with all fiduciary duties (including but not limited to the duty of loyalty) applicable to the Employee under the laws of the State of Delaware pursuant to the Employee's status as an executive officer (or, following the Employee's resignation or removal as an officer, a former executive officer) of Parent.

6. Clawback and Insider Trading Policies

The Employee understands and agrees that all amounts he receives from the Company and Parent remain subject to Parent's compensation recoupment, or "clawback", policy, as adopted in December 2012 and disclosed in Parent's public filings with the US Securities and Exchange Commission (most recently, on page 31 of Parent's proxy statement for its 2019 annual meeting of shareholders, which can be found at the following link: sec.gov/Archives/edgar/data/884624/000156459019013773/ofix-def14a_20190610.htm), and the Employee agrees to return any payments or amounts he receives that must be returned pursuant to such policy.

The Employee currently remains an "insider" under Parent's insider trading policy. It is Parent's intent that the Employee will cease receiving material, non-public information regarding the material operations of Parent and its subsidiaries during the garden leave period, such that the Employee would cease to be an "insider" subject to trading restrictions under such policy two business days following Parent's filing of its Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2020 (which filing currently is anticipated to occur sometime between May 7, 2020 and May 11, 2020). Assuming the Employee does not possess material, non-public information regarding Parent after such two business day period expires, and that the Employee

refrains from receiving any such material, non-public information from such date onward, the Employee would not be subject to further restrictions on trading Orthofix common stock under such policy, and the Employee would be free to sell shares of Orthofix common stock that he possesses.

7. Full and Final Settlement

Each Party confirms that, upon performance of the other Party's obligations under this Agreement, it shall have no claim whatsoever against the other Party or, in case of the Company, any of its affiliates and that all claims arising out of or in connection with the Employee's employment with the Company are fully and finally settled.

8. Severability

If any term or provision of this Agreement, or the application thereof shall for any reason and to any extent be invalid or unenforceable, all other terms of this Agreement, in particular the termination of the Employee's employment with the Company with effect on the Termination Effective Date, shall not be affected thereby, but rather shall be enforced to the fullest extent permitted by law.

Place, Date: Zug, May 4, 2020

Orthofix AG

/s/ Armin Landtwing
Armin Landtwing

Place, Date: Grenolier, 24-04-2020

/s/ Davide Bianchi
Davide Bianchi

Exhibit A: Amounts and Timeline for Payments of Accrued Amounts and Severance Amount
Exhibit B: Form of Release

Exhibit A

Amount and Timeline of Payment of Accrued Amounts and Severance Amount

Accrued Amounts:

- The Employee will receive his base salary and car allowance in the ordinary course during the garden leave period from April 1, 2020 to October 1, 2020, amounting to CHF 206,000 gross and CHF 12,000 gross in the aggregate, respectively, in each case less any applicable taxes and/or withholding. During this period, he would also remain enrolled in Orthofix's health and welfare benefit plans under the same terms that currently exist.

- The Employee will remain eligible to receive a 2020 *pro rata* Orthofix Medical Inc. incentive plan bonus. The amount payable, if any, depends on the financial performance from January 1, 2020 through December 31, 2020 of Parent and its subsidiaries on a consolidated basis (and, in Employee's case, the financial performance of the Extremities reporting segment) and, if any bonus is earned, it will be payable at the same time in the spring of 2021 that other executive bonuses are paid. The Employee's target bonus for the full calendar year of 2020 is CHF 288,400 gross (minimum bonus amount of CHF 0 if goals are achieved below threshold levels, and maximum amount of CHF 432,600 gross if goals are achieved at maximum levels), and thus Employee will be eligible to receive a *pro rata* portion of any bonus earned based on the percentage of the 2020 calendar year represented by the period from January 1, 2020 until October 1, 2020 (i.e., the *pro rata* portion would be approximately 75% of the full calendar year amount, if any). Any bonus paid would be less applicable taxes and/or withholding.

Equity Matters:

- The Employee will continue to vest in time-based stock option and restricted stock/RSU awards until October 1, 2020. Stock option awards will remain exercisable until December 30, 2020 (i.e., 90 days following end of garden leave period).

- Pursuant to its terms, the 2-year cliff vesting restricted stock unit award granted on April 1, 2020 in the amount of 7,366 shares will accelerate vest on October 1, 2020 in accordance with Section 5 of the Stock Unit Grant Agreement governing such award, and the underlying shares of Parent common stock (after any net share settlement to cover any applicable tax withholdings) will be delivered to Employee as soon as practicable thereafter. No other time-based vesting stock option or restricted stock/RSU grants will accelerate vest in connection with Employee's termination of employment.

- The Employee will remain eligible to pro rata vest in performance stock unit (PSU) awards based on the ultimate Parent achievement (if any), in a proportion equal to the portion of the applicable 3-year period during which he was employed (including the garden leave period) multiplied by the Company’s overall performance achievement percentage. Thus, he will receive (i) full service credit for the PSU awards granted on July 3, 2017, (ii) 83.3% service credit for the PSU awards granted on April 2, 2018, and (iii) 50% service credit for the PSU

awards granted on April 1, 2019. In each case, the service credit percentage will be multiplied by Parent's achievement percentage (which will be from 0% to 150%) to determine the number of shares received, if any. By way of example to illustrate the concept, if Parent's achievement based on the performance of its stock during the 3-year period were 50% of target for each of the 2017, 2018 and 2019 awards, the Employee would receive 50% of the target award for 2017, 41.65% for 2018 and 25% for 2019.

Severance Amount:

- The Employee's "Severance Amount" under his Change in Control and Severance Agreement, which will be paid in one lump sum, will be CHF 700,400 gross (which represents one-year of base salary amount plus one-year of target bonus amount) plus USD $12,500 gross (which will be payable in Swiss Francs based on currency conversion rate on payment date – approximately CHF 12,136 gross as of date hereof)). These amounts are subject to the Employee signing the Termination Agreement, signing and not revoking the agreed-upon release (in the form of Exhibit B) (the "Release"), and otherwise complying with his non-compete and other restrictive covenants as stated in Section 5 of the Termination Agreement.

- The Release will become effective 7 calendar days after he signs and delivers it to the Company (provided that such delivery must occur sometime between November 1, 2020 and December 15, 2020).

- The Severance Amount will be paid within 10 calendar days of the Release becoming effective. By way of illustration, if the Employee were to sign and deliver the Release to the Company on November 1, 2020, the Release would become effective on November 8, 2020, and the Company would make lump sum payment of the Severance Amount by November 18, 2020 (assuming compliance by the Employee with the other obligations described in Section 5 of the Termination Agreement).

- The Severance Amount payment will be less any applicable taxes and/or withholdings.

Exhibit B

Release

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 Delaware corporation, 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 under any federal, state or local statute or ordinance, public policy, or common law, including, without limitation, 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, 15 U.S.C. § 1681, et seq. and any similar state law, the Worker Adjustment and Retraining Notification Act, 29 U.S.C. § 2101, et seq., the Equal Pay Act and any similar state law, Texas Labor Code (specifically including the Texas Payday Law, the Texas Anti-Retaliation Act, Chapter 21 of the Texas Labor Code, and the Texas Whistleblower Act), 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, any claims under any other federal, state or local law, including those not specifically listed in this Release, any claims for compensatory or punitive damages, or any other claim for damages, monetary recovery or injury of any kind whatsoever, including without limitation, attorneys' fees, experts' fees, medical fees or expenses, costs, and disbursements, 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 Section 3 of the Change in Control and Severance Agreement, entered into as of September 7, 2016, 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, or 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.

Pursuant to the Defend Trade Secrets Act of 2016 ("DTSA"), 18 U.S.C. § 1833(b), you acknowledge that you will not be held criminally liable or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made under circumstances described therein, including: (1) in confidence to a government official or an attorney for the sole purpose of reporting or investigating a suspected violation of law; (2) in a complaint or other document filed in a legal proceeding, so long as such document is filed under seal; or (3) should you file a lawsuit against the Company for purported retaliation for reporting a suspected violation of law, then to your attorney, or in that court proceeding, so long as any document you file containing the trade secret is filed under seal and you do not disclose the trade secret except pursuant to court order. Unless expressly provided, the DTSA does not authorize, or limit liability for, an act that is otherwise prohibited by law, such as the unlawful access of material by unauthorized means.

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. Notwithstanding the foregoing, this Release does not preclude you from exercising any right you may have to: (1) provide any information in response to a valid subpoena, court order, other legal process or as otherwise required to be provided by law; or (2) communicate with, file a charge with, or participate in an investigation or proceeding conducted by the National Labor Relations Board, the Equal Employment Opportunity Commission, the Texas Workforce Commission, the Securities and Exchange Commission, or a similar federal, state or local agency (collectively, "Government Agency"), provided that this Release does waive your right to personally recover monies or reinstatement as a result of any complaint or charge filed against the Company with a Government Agency related to claims that are lawfully released in this Release.

You understand that the claims released in this Release do not include claims by you for: (1) unemployment insurance; (2) worker's compensation benefits; (3) state disability compensation; (4) previously vested benefits under any Company-sponsored benefits plan; and (5) any other rights that cannot by law be released by private agreement.

You acknowledge:

(a) That you were provided forty-five (45) full days during which to consider whether to sign this Release. If you have signed this Agreement prior to the expiration of the forty-five (45)-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 and are being advised herein to consult with an attorney about this Release prior to executing it.

(e) That you understand fully the terms and effect of 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 your 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 your 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 Chief Legal and Administrative Officer 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

_____

Davide Bianchi Date

Exhibit 21.1

The following is a list of our significant subsidiaries:

Company	Country of Incorporation	Ultimate Ownership by Parent
Orthofix Australia Pty. Ltd.	Australia	100%
Orthofix do Brasil Ltda.	Brazil	100%
Orthofix S.A.	France	100%
Orthofix GmbH	Germany	100%
Orthofix Spine GmbH	Germany	100%
Orthofix S.r.l.	Italy	100%
Orthofix Netherlands B.V.	Netherlands	100%
Implantes y Sistemas Medicos, Inc.	Puerto Rico	100%
Orthofix AG	Switzerland	100%
Orthofix Limited	UK	100%
Orthofix US LLC	US	100%
Spinal Kinetics, LLC	US	100%
Spinal Kinetics GmbH	Germany	100%
Spinal Kinetics France SARL	France	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.) Second Amended and Restated Stock Purchase Plan, as amended;

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

(4) Form S-8 No. 333-226503 pertaining to the Orthofix Medical Inc. (formerly Orthofix International N.V.) Amended and Restated 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;

(8) Form S-8 No. 333-233031 pertaining to the Orthofix Medical Inc. Employee Inducement Non-Qualified Stock Option Agreement for Jon Serbousek and Employee Inducement Restricted Stock Unit Agreement for Jon Serbousek;

(9) Form S-8 No. 333-239090 pertaining to the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan, as amended; and

(10) Form S-8 No. 333-248769 pertaining to the Orthofix Medical Inc. Employee Inducement Non-Qualified Stock Option Agreement for Paul Gonsalves and the Employee Inducement Restricted Stock Unit Agreement for Paul Gonsalves of Orthofix Medical Inc.

of our reports dated February 26, 2021, with respect to the consolidated financial statements of Orthofix Medical Inc. and the effectiveness of internal control over financial reporting of Orthofix Medical Inc. included in this Annual Report (Form 10-K) of Orthofix Medical Inc. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Dallas, Texas

February 26, 2021

Exhibit 31.1

CERTIFICATION

I, Jon Serbousek, 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 26, 2021

By: /s/ JON SERBOUSEK
Name: Jon Serbousek
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 26, 2021

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, 2020, (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, Jon Serbousek, 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 26, 2021

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

Dated: February 26, 2021

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