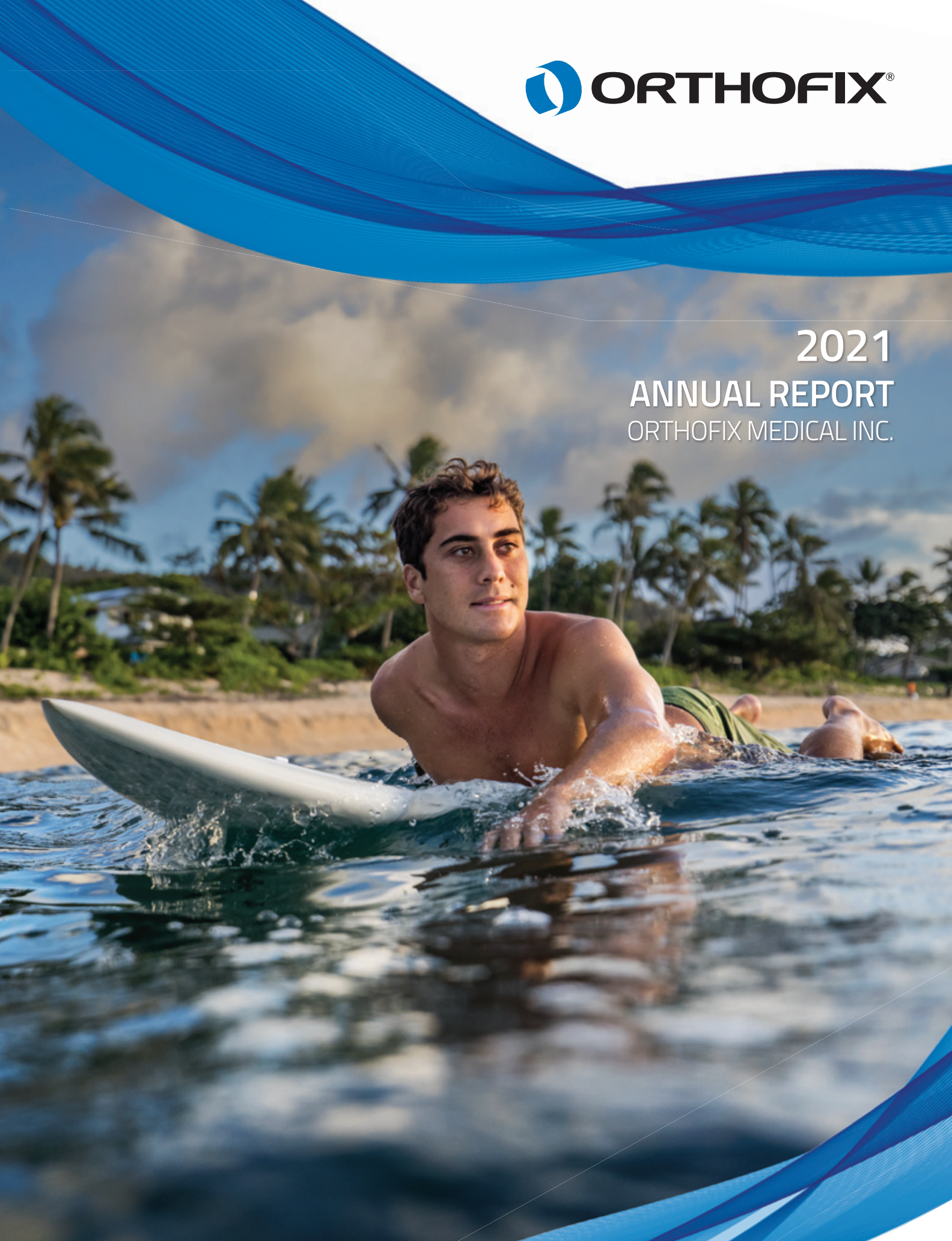
ORTHOFIX®

2021
ANNUAL REPORT
ORTHOFIX MEDICAL INC.



Improving Patient Mobility Through Innovation

"The M6 disc definitely changed my life. I'm surfing again. I'm just looking for the next big wave. And I honestly am just enjoying life feeling normal and pain free."

Koa Rothman
Professional Surfer and M6-C™ Disc Patient

From the President and CEO

DEAR SHAREHOLDERS,

I am extremely proud of how Orthofix upheld our commitments to surgeons and patients in 2021, while making important investments in our new product pipeline and business operations, all during the continuing challenges of the ongoing global pandemic. We accelerated our strategic plan by investing in our innovative portfolio and executing on our commercial channel and operational long-term strategies. Coming out of 2021, we continue to be "On The MOVE!"

LIVING OUR MISSION

Professional surfer Koa Rothman (featured on our cover) has been riding the waves in Hawaii since he was a small boy. However, a surfing accident at age 23 damaged his cervical disc and left him in such severe pain that he was facing the possibility of leaving behind both his passion and his sports career. Fortunately, Dr. Robert S. Bray, a renowned orthopedic surgeon, and our innovative M6-C™ artificial cervical disc technology helped Koa to heal and return to big wave surfing. Patients like Koa measure the success of their procedures by how quickly and fully they can return to normal. That is why ***Our Mission to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patient mobility*** is so important. We are proud to be part of the reason Koa is now back on the big waves.

In the fourth quarter of 2021, we hit a big milestone - one-million patients treated with our Bone Growth Therapy products. It is gratifying to know how many patients have had their bone healing supported by Orthofix products. It also demonstrates our committed leadership position in bone growth stimulation, one that we continue to build upon to provide important healing solutions for surgeons and their patients.

In fact, in 2021, we hit a number of other meaningful milestones including:

- 350,000 patients implanted with Trinity Elite™ and Trinity Evolution™ Allografts
- 150,000 children treated with the eight-Plate Guided Growth System™
- 125,000 patients treated with one of our spine solutions in 2021 alone
- 80,000 cases with TrueLok™ and TL-Hex™
- 60,000 M6-C artificial cervical discs implanted worldwide
- 400 patients implanted with the Fitbone™ Limb-Lengthening System since its launch in 2021

All of these milestones underscore the immeasurable value of our Mission and the importance of the work we are so privileged to do.

REFLECTING ON 2021

During 2021, we made solid progress developing and acquiring products and procedural solutions to address unmet needs in the marketplace and strengthen our product portfolio.
We were fueled by the investments we made in our product development and clinical trials, as well as our focus on operational improvements and building out our commercial channel to accelerate future revenue growth in both Spine and Orthopedics.

On The MOVE in Spine
In our Spine business, we made great strides in 2021. We had multiple key product introductions including the launch of the Construx™ Mini Ti and Forza™ Ti 3D-printed titanium interbody implants with Orthofix's unique Nanovate™ technology.

In our Bone Growth Therapies business, we entered into an exclusive license agreement to commercialize the innovative portfolio of Italy-based IGEA S.p.A's bone, cartilage and soft tissue stimulation products in the U.S. and Canada to expand our portfolio of Pulsed Electromagnetic Field (PEMF) products with additional treatment modalities. We also became the first and only company in the U.S. to offer a free recycling program to its bone growth therapy patients as part of our commitment to improve sustainability.

Within our Biologics business, we expanded our comprehensive offering of products and services with the introductions of the AlloQuent™ Structural Allograft Q-PACK, FiberFuse™ Strip preformed allograft, and the Opus™ Mg Set – a magnesium-based settable bone void filler for orthopedic procedures. We anticipate this more robust portfolio will continue to help drive incremental pull-through of our spine and orthopedics hardware products.

We also increased investments in R&D related to product development. In our clinical trial program, we began enrollment in our two-level M6-C artificial cervical disc IDE trial and continued to drive patient recruitment in our Bone Growth Therapies rotator cuff repair study. The latter study represents our initial entry into the soft tissue regeneration market with a first-of-its-kind therapy. If successful, we will have first to market advantage to tap into the more than 650,000 patients who receive rotator cuff repair surgery in the U.S. every year.

Keeping a pipeline of new technology and therapy applications is key to our strategy to drive future revenue growth.

On The MOVE in Orthopedics
Within Orthopedics, we focused on investments in limb reconstruction and pediatric deformity, which included enhancements and improvements to existing products as well as launching new products with incremental indications to increase our addressable markets. The strong performance of the Fitbone Limb-Lengthening System throughout the year is one example of the success we have had in bringing highly innovative technology to the market to address unmet needs.

While we are pleased with the progress made this year, we anticipate further growth acceleration of these products as they gain traction in the market. We are On The MOVE!

Commercial Channel Development
An important strategy in 2021 was our intense concentration on developing our commercial channels. We focused on our U.S. sales pathways for biologics, spinal implants and orthopedics – working to expand relationships with the goal of making these channels as dedicated and steady as those in our current Bone Growth Therapies business. In Q4, our U.S. strategic channel partners – which we define as distributors that carry multiple Orthofix product categories – generated over one-third of our U.S. revenue, growing 5 percent when compared to the prior year quarter and 15 percent when compared to the fourth quarter of 2019. We will continue to invest in the development and optimization of these channels to support our growth initiatives.

Operational Improvements
Throughout 2021 we have successfully managed through several supply chain challenges, including the microchip shortage, without missing a beat. We are very pleased with how our team navigated all of the macro challenges during a challenging year, and we believe that we are well-positioned to continue to execute across all aspects of our global supply chain. We look forward to continuing our enhancements and momentum into 2022 and beyond.

2022 – A YEAR OF IMPLEMENTATION

Looking ahead, we view 2022 as an inflection year for Orthofix. We have invested in our product portfolio and commercial channels and more importantly, we have worked hard to attract top talent and experienced leaders to help guide Orthofix as we lay the foundation for the future. We are now well-positioned to drive the next phase of Orthofix's growth, and to do this we will focus strategically on two areas: product innovation and differentiation and developing our commercial channel.

Accelerating Growth through Product Innovation and Differentiation
We are passionate about outcome-driven innovation that provides benefits to our surgeons and to patients. In 2022, we will focus on delivering near-term growth through the increased adoption of recently launched new products, accelerate our organic and inorganic investments in new technologies, indications and solutions that continue to build on our core portfolio and organizational strengths.

In a continuation of last year, the primary drivers of growth in 2022 will be our M6-C artificial cervical disc, our Fitbone Limb-Lengthening System, and our recently bolstered, technology-leading interbody portfolio. We also expect additional top-line growth to benefit from the 20+ new products we launched since 2020 and the products we will launch in 2022.

As we work to drive accelerated growth in future years, we plan to increase investments during 2022 in key areas of strength within our product portfolio. While we have a relatively broad product portfolio today, which is required to enable the type of distribution needed to compete in the market, we by no means intend to be everything to everyone. There are several areas of our business where we have clearly differentiated ourselves, and other areas where we believe we have products and procedural solutions that position us well for pursuing additional opportunities. We intend to put capital to work in those places to leverage our expertise and current market position to accelerate our growth. These key areas of strength and opportunity are:

- Biologics and Regenerative technologies
- Spine technologies
- Limb reconstruction and pediatric deformity
- Enabling technologies
- Alternative surgical site development and single-use sterile pack product technologies

Biologics and Regenerative Technologies
One of the fundamental aspects of our business that differentiates us from other spine and orthopedics companies is our industry-leading biologics and regenerative technology portfolios – a category that includes bone and soft tissue stimulation and biologics.

We anticipate premarket approval in the second quarter of 2022 from the U.S. Food and Drug Administration for the AccelStim™ bone healing therapy device. This product, part of the portfolio we exclusively licensed last year from IGEA, is a low-intensity pulsed ultrasound therapy for the healing of both indicated fresh fractures and nonunion fractures. The AccelStim device will expand our bone growth therapies portfolio and complement our current PEMF technologies which focus on nonunion fractures.

We believe 2022 will be a big year for our biologics and regenerative technology portfolios. We are making meaningful investments and recently extended our exclusive partnership agreement with MTF Biologics for the Trinity allograft lines through 2032. Included in this partnership, we look forward to launching two additional biologics products mid-year, one of which is a demineralized bone matrix (DBM) and the other we believe will be an important differentiated solution in the biologics market. We are striving to offer a full portfolio of biologic solutions and pursue future regenerative technologies so that we can meet the specific needs of the surgeon and the patient.

Spinal Implants
We currently offer an extensive portfolio of products and technologies, including a comprehensive cervical offering and a differentiated artificial cervical disc. Additionally, we have been re-evaluating our portfolio to bring in additional innovative and differentiated products and procedures.

As mentioned above, we initiated five new key spine R&D projects in 2021. These projects include developing innovative spine products and solutions for anterior column support, a minimally invasive spinal platform for lumbar, a posterior cervical system, a deformity correction system, and the FitSpine™ deformity technology platform. Through these organic innovation programs, we have engaged key surgeon thought leaders from around the world to contribute in the development of these clinical solutions to enable Orthofix to stand out in the market and create long-term top-line growth.

Limb Reconstruction and Pediatric Deformity
Another key area of differentiation for our business is our narrow and dedicated focus on limb reconstruction and pediatric deformity within the orthopedics market. Many of our orthopedic peers participate in highly competitive and crowded markets like hips and knees. We are squarely focused on the complex limb reconstruction and deformity correction segments of the orthopedics market where we have expertise and a longstanding track record of leadership and innovation.

We have a number of exciting new projects in this space. In Q1, we introduced the TrueLok EVO Ring Fixation system, the only circular fixator that features both radiolucent rings and struts to enable clear radiographic visualization. This innovative design allows physicians to better assess bone anatomy

both during surgery and for post-operative care. We will also continue to invest in our cutting-edge Fitbone technology with the development of new products in response to the input of leading U.S. pediatric orthopedic surgeons and an identified need in the market. These two projects, along with our JuniOrtho™ Plating System that is designed to address the specific demands of advanced deformity and trauma reconstructions of the lower extremities, will give Orthofix the broadest deformity care portfolio in pediatrics.

Enabling Technologies
Orthofix is focused on the future of digital preoperative planning of limb reconstructions and deformity corrections for clinicians across the world. OrthoNext™, our internally developed planning software, will have expanded applications and will soon be connected to most of the major products within our Orthopedics business. Our goal is to provide preoperative planning and surgical assurance to surgeons through our intuitive preplanning software on both pediatric and adult patients.

In January, we also announced a partnership and investment agreement to jointly develop and co-market the innovative nView™ system with cervical spine and pediatric limb deformity correction procedural solutions. The nView s1 imaging and surgical guidance system features the unique ability to instantly capture 3D images with very low-dose radiation, thereby making the 3D images available throughout surgery and enabling real-time visualization. This technology complements our preoperative and post-operative software platforms, and we are excited to collaborate with nView to broaden the use of this technology in cervical spine surgeries and pediatric procedures.

Alternative Surgical Site Development and Single-Use Sterile Pack Technologies
Finally, under product differentiation and innovation, we are looking to continue to develop procedures for alternative surgical sites of care (ASC) as more procedures are moved out of the hospital and into ASCs. An example of this is our partnership with Neo Medical to develop single-use sterile pack instrument technologies with patient-centric solutions.

Developing Our Commercial Channel
Throughout last year, we added leadership in our commercial organization, leveraging both internal and external talent to drive further penetration in the market and globalization of our business. We will continue to invest further in the expansion of our distribution channel with the addition of targeted direct represenatives in our U.S. limb reconstruction and deformity business to increase focus on pediatrics in geographies where direct employees make sense.

With the anticipated 2022 launch of the AccelStim system, we are making investments in our Bone Growth Therapies channel to drive the expansion of our market in long bone application for both indicated fresh fractures and nonunion care. We are also continuing to focus our efforts on driving synergies within our commercial channels to increase the number of strategic partners carrying multiple Orthofix product lines, which improves our product pull through and provides for a more predictable and reliable sales channel. We believe the combination of our differentiated technologies along with our talented, clinically trained commercial teams will deliver on our goal of putting our products into the hands of surgeons and physicians worldwide.

LOOKING AHEAD

In summary, we are very excited about the future of Orthofix. We have generated tremendous momentum over the last two years and are moving into an inflection period in our growth trajectory. We will continue to invest to accelerate growth in the near term and future years, and importantly, do so while remaining sustainably profitable.

We entered 2022 with full confidence in our team and in our long-term strategic plan to drive sustainable growth and deliver shareholder value. I want to close this letter by acknowledging and thanking Catherine Burzik, our new Chair of the Board of Directors who joined us last year, and our full Board of Directors for their support in 2021. I would like to give a big shout out to all our great team members – you make what we do possible each and every day – and I especially want to thank you for being so resilient and adaptive, while always staying patient focused. And to you, our shareholders, thank you for your support as we have executed on our plans. Like Koa, the patient on our cover, we look forward to staying On The MOVE in 2022 – and beyond.

Jon Serbousek
President and Chief Executive Officer
Orthofix Medical Inc.

"Our Mission is to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patient mobility."

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, 2021

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, 2021, as reported by the Nasdaq Global Select Market, was approximately $788.9 million.

As of February 22, 2022, 19,852,951 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, 2021
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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;
- the continuing and/or future effects of the COVID-19 pandemic on our sales and business operations; 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 company with a spine and orthopedics focus. Our mission is to deliver innovative, quality-driven solutions as we partner with health care professionals to improve patient mobility. Headquartered in Lewisville, Texas, our spine and orthopedic products are distributed in more than 60 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

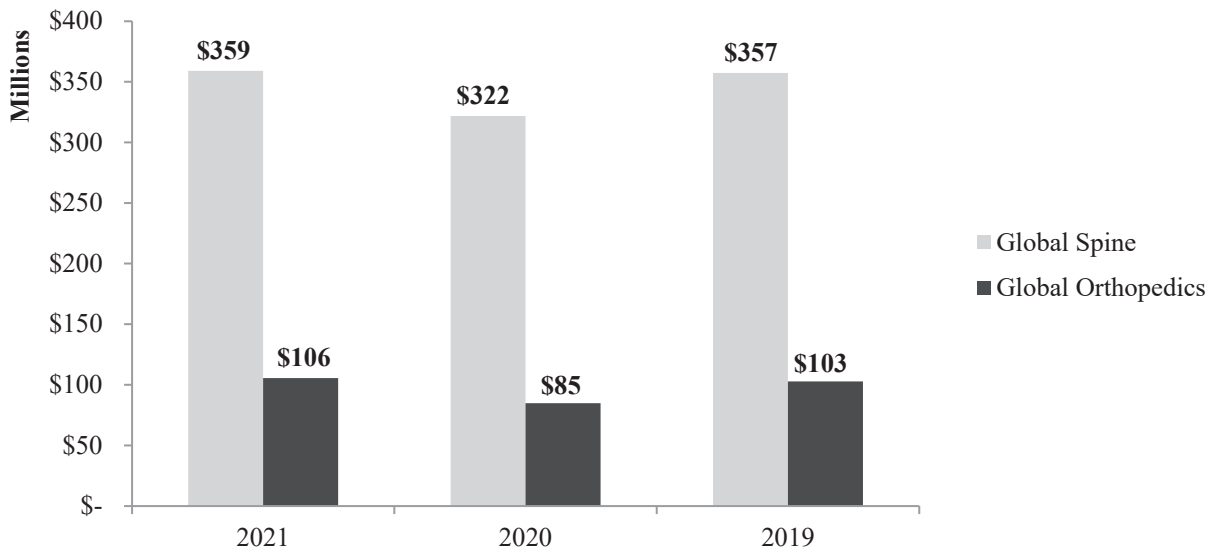
Our filings with the Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, Proxy Statements for Meetings of Shareholders, any registration statements, and amendments to those reports, are available free of charge 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 2021 and of its expected impact in 2022 and beyond.

Business Segments

We manage our business by our two reporting segments, Global Spine and Global Orthopedics, which account for 77% and 23%, respectively, of our total net sales in 2021. 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, 2021, 2020, and 2019.



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 that 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, publication of clinical evidence, patient education, and sales channel support
- A regular cadence of 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 products and tissue forms that allow physicians to successfully treat a variety of spinal and orthopedic conditions. We market tissue forms provided 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, fiberFUSE, and fiberFUSE Strip tissue forms for musculoskeletal defects to enhance bony fusion.

In addition, we market regenerative non-tissue biologic solutions derived from synthetic materials. Our Opus MG Set is our current synthetic, biologic offering.

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
AccelStim	LIPUS healing therapy used to enhance bone growth in fresh, long-bone 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
FORZA Ti Spacer System	Fully 3D printed titanium 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	An anterior cervical interbody with 3D printed porous titanium end plates that may promote bone ingrowth and a PEEK core to maintain imaging characteristics
CONSTRUX Mini Ti Spacer System	Fully 3D printed titanium anterior cervical interbody spacer system

Product	Primary Application
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
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
Opus Mg	Injectable, modable, and biocompatible bone void filler

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. It is indicated for 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 a single-level 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. The M6-C disc has become our leading spinal implant device and contributed significantly to our growth in 2021. In addition, we have initiated a U.S. 2-level investigational device exemption ("IDE") study for the M6-C artificial cervical disc.

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 the Trinity ELITE product 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 with Orthofix to expand our 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 remain very active with multiple internal developments to support future, new technology commercialization efforts. These new technologies will apply to both the cervical and thoracolumbar spinal anatomy. In addition, we remain active in evaluating external licensing and acquisition opportunities to add implant, biologics, and other emerging technologies to our spine portfolio. We expect that the contribution of new, internally developed technologies and undefined external acquisitions will be the primary driver of future growth.

Regarding our Bone Growth Therapy business, 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 have initiated a U.S. 2-Level IDE study for the M6-C artificial cervical disc.

Global Orthopedics

The Global Orthopedics 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 Orthopedics Strategy

Our strategy for the Global Orthopedics reporting segment is to continue to offer pioneering 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:

- Global market and product focus on:
    - Adult and pediatric limb reconstruction
    - Adult and Pediatric deformity correction
    - Complex periarticular fracture reconstruction
- Expand our position as the worldwide leader in complex deformity and limb reconstruction, including both internal and external solutions, through a patient-centric approach and digital treatment journey
- Promote the advantages of our JuniOrtho family of pediatric product portfolio and support tools
- Leverage our cross product digital platform, a uniquely developed pre and post planning digital platform called OrthoNext to allow our clinicians to pre-plan surgery for patients before surgery to save time, dose, and start surgeries with a greater degree of confidence, and follow up post operatively to evaluate their chosen surgical plan success
- Leverage the market appeal and acceptance of our software platforms: HEX-ray and OrthoNext
- Build on our historical position as a company highly focused on complex and challenging 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 Orthopedics Focus Products

Global Orthopedics offers a comprehensive line of limb reconstruction and complex deformity correction technologies. We provide 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 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 Orthopedics products by trade name and describes their primary applications:

Product	Primary Application
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
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
JuniOrtho Pediatric Portfolio	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
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
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

Product	Primary Application
External Fixators	External fixation, including our limb-lengthening systems, ProCallus, XCaliber, Pennig, Radiolucent Wrist Fixators, and Calcaneal Fixator
eight-Plate and eight-Plate Plus	The first and a market-leading system for gradual correction of the growth plate in pediatric patients
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
OrthoNext Digital Platform	A digital platform software developed specifically for use with the JuniOrtho Plating System, which enables the surgeon to accurately plan the osteotomy position to visualize the implant in relation to the anatomy
- HEX-ray Module	Part of the OrthoNext offering, 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 Module	Part of the OrthoNext offering, 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)

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 Lewisville, Texas and Verona, Italy. We work with leading hospital research institutions, as well as with MTF Biologics, surgeons, 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 2021, 2020, and 2019, we incurred research and development expenses of $49.6 million, $39.1 million, and $34.6 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 is dependent, in part, on us not infringing upon 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 Orthopedics 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.

In 2017, the European Union ("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 provided a transition period that went into effect on May 2021 for all currently-approved medical devices prior to May 2021 (under the European Medical Device Directive) to meet the additional requirements and for certain devices this transition period was extended until May 2024. After this transition period, all medical devices marketed in the E.U. will require certification according to these new requirements. Compliance with this new regulation has required us to incur significant costs over the transition period and we expect to continue to incur significant costs associated with this effort through May 2024. 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 and Trinity Evolution, our allogeneic bone matrices comprised of cancellous bone containing viable stem cells and a demineralized cortical bone component. In addition, we provide structural allografts for spinal fusion under the brand name AlloQuent, demineralized cortical fiber technologies under the brand name fiberFUSE, and an amniotic membrane, VersaShield, which is a natural tissue barrier. 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. 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.

In addition to our allograft solutions (HCT/Ps), we market and distribute additional biologics products that are synthetic in nature and are regulated by the FDA as medical devices, specifically Collage Synthetic Osteoconductive Matrix and the Opus MG line of synthetic grafts. We also provide ancillary technologies regulated by the FDA as medical devices that aid in the delivery of our bone grafting options clinically. These products are sourced from third party manufacturers, which we believe adequate inventory supply is maintained to avoid product flow disruptions.

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. These 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; 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. Such additional regulation, whether in the U.S. or internationally, 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 a willingness to 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 (i) 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); (ii) require that claims for payment submitted to federal healthcare programs be truthful; (iii) prohibit the transmission of protected healthcare information to persons not authorized to receive that information; and (iv) 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, such as Massachusetts and Vermont.

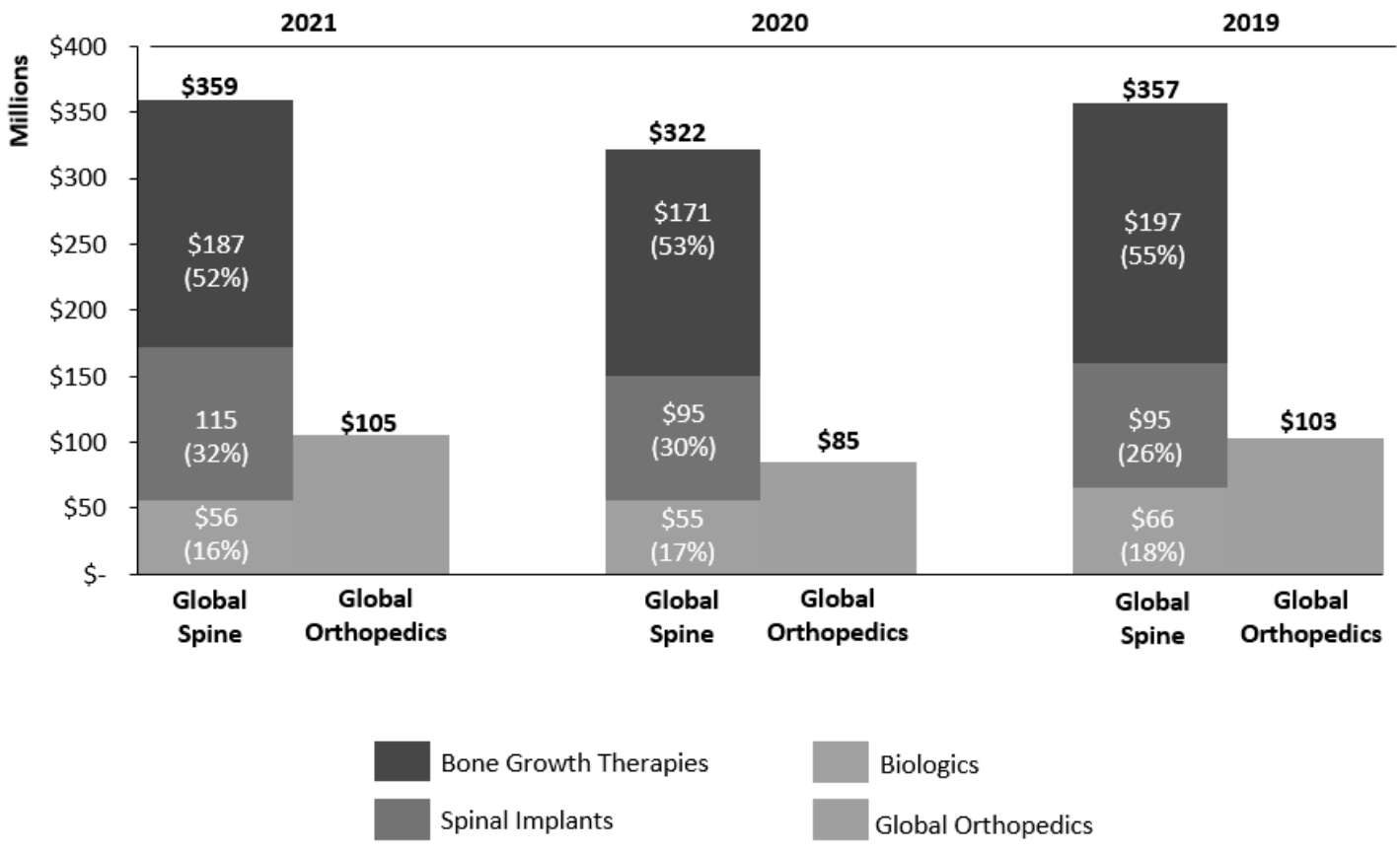
Sales, Marketing and Distribution

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 Orthopedics. 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, 2021, 2020, and 2019.



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 60 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 Orthopedics 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 also offered 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 Orthopedics devices, our principal competitors include DePuy Synthes; Zimmer Biomet, Inc.; Stryker Corp.; Smith & Nephew plc; and OrthoPediatrics Corp.

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, OrthoNEXT preoperative planning, and our medical education 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 bone growth stimulation, motion preservation, orthopedic, and spinal implant products, and subcontract the manufacturing 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. 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 and have a non-exclusive marketing agreement for our Versashield amniotic membrane.

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.

Human Capital Resources

Our key human capital objectives in managing our business include attracting, developing, and retaining top talent while integrating diversity, equity, and inclusion principles and practices into our core values.

Employees

At December 31, 2021, we had 1,087 employees worldwide. Of these, 786 were employed in the U.S. and 301 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 208 at December 31, 2021, 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.

Compensation and Benefits

Because attracting, developing, and retaining high-level talent is a key component of our human capital objectives, we seek to provide competitive compensation and benefits packages, and to prioritize the health and wellness our employees. In addition to the comprehensive and competitive health plans that we offer, our employees receive access to the following benefits: a 401(k) retirement plan with a Company match, an employee stock purchase plan, virtual physician consults, an employee health advocate, a Company-provided basic life insurance and disability benefits corporate wellness program, an onsite fitness center, paid parental leave, an employee assistance program, a flexible spending account, health savings accounts, and local employee discounts programs.

Talent Development

We believe that success comes from investing in our people and ensuring our workforce is aligned with our mission and values. To achieve this goal, we devote time and resources to assist our employees in being familiar with our business, industry, and product offerings. We put an emphasis on training our employees and sales representatives to understand our business, including the underlying medical conditions that our products treat. In addition, we strive to support our teams in the areas of development, mentoring, engagement, and health and wellness, enabling them to do their best work as they grow their careers. In 2021, we launched an internship program with a diversity, equity, and inclusion focus and a global mentorship program to employees across all departments.

Diversity and Inclusion

The Company's mission is to deliver innovative, quality-driven solutions as we partner with health care professionals to improve patient mobility. It is our corporate values and the diverse individuals who bring these values to life that make our high-achieving capabilities a reality. We are committed to fostering, cultivating, and preserving a culture that promotes diversity, equity, and inclusion. We seek to demonstrate our commitment to providing equal and equitable opportunities to all employees through programs such as our Moving 4ward initiative, a program created to embrace the value of diversity and reflect the communities where we live and work. Additionally, we proudly support the Orthofix Women's Network, a program that provides opportunities for women to learn from each other and grow within our company and our industry. Throughout the year, we promote a variety of diverse voices to our employees by recognizing events such as Black History Month, Martin Luther King Jr. Day, Women's History Month, Asian Pacific American Heritage Month, LGBTQ Pride Month, Juneteenth, and Hispanic Heritage Month. We seek to embrace and encourage our employees' differences and know that diversity, equity and inclusion help build a truly global, transformative business and will continue to be a source of our strength. Building on this belief, all employees participated in an unconscious bias training in 2021 to increase awareness and promote equity and inclusion amongst employees.

Health and Safety

Promoting and protecting the safety of our workforce is a top priority. Health and safety is a responsibility that we share throughout our organization and it is a responsibility that has evolved during the last two years to meet the needs of our workforce during the COVID-19 pandemic. Employees' safety risks vary depending on the roles they perform, and we seek to tailor our safety efforts accordingly.

Community

We support a variety of charitable organizations through donations, fundraising efforts, educational partnerships with colleges and universities, and local community development. Over the years, we have raised funds and awareness for veteran support groups, food and homebuilding organizations, and health-related institutions. In 2020, we initiated a global food drive in response to food shortages caused by the pandemic. Through employee donations and matching funds we provided meaningful support to 20 food

banks around the world. Orthofix also partners with Donate Life America, a U.S.-based nonprofit organization that promotes the importance of organ, eye, and tissue donation. Additionally, we have an ongoing engineering partnership with the University of Texas, Dallas, enabling students to work on real life healthcare solutions as we invest in the next generation of engineers and business leaders.

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. 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. In addition, 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. Further, 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 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 will 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 COVID-19 pandemic has materially adversely affected, and could continue to materially adversely affect, our operations, supply chain, manufacturing, product demand, product distribution, customers and other business activities.

The novel coronavirus discovered in late 2019, and the disease it causes, known as COVID-19, has led to significant disruptions in the healthcare market and the United States and international economies that may continue for a prolonged duration. The rapid spread of the coronavirus in 2020 and variants of the virus in 2021, the persistence of the resulting pandemic, the measures governments and private parties have implemented in order to stem the spread of this pandemic, and the general concern about the virus, have had, and are continuing to have, a negative effect on the demand for many of our products compared to historical levels, and consequently upon our business. In particular, many of our products are particularly sensitive to reductions in elective medical procedures. Elective medical procedures were suspended or reduced at various times in 2020 and 2021 in many of the markets where our products are marketed and sold, which negatively affected our business, cash flows, financial condition and results of operations.

The reduction in elective 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. While cases again increased in the Fall of 2021 during the rise of the Delta variant, we did not experience a significant reduction in sales volume during this period, as we believe that the widespread availability of vaccines provided additional comfort to many patients and providers. More recently, the highly transmissible Omicron variant, coupled with a pronounced nursing shortage, placed renewed capacity stress on hospitals between December 2021 and February 2022, which has caused renewed negative pressure on elective surgeries, though these effects have somewhat dissipated in the past several weeks as case counts and hospitalizations have declined.

The future trajectory of the COVID-19 pandemic remains uncertain, both in the U.S. and in other markets, particularly due to the uncertainty as to the nature of future variants, and whether vaccines will protect against severe illness with respect to such future variants.

Given these various uncertainties, it is unclear the extent to which lingering slowdowns in elective procedures will continue to affect our business in 2022 and beyond. We expect that the effects of COVID-19 on our business will depend on various factors including (i) the magnitude, length and virulence of additional case waves and future variants, (ii) the continued distribution, efficacy, refinement, and public acceptance of COVID-19 vaccines, (iii) the comfort level of patients in visiting clinics and hospitals, and (iv) the extent to which further elective surgery slowdowns occur during periods when hospital capacity is stretched because of the need to treat COVID-19 patients.

In addition to its effect on elective surgeries, the pandemic could also negatively affect our ability, and the ability of our third-party suppliers, manufacturers, distributors and customers, to retain key employees and ensure the continued service and availability of skilled personnel necessary to run our, and their, complex operations. To the extent our management or other personnel, or the management or other personnel of our third-party suppliers, manufacturers, distributors and customers, are negatively affected by the pandemic and are not available to perform their job duties, we could experience delays in, or the suspension of, our manufacturing operations, sales activities, research and product development activities, regulatory work streams, clinical development programs and other important commercial and corporate functions. Moreover, our relationships with our employees may be disrupted due to measures implemented in response to the COVID-19 pandemic. We have observed an overall tightening and increasingly competitive labor market due to labor shortages caused in part by the COVID-19 pandemic and responsive measures, which has included increased wages offered by other employers and voluntary attrition of employees in the industry, including at third-party suppliers, manufacturers, distributors and customers.

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

The COVID-19 pandemic and related supply chain and raw material disruptions could have a continuing material impact on our global operations and the operations of our supply chain, which could adversely impact our business results and financial condition.

We rely on a limited number of suppliers to manufacture or supply certain products or components. In the event of interruption within our supply chain, or global shortages of key supplies or components, we may not be able to increase capacity from other sources or develop alternative or secondary sources without incurring significant additional costs and/or substantial delays. For example, the COVID-19 pandemic has led to a global shortage of semiconductor chips, which are used in certain of our products. This shortage appears primarily to have been caused by manufacturers experiencing shutdowns or slowdowns during the pandemic,

and it may take several fiscal quarters or longer for normalized capacity to return. In addition, limitations in key raw material supplies could also cause semiconductor chip and other component shortages to continue. To the extent it continues, or more shortages are experienced, particularly on a longer term basis, this could adversely affect our ability to procure such components and manufacture certain of our products or it could require us to redesign any affected products in order to incorporate more readily available components, which may require additional regulatory testing and approvals. Thus, our business could be adversely affected in a significant manner if one or more of our suppliers are impacted by any interruption at a particular location or in relation to a particular material or component.

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 spine and 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 cyber-attack, data breach or ransomware attack, 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 make them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy, ransomware attack, 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, disrupt the performance of our products, or access our proprietary information. We could also be subject to a ransomware attack, which is a type of malicious software that infects a computer and restricts users' access to it until a ransom is paid to unlock it. 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 the 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 effects 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 used by attackers has increased in recent years, and a successful attack against us could lead to the loss of significant funds.

Although we possess insurance against the risk of cyber-attacks, there can be no assurance that the liability related to any such events will not exceed or insurance coverage limits or that such insurance will continue to be available on reasonable, commercially acceptable terms, or at all. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely impacted.

The physical effects of climate change or legal, regulatory or market measures intended to address climate change could adversely affect our operations and operating results.

Shifts in weather patterns caused by climate change are expected over time to increase the frequency, severity or duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures or flooding, each of which could cause more significant business and supply chain interruptions, damage to our products and facilities as well as the infrastructure of hospitals, medical care facilities and other customers, reduced workforce availability, and increased costs of raw materials and components. While we do not expect climate change to materially affect the demand for our products, or the amount of persons with medical conditions we treat, climate change could also contribute to collateral effects such as increased transmission of viruses or airborne illnesses, which could contribute to unpredictable events, such as putting stress on hospital and other medical facilities and/or supply chains, and thus disrupting the elective surgery market in which we do business. In addition, increased public concern over climate change could result in new legal or regulatory requirements designed to mitigate the effects of climate change, which could include the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. Such developments could result in increased compliance costs and adverse impacts on raw material sourcing, manufacturing operations and the distribution of our products, which could adversely affect our operations and operating results.

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 representing diverse backgrounds, experiences, and skill sets. 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. Maintaining our brand and reputation, as well as a diverse and inclusive work environment that enables all our employees to thrive,

are important to our ability to recruit and retain employees. If we are less successful in our recruiting efforts, or if we cannot retain highly skilled workers and key leaders, our ability to develop and deliver successful products and services may be adversely affected.

To attract, retain, and motivate qualified executives and key employees, we offer flexible working arrangements, such as remote and hybrid models. Offering a practical solution to the workforce allows our employees to balance their many commitments, providing our business a competitive edge in attracting and retaining talented employees. In addition, 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 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 over $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. We then made an additional investment of $0.7 million in 2021 in the form of a convertible loan. We made the election to convert the additional investment into shares of Neo Medical's preferred stock in January 2022.

Neo Medical is using the proceeds of our preferred stock purchase and loans 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.

Our goodwill, intangible assets and fixed assets are subject to potential impairment; we have recorded significant goodwill impairment charges and may be required to record additional charges to future earnings if our remaining goodwill or intangible assets become impaired.

A significant portion of our assets consists of goodwill, intangible assets and fixed assets. The carrying value of these assets may be reduced if we determine that those assets are impaired, including intangible assets from recent acquisitions.

Most of our intangible and fixed assets have finite useful lives and are amortized or depreciated over their useful lives on a straight-line basis. The underlying assumptions regarding the estimated useful lives of these intangible assets are analyzed on at least an

annual basis and more often if an event or circumstance occurs making it likely that the carrying value of the assets may not be recoverable. Any such changes are adjusted through accelerated amortization, if necessary. Whenever events or changes in circumstances indicate that the carrying value of the assets may not be recoverable we test intangible assets for impairment based on estimates of future cash flows. Factors that may be considered a change in circumstances indicating that the carrying value of our intangible assets and/or goodwill may not be recoverable include a decline in stock price and market capitalization, slower growth rates in our industry, the introduction of newer technology or competing products that may cannibalize future sales, or other materially adverse events that have implications on the profitability of our business. When testing for impairment of finite-lived intangible assets held for use, we group assets at the lowest level for which cash flows are separately identifiable. If an intangible asset is considered to be impaired, the amount of the impairment will equal the excess of the carrying value over the fair value of the asset.

Goodwill is required to be tested for impairment at least annually. We review our two reporting units for potential goodwill impairment in the fourth fiscal quarter of each year as part of our annual goodwill impairment testing, and more often if an event or circumstance occurs making it likely that impairment exists. During the fourth quarter of 2021, we recorded a full impairment of the Global Orthopedics goodwill. This resulted in an impairment charge of $11.8 million, which is reflected within acquisition-related amortization and remeasurement on the Consolidated Statement of Operations. If actual results differ from the assumptions and estimates used in the goodwill and intangible asset calculations, we could incur future impairment or amortization charges, which could negatively impact our financial condition and results of operations.

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 2021 had a favorable impact of $3.0 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.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the option to deduct research and development expenditures immediately in the year incurred and requires taxpayers to amortize such expenditures over five years. If these provisions are not deferred, modified, or repealed by Congress with retroactive effect to January 1, 2022, we will be subject to additional income tax expense and the resulting cash liability. The impact cannot be reasonably estimated as many factors impact income tax expense and liabilities.

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, 2021, or as of the date hereof, but we 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, and 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, 2021 (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, 2021 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 orthopedics 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, 2022, we had 265 holders of record of our common stock. The closing price of our common stock on February 22, 2022 was $31.12. 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
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
2021		
First Quarter	$ 48.50	$ 39.34
Second Quarter	45.96	39.23
Third Quarter	43.30	36.35
Fourth Quarter	39.98	28.65

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.

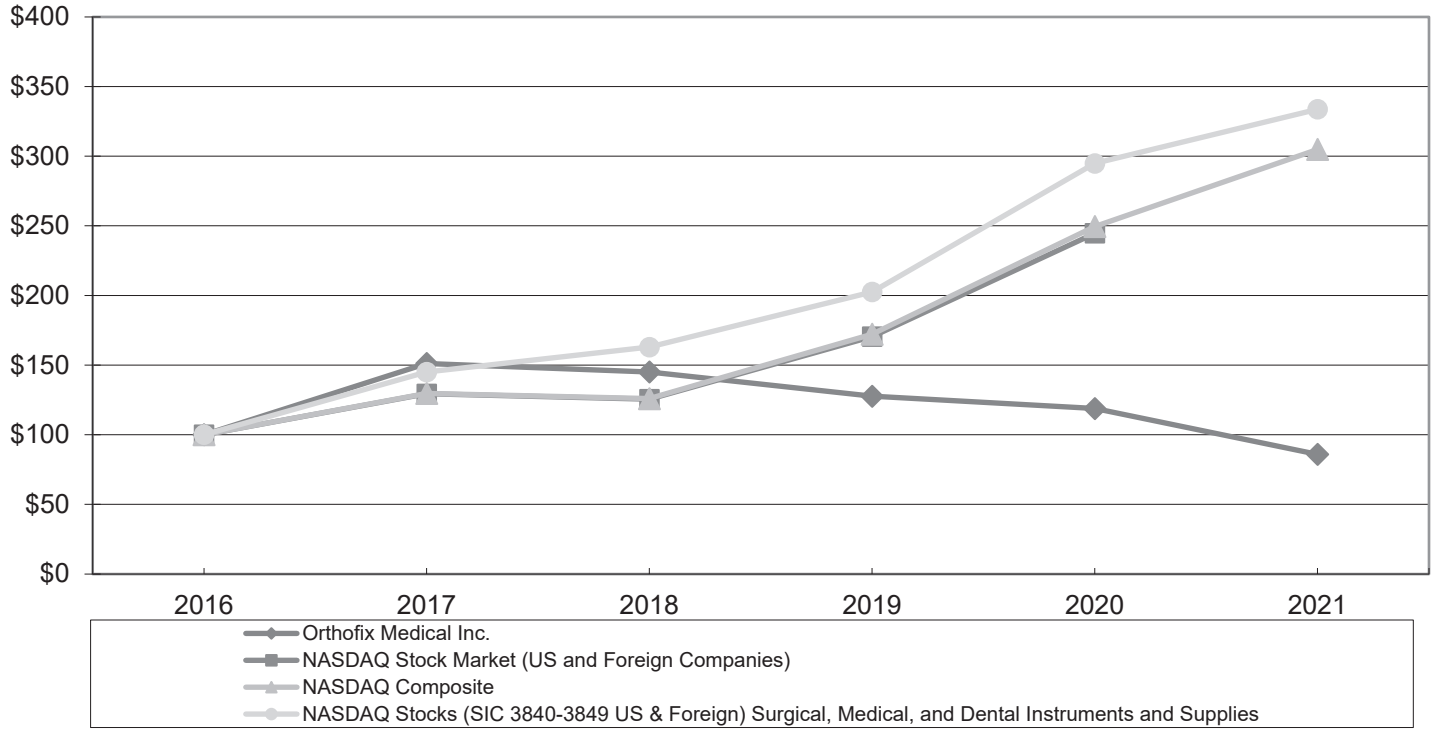
Recent Sales of Unregistered Securities

We did not sell any unregistered securities during the fourth quarter of 2021.

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 following graph compares our annual percentage change in cumulative total return on common shares over the past five years with the cumulative total return of companies comprising the NASDAQ Composite Index and the NASDAQ Stocks (SIC 3840-3849 US & Foreign) Surgical, Medical, and Dental Instruments and Supplies Index. This presentation assumes that $100 was invested in shares of the relevant issuers on December 31, 2016, and that dividends received were immediately invested in additional shares. The graph plots the value of the initial $100 investment at one-year intervals for the fiscal years shown. The NASDAQ Composite Index replaces the CRSP NASDAQ Stock Market (US and Foreign Companies) Index in this analysis and going forward, as the CRSP Index data is no longer accessible. The CRSP index has been included with data through 2020.



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 2021 and 2020 financial results, including comparisons of our year-over-year performance between these years. Discussion and analysis of our 2019 fiscal year specifically, as well as the year-over-year comparison of our 2020 financial performance to 2019, 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, 2020, filed with the SEC on February 26, 2021, which is available on our website at www.orthofix.com and the SEC's website at www.sec.gov.

Executive Summary

We are a global medical device company with a spine and orthopedics focus. Our mission is to deliver innovative, quality-driven solutions as we partner with health care professionals to improve patient mobility. Headquartered in Lewisville, Texas, our spine and orthopedic products are distributed in over 60 countries via our sales representatives and distributors.

Notable financial results in 2021 include the following:

- Net sales were $464.5 million, an increase of 14.2% on a reported basis and 13.5% on a constant currency basis
- Double-digit net sales growth over the prior year for both Global Spine (11.6%) and Global Orthopedics (24.4%)
- Net sales growth in the U.S. and internationally for both the Global Spine and Global Orthopedics segments
- Generation of net cash flows from operations of $18.5 million

COVID-19 Update and Outlook

The global COVID-19 pandemic has significantly affected our hospital and physician customers, patients, communities, employees, and business operations over the last two years. At various points in time, the pandemic has led to the cancellation or deferral of elective surgeries and procedures with 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. At this time, the future trajectory of the COVID-19 pandemic remains uncertain, both in the U.S. and in other markets, particularly due to the uncertainty as to the nature of future variants, and whether vaccines will protect against severe illness with respect to such future variants.

Given these various uncertainties, it is unclear the extent to which lingering slowdowns in elective procedures will affect our business during 2022 and beyond. We expect that the effects of COVID-19 on our business will depend on various factors including (i) the magnitude, length, and virulence of additional case waves and future variants, (ii) the continued distribution, efficacy, refinement, and public acceptance of COVID-19 vaccines, (iii) the comfort level of patients in visiting clinics and hospitals, and (iv) the extent to which further elective surgery slowdowns occur during periods when hospital capacity is stretched because of the need to treat COVID-19 patients.

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,		
	2021 (%)	2020 (%)	2019 (%)
Net sales	100.0	100.0	100.0
Cost of sales	24.7	25.1	21.9
Gross profit	75.3	74.9	78.1
Sales and marketing	47.6	50.3	48.6
General and administrative	14.9	16.7	18.6
Research and development	10.7	9.6	7.5
Acquisition-related amortization and remeasurement	3.9	(0.2)	7.5
Operating income (loss)	(1.8)	(1.5)	(4.1)
Net income (loss)	(8.3)	0.6	(6.2)

Net Sales by Reporting Segment

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

				Percentage Change			
				2021/2020	2021/2020 Constant	2020/2019	2020/2019 Constant
(U.S. Dollars, in thousands)	2021	2020	2019	Reported	Currency	Reported	Currency
Bone Growth Therapies	$ 187,448	$ 171,396	$ 197,181	9.4%	9.4%	-13.1%	-13.1%
Spinal Implants	115,094	94,857	94,544	21.3%	20.8%	0.3%	0.2%
Biologics	56,421	55,482	65,496	1.7%	1.7%	-15.3%	-15.3%
Global Spine	358,963	321,735	357,221	11.6%	11.4%	-9.9%	-10.0%
Global Orthopedics	105,516	84,827	102,734	24.4%	21.3%	-17.4%	-18.2%
Net sales	$ 464,479	$ 406,562	$ 459,955	14.2%	13.5%	-11.6%	-11.8%

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.

2021 Compared to 2020

Net sales increased $37.2 million or 11.6%

- Bone Growth Therapies net sales increased $16.1 million or 9.4%, primarily driven by an increase in gross orders across all sales channels as restrictions associated with the COVID-19 pandemic have lessened, particularly when compared to the second quarter of 2020
- Spinal Implants net sales increased $20.2 million or 21.3%, primarily driven by the continued recovery from the effects of the COVID-19 pandemic within our Spine Fixation product line, both in the U.S. and internationally, and from the continued growth and adoption of our Motion Preservation product line in the U.S.
- Biologics net sales increased $0.9 million or 1.7%, primarily driven by the continued recovery from the effects of the COVID-19 pandemic and an increase in revenues from new distributors added over the last 12 months

Global Orthopedics

Global Orthopedics offers products and solutions that allow physicians to successfully treat a variety of orthopedic conditions specifically related to limb reconstruction and deformity correction unrelated to the spine. Global Orthopedics distributes its products world-wide through a network of distributors and sales representatives to sell orthopedic products to hospitals and healthcare providers.

2021 Compared to 2020

Net sales increased $20.7 million, or 24.4%

- Increase of $18.1 million, primarily driven by the continued recovery from the effects of the COVID-19 pandemic, coupled with the continued growth of our FITBONE product line, in both the U.S. and international markets

- Increase of $2.6 million due to changes in foreign currency exchange rates, which had a favorable impact on net sales

Gross Profit

(U.S. Dollars, in thousands)	2021	2020	2019	Percentage Change 2021/2020	Percentage Change 2020/2019
Net sales	$ 464,479	$ 406,562	$ 459,955	14.2%	-11.6%
Cost of sales	114,914	101,889	100,607	12.8%	1.3%
Gross profit	$ 349,565	$ 304,673	$ 359,348	14.7%	-15.2%
Gross margin	75.3%	74.9%	78.1%	0.4%	-3.2%

2021 Compared to 2020

Gross profit increased $44.9 million, or 14.7%

- Increase in gross profit is primarily due to the continued recovery from the effects of the COVID-19 pandemic as net sales have recovered to levels consistent with periods prior to the COVID-19 pandemic and due to increased absorption of fixed costs when compared to the prior year period
- Increase in gross margin primarily as a result of significant non-cash inventory related charges recorded in the prior year due to lower procedure volumes, largely as a result of COVID-19, and partially offset by unfavorable shifts in product mix, and from a short-term increase in electronic procurement costs caused by a global shortage of semiconductor chips, which are used in certain of our products

Sales and Marketing Expense

(U.S. Dollars, in thousands)	2021	2020	2019	Percentage Change 2021/2020	Percentage Change 2020/2019
Sales and marketing	$ 221,318	$ 204,434	$ 223,676	8.3%	-8.6%
As a percentage of net sales	47.6%	50.3%	48.6%	-2.7%	1.7%

2021 Compared to 2020

Sales and marketing expense increased $16.9 million

- Increase of $14.0 million in variable compensation expenses as a result of the recovery in net sales
- Increase of $4.6 million as a result of additional headcount, increased benefit costs, and increased travel and professional expenses, as the majority of marketing events and trade shows were virtual in 2020
- Partially offset by a decrease in expense of $2.7 million related to the Italian Medical Device Payback liability, as a result of temporary relief provided by the Italian National Healthcare System in response to the COVID-19 pandemic through a law enacted in December 2021

General and Administrative Expense

(U.S. Dollars, in thousands)	2021	2020	2019	Percentage Change 2021/2020	Percentage Change 2020/2019
General and administrative	$ 69,353	$ 67,948	$ 85,607	2.1%	-20.6%
As a percentage of net sales	14.9%	16.7%	18.6%	-1.8%	-1.9%

2021 Compared to 2020

General and administrative expense increased $1.4 million

- Increase of $2.9 million a result of savings initiatives executed in 2020 in response to the COVID-19 pandemic, including temporary salary reductions in the U.S., suspension of the 401(k) match, and restrictions on travel and related expenses, which are no longer in place for 2021
- Offset by a decrease of $1.6 million related to the 2019 CEO transition

Research and Development Expense

(U.S. Dollars, in thousands)	2021	2020	2019	Percentage Change 2021/2020	Percentage Change 2020/2019
Research and development	$ 49,621	$ 39,056	$ 34,637	27.1%	12.8%
As a percentage of net sales	10.7%	9.6%	7.5%	1.1%	2.1%

2021 Compared to 2020

Research and development expense increased $10.6 million

- Increase of $4.2 million related directly to our European Union medical device regulation implementation efforts
- Increase of $3.3 million related to increased employee costs as a result of planned headcount increases in 2021
- Increase of $2.5 million to support our development of new, innovative, and differentiated products or indications and the integration of certain acquired products and assets into our business

Acquisition-related Amortization and Remeasurement

(U.S. Dollars, in thousands)	2021	2020	2019	Percentage Change 2021/2020	Percentage Change 2020/2019
Acquisition-related amortization and remeasurement	$ 17,588	$ (499)	$ 34,212	-3624.6%	-101.5%
As a percentage of net sales	3.9%	-0.2%	7.5%	4.1%	-7.7%

2021 Compared to 2020

Acquisition-related amortization and remeasurement increased $18.1 million

- Increase of $11.8 million attributable to the impairment of our Global Orthopedics goodwill in 2021 primarily due to current and planned investments in our growth
- Increase of $4.1 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
- Increase of $1.5 million associated with acquired in-process research and development assets in 2021, which were recognized immediately upon acquisition
- Increase of $1.1 million from amortization of intangible assets acquired through business combinations or asset acquisitions
- Partially offset by a decrease of $0.4 million associated with the reassessment of contingent consideration associated with the acquisition of a former distributor

Non-operating Expense

(U.S. Dollars, in thousands)	2021	2020	2019	Percentage Change 2021/2020	Percentage Change 2020/2019
Interest expense, net	$ (1,837)	$ (2,483)	$ (122)	-26.0%	1935.2%
Other income (expense)	(3,343)	8,381	(8,143)	-139.9%	-202.9%

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.

2021 Compared to 2020

Interest expense, net, decreased $0.6 million

- Decrease of $0.8 million associated with interest expense incurred in the prior year on our outstanding indebtedness under the secured revolving credit facility

Other income (expense), net, decreased $11.7 million

- Decrease of $7.9 million associated with changes in foreign currency exchange rates, as we recorded a non-cash remeasurement loss of $4.0 million in 2021 compared to a gain of $3.9 million in 2020
- Decrease of $4.7 million attributable to funds received in the prior year 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"
- Partially offset by gains recognized in total of $0.6 million associated with our equity investments in Neo Medical and Bone Biologics

Income Tax Expense

(U.S. Dollars, in thousands)	2021	2020	2019	Percentage Change 2021/2020	Percentage Change 2020/2019
Income tax expense (benefit)	$ 24,884	$ (2,885)	$ 1,413	-962.5%	-304.2%
Effective tax rate	-184.4%	784.0%	-5.2%	-968.4%	789.2%

2021 Compared to 2020

Net income tax expense increased $27.7 million

- Increase of $16.0 million primarily due to statute expirations on uncertain tax positions that did not recur in 2021
- Increase of $13.3 million for net increase in valuation allowances recognized on domestic and foreign deferred tax assets primarily due to cumulative losses
- Increase of $0.8 million for lower tax benefit on the change in fair value of contingent consideration
- Partially offset by tax benefit driven by lower earnings

2020 Compared to 2019

Net income tax expense decreased by $4.3 million

- Decrease of $14.6 million primarily due to statute expirations on uncertain tax positions
- Decrease of $7.1 million due to the net decrease in the fair value of contingent consideration
- Increase of $14.7 million due to net increase in valuation allowance recognized on foreign deferred tax assets primarily due to cumulative losses
- Further offset by tax expense driven by higher earnings

A reconciliation of the effective tax rate for each year is reported in Note 20 to the Notes to the Consolidated Financial Statements contained in Item 8 of this Annual Report.

Segment Review

Our business is managed through two reporting segments: Global Spine and Global Orthopedics. 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 loss before income taxes:

(U.S. Dollars, in thousands)	Year Ended December 31, 2021	2020	2019
Global Spine	$ 58,014	$ 63,036	$ 39,528
Global Orthopedics	3,374	(4,993)	7,496
Corporate	(31,691)	(25,382)	(49,252)
Total EBITDA	29,697	32,661	(2,228)
Depreciation and amortization	(29,599)	(30,546)	(24,699)
Goodwill impairment	(11,756)	—	—
Interest expense, net	(1,837)	(2,483)	(122)
Loss before income taxes	$ (13,495)	$ (368)	$ (27,049)

Liquidity and Capital Resources

Cash, cash equivalents, and restricted cash at December 31, 2021, was $87.8 million compared to $96.8 million at December 31, 2020.

(U.S. Dollars, in thousands)	Year Ended December, 31, 2021	2020	Change
Net cash from operating activities	$ 18,475	$ 74,272	$ (55,797)
Net cash from investing activities	(23,013)	(52,334)	29,321
Net cash from financing activities	(3,621)	3,245	(6,866)
Effect of exchange rate changes on cash and restricted cash	(815)	1,235	(2,050)
Net change in cash, cash equivalents, and restricted cash	$ (8,974)	$ 26,418	$ (35,392)

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.

(U.S. Dollars, in thousands)	Year Ended December, 31, 2021	2020	Change
Net cash from operating activities	$ 18,475	$ 74,272	$ (55,797)
Capital expenditures	(19,592)	(17,094)	(2,498)
Free cash flow	$ (1,117)	$ 57,178	$ (58,295)

Operating Activities

Cash flows from operating activities decreased $55.8 million

- Decrease in net income (loss) of $40.9 million
- Net increase of $29.5 million in non-cash gains and losses, largely related to our impairment of Global Orthopedics goodwill, deferred income taxes, and changes in fair value of contingent consideration
- Net decrease of $44.4 million relating to changes in working capital accounts, primarily attributable to changes in our contract liability associated with the CMS Accelerated and Advance Payment Program and from changes in accounts receivable

Two of our primary working capital accounts are accounts receivable and inventory. Day's sales in receivables remained consistent and was 58 days at December 31, 2021, compared to 57 days at December 31, 2020 (calculated using fourth quarter net sales and ending accounts receivable). Inventory turns were 1.4 times as of December 31, 2021, compared to 1.2 times at December 31, 2020, primarily resulting from an increase in sales volumes, and thus an increase in cost of sales, as 2020 results were heavily impacted by the COVID-19 pandemic.

Investing Activities

Cash flows from investing activities increased $29.3 million

- Increase of $18.0 million associated with cash paid in March 2020 to acquire assets associated with the FITBONE intramedullary lengthening system for limb lengthening of the femur and tibia bones
- Increase of $7.8 million associated with cash paid for purchases of investment securities, primarily attributable to our investments in Neo Medical SA in the form of preferred stock and convertible loans
- Increase of $6.0 million associated with cash paid for asset acquisitions and other investments
- Partially offset by a decrease in capital expenditures of $2.5 million

Financing Activities

Cash flows from financing activities decreased $6.9 million

- Decrease of $8.4 million associated with cash paid for the achievement of a revenue-based milestone associated with the Spinal Kinetics acquisition; the milestone payment totaled $15.0 million with a portion of the payment reflected in both operating and financing activities
- Partially offset by an increase in net proceeds of $1.2 million from the issuance of common shares

Credit Facilities

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

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

As of December 31, 2021, 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 Italian line of credit of €5.5 million ($6.3 million) as of December 31, 2021. 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 March 2020, the CARES Act entered 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. Starting in April 2021, Medicare began to recoup 25% of Medicare payments otherwise owed to the provider or supplier for submitted claims. Beginning March 2022, recoupment increases to 50% for another six 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. As of December 31, 2021, the balance of the liability associated with the Accelerated and Advance Payment Program of the CARES Act totaled $4.8 million, which is classified within other current liabilities based upon our estimates of when such funds will be recouped.

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 decreases or delays of 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 make contingent milestone payments of up to $60.0 million. 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. A second milestone payment, totaling $15.0 million, was achieved and paid in 2021 upon meeting certain net sales targets.

The remaining milestone payment is a revenue-based milestone payment of $30.0 million in connection with future sales of the acquired artificial discs. The fair value of the contingent consideration arrangement as of December 31, 2021, was $17.2 million; however, the actual amount ultimately paid could be higher or lower than the fair value of the contingent consideration (ultimate payment will either be $30.0 million or the liability will be reversed if the milestone is not met within the required timeline). As of December 31, 2021, we classified the remaining contingent consideration liability within other current liabilities, as we expect to pay the revenue-based milestone in the next twelve months. For additional discussion of this matter, see Note 12 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. For additional discussion of this transaction, see Note 4 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

IGEA S.p.A Exclusive License and Distribution Agreement

On April 7, 2021, we entered into an Exclusive License and Distribution Agreement (the "License Agreement") with IGEA S.p.A ("IGEA"), an Italian manufacturer and distributor of bone and cartilage stimulation systems. Per the terms of the License Agreement, we will have the exclusive right to sell IGEA products in the U.S. and Canada. As consideration for the License Agreement, we agreed to pay up to $4.0 million, of which $0.5 million was paid in 2021, with certain payments contingent upon achieving an FDA milestone. The License Agreement also includes certain minimum purchase requirements.

Neo Medical Investment and Convertible Loan

In October 2020, we entered into a Convertible Loan Agreement (the "Convertible Loan") with Neo Medical SA, a privately held Swiss-based Medtech company ("Neo Medical"), whereby we loaned CHF 4.6 million to Neo Medical ($5.0 million as of the issuance date). The loan bears interest at 8.0%, with interest due semi-annually. The Convertible Loan matures in October 2024; however, if a change in control of Neo Medical occurs prior to maturity, the Convertible Loan shall become immediately due upon such event.

FITBONE Asset Acquisition and Contract Manufacturing and Supply Agreement ("CMSA")

In February 2020, we entered into an 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. At the time of the acquisition, we also entered into a CMSA with Wittenstein to manufacture the FITBONE product line. The CMSA has an initial term of up to two years. As consideration for the CMSA, we will pay $2.0 million to Wittenstein at the conclusion of the agreement if certain conditions are met. This payment is expected to be made in the first half of 2022.

Unremitted Foreign Earnings

Unremitted foreign earnings decreased from $53.7 million at December 31, 2020, to $50.0 million at December 31, 2021, 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) contingent consideration arrangements associated with certain asset acquisitions, iii) operating lease and finance lease obligations, and iv) uncertain tax positions.

Refer to the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report for a further description of our contingent consideration arrangements (Notes 4, 12, and 17), lease obligations (Note 9), and uncertain tax positions (Note 20).

Off-balance Sheet Arrangements

As of December 31, 2021, 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 as of 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 and receipt of a confirming purchase order.

Spinal Implants and Global Orthopedics 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 Orthopedics 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 our 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, 2021, 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, 2021, would result in an increase or decrease to net sales of $0.4 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, and net income.

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 has not occurred.

In the fourth quarter of 2021, we performed a quantitative assessment of goodwill as part of our annual goodwill impairment analysis. Upon estimating the fair value of each of its reporting units, we determined the Global Orthopedics reporting unit's fair value was less than its carrying value of net assets. This resulted in recording a full impairment of the Global Orthopedics goodwill of $11.8 million, which is reflected within Acquisition-related amortization and remeasurement. The assessment concluded there were no indicators of impairment for the Global Spine goodwill.

We estimate the fair value of each reporting unit using a weighted average of fair value derived from both an income approach and a market approach. The fair value measurements are based on significant inputs that are unobservable in the market, with key assumptions including, but not limited to, our forecasted future net sales and expenses, terminal growth rates, discount rates applied, and allocation of corporate-level expenses to each reporting unit. Significant changes in these assumptions could result in a significantly higher or lower fair value, which in turn can affect the ultimate conclusion regarding if goodwill is impared.

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 as of December 31, 2021, include (i) contingent consideration attributable to the Spinal Kinetics acquisition and (ii) our convertible loan agreements with Neo Medical.

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 2019 and one of the revenue-based milestones, resulting in a payment of $15.0 million, was achieved and paid in 2021.

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 revenue-based milestone payment 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 $4.8 million, whereas a decrease in our forecasted future revenues by 5% would have resulted in a decrease in the fair value of the contingent consideration by $5.2 million.

We estimate the fair value of our convertible loan agreements with Neo Medical using 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 $1.2 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 $1.7 million.

Our fair value measurements are a “critical accounting estimate” because changes in the assumptions used to develop the estimate could materially affect key financial measures, 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 treatment 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 restricted 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 the awards 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 the grants 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 (including the impacts of any goodwill impairment). 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, 2021, 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, Australian Dollas, Swiss Franc, or British Pound. 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, 2021, we recorded a foreign currency loss of $4.0 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 years ended December 31, 2021, and December 31, 2020, 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 $9.1 million and a decrease in operating income of $0.7 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 $9.1 million and an increase in operating income of $0.7 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, 2021, 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, 2021, 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 2021 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, 2021, 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, 2021, 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, 2021 and 2020, 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, 2021, and the related notes and our report dated February 25, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

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

Definition and Limitations of Internal Control Over Financial Reporting

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

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

/s/ Ernst & Young LLP

Dallas, Texas
February 25, 2022

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

None.

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*†	Amended and Restated Matrix Commercialization Collaboration Agreement, entered into as of February 7, 2022, by and between Orthofix US LLC and Muscoloskeletal Transplant Foundation Inc.
10.3	Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as amended by Amendment No. 1 thereto (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and incorporated herein by reference).
10.4	Amendment No. 2 to the Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan (filed as an exhibit to the Company's Current Report on Form 8-K filed June 21, 2021 and incorporated by reference).
10.5	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).
10.6	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).
10.7	Amendment No. 2 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 filed June 21, 2021 and incorporated by reference).

Exhibit Number	Description
10.8*	Form of Employee Performance Stock Unit Agreement (2022 grant) under the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan.
10.9	Form of Employee Performance Stock Unit Agreement (2016 – 2021 grants) 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).
10.10*	Form of Time-Based Vesting Employee Restricted Stock Unit Grant Agreement (2018 – 2021 grants) under the Orthofix Medical Inc. Amended and Restated 202 Long-Term Incentive Plan.
10.11	Form of Time-Based Vesting Employee Restricted Stock Grant Agreement (pre-2018 grants) under the 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 filed July 8, 2016 and incorporated here by reference).
10.12	Form of Time-Based Vesting Employee Non-Qualified Stock Option Agreement under the 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 filed July 8, 2016 and incorporated here by reference).
10.13	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix Medical Inc. Amended and Restated 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).
10.14	Form of Employee Non-Qualified Stock Option Agreement under the Orthofix Medical Inc. Amended and Restated 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).
10.15	Form of Non-Employee Director Restricted Stock Unit Agreement under the Orthofix Medical Inc. Amended and Restated 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).
10.16	Form of Time-Based Vesting Non-Employee Director Non-Qualified Stock Option Agreement under the Orthofix Medical Inc. Amended and Restated 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).
10.17	Form of Non-Employee Director Non-Qualified Stock Option 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 fiscal year ended December 31, 2012 and incorporated herein by reference).
10.18	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).
10.19	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).
10.20	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).
10.21	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).
10.22	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).
10.23	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).
10.24	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).

Exhibit Number	Description
10.25	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).
10.26	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).
10.27	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).
10.28	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).
10.29	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).
10.30	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).
10.31	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).
10.32	Letter agreement, dated August 21, 2020, between the Company and Paul Gonsalves (filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 and incorporated herein by reference).
10.33	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).
10.34	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).
10.35	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).
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.INS	Inline XBRL Instance Document – the instance document does not appear in the interactive Data File because its XBRL tags are embedded within the XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Definition Linkbase Document.

Exhibit Number	Description
101.LAB*	Inline XBRL Taxonomy Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed with this Form 10-K.

† Certain private or confidential portions of this exhibit that are not material were omitted by means of redacting a portion of the text and replacing it with a bracketed asterisk.

Item 16. Form 10-K Summary

None

SIGNATURES

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

ORTHOFIX MEDICAL INC.

Dated: February 25, 2022

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

Dated: February 25, 2022

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 25, 2022
/s/ DOUG RICE **Doug Rice**	Chief Financial Officer (Principal Financial and Accounting Officer)	February 25, 2022
/s/ CATHERINE BURZIK **Catherine Burzik**	Chair of the Board of Directors	February 25, 2022
/s/ WAYNE BURRIS **Wayne Burris**	Director	February 25, 2022
/s/ JASON HANNON **Jason Hannon**	Director	February 25, 2022
/s/ JAMES HINRICHS **James Hinrichs**	Director	February 25, 2022
/s/ LILLY MARKS **Lilly Marks**	Director	February 25, 2022
/s/ MICHAEL PAOLUCCI **Michael Paolucci**	Director	February 25, 2022
/s/ JOHN SICARD **John Sicard**	Director	February 25, 2022
/s/ THOMAS WEST **Thomas West**	Director	February 25, 2022

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 tests 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, 2021 and 2020, 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, 2021, 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, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, 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, 2021, 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, 2022, expressed an unqualified opinion thereon.

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, 2021, the fair value of contingent consideration was $17.2 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, 2021, the Company's inventory balance is $83.0 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.

/s/ Ernst & Young LLP

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

Dallas, Texas
February 25, 2022

ORTHOFIX MEDICAL INC.

Consolidated Balance Sheets as of December 31, 2021 and 2020

(U.S. Dollars, in thousands except share and per share data)	2021	2020
Assets		
Current assets		
Cash and cash equivalents	$ 87,847	$ 96,291
Restricted cash	—	530
Accounts receivable, net of allowances of $4,944 and $4,848, respectively	78,560	72,423
Inventories	82,974	84,635
Prepaid expenses and other current assets	20,141	16,500
Total current assets	269,522	270,379
Property, plant and equipment, net	59,252	63,613
Intangible assets, net	52,666	60,517
Goodwill	71,317	84,018
Deferred income taxes	1,771	25,042
Other long-term assets	22,095	22,292
Total assets	**$ 476,623**	**$ 525,861**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 26,459	$ 23,118
Current portion of finance lease liability	2,590	510
Other current liabilities	76,781	80,271
Total current liabilities	105,830	103,899
Long-term portion of finance lease liability	19,890	22,338
Other long-term liabilities	13,969	42,760
Total liabilities	139,689	168,997
Contingencies (Note 13)		
Shareholders' equity		
Common shares $0.10 par value; 50,000,000 shares authorized; 19,836,937 and 19,423,874 issued and outstanding as of December 31, 2021 and 2020, respectively	1,983	1,942
Additional paid-in capital	313,951	292,291
Retained earnings	21,000	59,379
Accumulated other comprehensive income	—	3,252
Total shareholders' equity	336,934	356,864
Total liabilities and shareholders' equity	**$ 476,623**	**$ 525,861**

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, 2021, 2020, and 2019

(U.S. Dollars, in thousands, except share and per share data)	2021	2020	2019
Net sales	$ 464,479	$ 406,562	$ 459,955
Cost of sales	114,914	101,889	100,607
Gross profit	349,565	304,673	359,348
Sales and marketing	221,318	204,434	223,676
General and administrative	69,353	67,948	85,607
Research and development	49,621	39,056	34,637
Acquisition-related amortization and remeasurement	17,588	(499)	34,212
Operating loss	(8,315)	(6,266)	(18,784)
Interest expense, net	(1,837)	(2,483)	(122)
Other income (expense), net	(3,343)	8,381	(8,143)
Loss before income taxes	(13,495)	(368)	(27,049)
Income tax benefit (expense)	(24,884)	2,885	(1,413)
Net income (loss)	**$ (38,379)**	**$ 2,517**	**$ (28,462)**
Net income (loss) per common share:			
Basic	$ (1.95)	$ 0.13	$ (1.51)
Diluted	(1.95)	0.13	(1.51)
Weighted average number of common shares:			
Basic	19,690,593	19,267,920	18,903,289
Diluted	19,690,593	19,391,718	18,903,289
Other comprehensive income (loss), before tax			
Unrealized gain (loss) on debt securities	(942)	1,881	(2,593)
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	(2,544)	4,872	(653)
Other comprehensive income (loss), before tax	(3,486)	6,753	(9,473)
Income tax benefit (expense) related to items of other comprehensive income (loss)	234	(462)	2,201
Other comprehensive income (loss), net of tax	(3,252)	6,291	(7,272)
Comprehensive income (loss)	$ (41,631)	$ 8,808	$ (35,734)

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, 2021, 2020, and 2019

(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, 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 expense	—	—	21,540	—	—	21,540
Common shares issued, net	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 expense	—	—	16,207	—	—	16,207
Common shares issued, net	401,255	40	5,065	—	—	5,105
At December 31, 2020	**19,423,874**	**$ 1,942**	**$ 292,291**	**$ 59,379**	**$ 3,252**	**$ 356,864**
Net loss	—	—	—	(38,379)	—	(38,379)
Other comprehensive loss, net of tax	—	—	—	—	(3,252)	(3,252)
Share-based compensation expense	—	—	15,432	—	—	15,432
Common shares issued, net	413,063	41	6,228	—	—	6,269
At December 31, 2021	**19,836,937**	**$ 1,983**	**$ 313,951**	**$ 21,000**	$ —	**$ 336,934**

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, 2021, 2020, and 2019

(U.S. Dollars, in thousands)	2021	2020	2019
Cash flows from operating activities			
Net income (loss)	$ (38,379)	$ 2,517	$ (28,462)
Adjustments to reconcile net income (loss) to net cash from operating activities			
Depreciation and amortization	29,599	30,546	24,699
Impairment of goodwill	11,756	—	—
Amortization of operating lease assets, debt costs, and other assets	3,496	3,730	3,778
Provision for expected credit losses	444	199	1,891
Deferred income taxes	24,482	10,787	1,393
Share-based compensation expense	15,432	16,207	21,540
Interest and (gain) loss on the valuation of investment securities	(1,146)	116	5,000
Change in fair value of contingent consideration	(3,575)	(7,300)	29,140
Other	1,064	(2,228)	2,433
Changes in operating assets and liabilities, net of effects of acquisitions			
Accounts receivable	(7,049)	13,283	(11,037)
Inventories	619	(873)	(5,712)
Prepaid expenses and other current assets	(2,834)	4,526	(3,698)
Accounts payable	4,253	2,532	2,138
Other current liabilities	1,013	5,975	(7,716)
Contract liability (Note 15)	(9,060)	13,851	—
Payment of contingent consideration	(6,595)	—	(1,340)
Other long-term assets and liabilities	(5,045)	(19,596)	(2,014)
Net cash from operating activities	**18,475**	**74,272**	**32,033**
Cash flows from investing activities			
Acquisition of a business	—	(18,000)	—
Capital expenditures for property, plant and equipment	(17,785)	(15,485)	(18,997)
Capital expenditures for intangible assets	(1,807)	(1,609)	(1,527)
Purchase of investment securities	(2,171)	(10,000)	—
Asset acquisitions and other investments	(1,250)	(7,240)	(2,400)
Net cash from investing activities	**(23,013)**	**(52,334)**	**(22,924)**
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	8,824	7,598	11,551
Payments related to withholdings for share-based compensation	(2,555)	(2,493)	(5,193)
Payment of contingent consideration	(8,405)	—	(13,660)
Payments related to finance lease obligation	(537)	(323)	(365)
Payment of debt issuance costs and other financing activities	(948)	(1,537)	(3,021)
Net cash from financing activities	**(3,621)**	**3,245**	**(10,688)**
Effect of exchange rate changes on cash and restricted cash	(815)	1,235	(207)
Net change in cash, cash equivalents, and restricted cash	(8,974)	26,418	(1,786)
Cash, cash equivalents, and restricted cash at the beginning of the year	96,821	70,403	72,189
Cash, cash equivalents, and restricted cash at the end of the year	**$ 87,847**	**$ 96,821**	**$ 70,403**
Components of cash, cash equivalents, and restricted cash at the end of the year			
Cash and cash equivalents	$ 87,847	$ 96,291	$ 69,719
Restricted cash	—	530	684
Cash, cash equivalents, and restricted cash at the end of the year	**$ 87,847**	**$ 96,821**	**$ 70,403**

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 company with a spine and orthopedics focus. The Company's mission is to deliver innovative, quality-driven solutions while partnering with health care professionals to improve patient mobility. Headquartered in Lewisville, Texas, the Company's spine and orthopedic products are distributed in over 60 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.

Footnote	Footnote Reference
Business, basis of presentation, COVID-19 update, and CARES Act	1
Significant accounting policies	2
Recently adopted accounting standards and recently issued accounting pronouncements	3
Acquisitions	4
Inventories	5
Property, plant, and equipment	6
Intangible assets	7
Goodwill	8
Leases	9
Other current liabilities	10
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Fair value measurements and investments	12
Commitments and contingencies	13
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Acquisition-related amortization and remeasurement	17
Share-based compensation	18
Defined contribution plans and deferred compensation	19
Income taxes	20
Earnings per share	21

COVID-19 and the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act")

The global Coronavirus Disease 2019 ("COVID-19") pandemic has significantly affected the Company's hospitals and physician customers, patients, communities, employees, and business operations. At various points in time, 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. The Company's consolidated financial statements reflect estimates and assumptions made by management as of December 31, 2021. At this time, the future trajectory and duration of the COVID-19 pandemic remains uncertain, both in the U.S. and in other markets.

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

In March 2020, the CARES Act entered 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 to provide general support to the U.S. economy. The CARES Act, among other things, included provisions relating to the deferment of employer side social security payments and technical corrections to tax depreciation methods for qualified improvement property. The CARES Act had no impact to the

Company's income tax expense/benefit reported within the consolidated statements of operations for each of the years ended December 31, 2021 and 2020. The CARES Act also provided financial relief to the Company through other various programs, each of which are 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.

In April 2020, the Company also automatically received $4.7 million in funds from the U.S. Department of Health and Human Services as part of the Provider Relief Fund. The Company recognized this in-substance grant within other income 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 subsequent to the CARES Act being signed into federal law, such that 50% of the taxes could be deferred until December 31, 2021, with the remaining 50% deferred until December 31, 2022. As of December 31, 2020, the Company had deferred $0.6 million associated with this program, all of which was classified within other current liabilities. This deferred balance was then voluntarily repaid, in full, in the first quarter of 2021.

Consolidated Appropriations Act of 2021 (the "Consolidated Appropriations Act")

On December 27, 2020, the Consolidated Appropriations Act entered into federal law. The Consolidated Appropriations Act did not have a material impact to the Company's income tax provision for the year ended December 31, 2021.

American Rescue Plan Act of 2021 ("the American Rescue Plan")

On March 11, 2021, the American Rescue Plan entered into federal law. The American Rescue Plan, among other things, included provisions related to the deduction of executive compensation beginning in 2027. The American Rescue Plan had no impact to the Company's condensed consolidated financial statement for the year ended December 31, 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 these estimates.

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

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 U.S. are generally maintained in their local currency. All foreign currency denominated balance sheet accounts, except shareholders' equity, are translated to U.S. Dollars at year end exchange rates, and revenue and expense items are translated at average rates of exchange prevailing during the year. Gains and losses resulting from the translation of foreign currency are recorded in the accumulated other comprehensive income (loss) component of shareholders' equity. Transactional foreign currency gains and losses, including those generated from intercompany operations, are included in other expense, net and were a loss of $4.0 million, a gain of $3.9 million, and a loss of $1.4 million for the years ended December 31, 2021, 2020, and 2019, 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, 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 expected credit losses. The Company believes that a concentration of credit risk related to accounts receivable is limited because customers are geographically dispersed and end users are diversified.

Cash, cash equivalents, and restricted cash

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

In 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. In December 2021, the dispute was settled and the cash was disbursed to the former distributor.

Investing activities that did not result in cash receipts or cash payments during the years ended December 31, 2021, 2020, and 2019 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)	2021	2020	2019
Supplemental disclosure of cash flow information:			
Noncash investing activities:			
Intangible assets acquired in asset acquisitions	$ —	$ 1,575	$ 1,600
Contingent consideration recognized at acquisition date	—	375	—

Advertising costs

Advertising costs are expensed as incurred. Advertising costs are included within sales and marketing expense and totaled $0.5 million, $0.9 million, and $0.8 million for the years ended December 31, 2021, 2020, and 2019, 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 and $0.8 million in research and development expense for the years ended December 31, 2021 and 2020, respectively, under the collaborative arrangement with MTF and did not recognize any such expenditures for the year ended December 31, 2019.

In October 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 co-development agreement covering the parties' joint development of single use instruments for cervical spine procedures. 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, 2021 totaled $0.6 million and for the year ended December 31, 2020, totaled less than $0.1 million.

In December 2021, the Company and nView medical, a Salt Lake City-based company developing surgical imaging and guidance systems enabled by artificial intelligence ("AI"), entered into an agreement to jointly develop and co-market the innovative nView systems with the Company's cervical spine and pediatric limb deformity correction procedural solutions. Each party is responsible for payment of its own development and marketing costs incurred in association with the collaborative arrangement. No such costs were incurred for the year ended December 31, 2021.

3. Recently adopted accounting standards and recently issued accounting pronouncements

Adoption of Accounting Standards Update ("ASU") 2021-10—Government Assistance (Topic 832): Disclosures by Business Entities about Government Assistance

In November 2021, the Financial Accounting Standards Board ("FASB") issued ASU 2021-10, which aims to increase the transparency of government assistance by requiring entities to provide information about the nature of the transaction, terms and conditions associated with the transaction, and financial statement line items affected by the transaction. The Company voluntarily elected to early adopt this standard for the year ended December 31, 2021, on a prospective basis. Adoption of this standard did not have a significant impact to the existing disclosures made in relation to government assistance received by the Company in 2020 as part of the CARES Act.

Adoption of ASU 2019-12, Simplifying the accounting for income taxes

In December 2019, the FASB issued ASU 2019-12, which reduces the complexity of accounting for income taxes by eliminating certain exceptions to the general principles in ASC 740, *Income Taxes*. Additionally, the ASU simplifies U.S. 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. The Company adopted this ASU effective January 1, 2021, with certain provisions applied retrospectively and other provisions applied prospectively. Adoption of this ASU did not have a material impact to the Company's condensed consolidated balance sheet, statements of operations, or cash flows

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

In June 2016, the FASB issued ASU 2016-13 (which was then further clarified in subsequent ASUs), which required that credit losses for certain types of financial instruments, including accounts receivable, be estimated based on expected credit losses among other changes. The Company adopted this ASU effective as of January 1, 2020, 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 eliminated 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 is now 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 and followed this guidance to measure the goodwill impairment of $11.8 million recorded in the year ended December 31, 2021.

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 eliminated certain disclosures, such as the amount and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, and added 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 aligned 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 provided temporary optional guidance to ease the potential financial reporting burden of the expected market transition away from LIBOR. The new guidance provided 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 ASU 2016-02, Leases (Topic 842)

In February 2016, the FASB issued ASU 2016-02, which changed how lessees account for leases, requiring a liability to be recorded on the balance sheet in most cases based on the present value of future lease obligations with a corresponding right-of-use asset. The Company adopted this ASU effective January 1, 2019, using a modified retrospective approach. Upon adoption, the Company elected a package of practical expedients permitted within the new standard. The elected practical expedients allowed 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. 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 allowed 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 ASU 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.

4. Acquisitions

FITBONE Asset Purchase Agreement

In March 2020, the Company completed 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 for $18.0 million in cash consideration. The Company also entered into a Contract Manufacturing and Supply Aggreement ("CMSA") with Wittenstein.

Distributor Acquisition

In July 2020, the Company, acquired certain assets of a medical device distributor for consideration of up to $7.6 million.

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 for $6.4 million. Under the terms of the acquisition, the parties terminated 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.

Purchase Price Allocations for Acquisitions Completed in 2020 and 2019

(U.S. Dollars, in thousands)	FITBONE	Assigned Useful Life	Distributor Acquisition	Assigned Useful Life	Options Medical	Assigned Useful Life
Assets acquired						
Inventories	$ 528		$ —		$ —	
Other long-term assets	—		—		175	
Intangible assets						
Customer relationships	800	15 years	7,340	5 years	5,832	10 years
Developed technology	4,500	8 years	—	N/A	—	N/A
IPR&D	300	Indefinite	—	N/A	—	N/A
Trade name	600	15 years	—	N/A	—	N/A
Assembled workforce	—	N/A	235	5 years	568	5 years
Total identifiable assets acquired	$ 6,728		$ 7,575		$ 6,575	
Liabilities assumed						
Other current liabilities	$ —		$ —		$ 69	
Other long-term liabilities	—		—		106	
Total liabilities assumed	—		—		175	
Goodwill	11,272		—		—	
Total fair value of consideration transferred	$ 18,000		$ 7,575		$ 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 cost, 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)	2021	2020
Raw materials	$ 9,589	$ 8,442
Work-in-process	15,096	12,149
Finished products	15,149	29,142
Field/consignment	43,140	34,902
Inventories	$ 82,974	$ 84,635

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 $20.2 million, $19.3 million and $17.7 million for the years ended December 31, 2021, 2020, and 2019, 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)	2021	2020
Cost		
Buildings	$ 3,925	$ 4,096
Plant and equipment	50,275	50,159
Instrumentation	100,515	93,252
Computer software	53,200	52,565
Furniture and fixtures	8,307	8,024
Construction in progress	2,597	1,628
Finance lease assets	23,397	23,337
Property, plant, and equipment, gross	242,216	233,061
Accumulated depreciation	(182,964)	(169,448)
Property, plant, and equipment, net	$ 59,252	$ 63,613

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.

Long-lived assets are evaluated for impairment annually or 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, such as for in-process research and development ("IPR&D") assets. 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 the assets.

(U.S. Dollars, in thousands)	Weighted Average Amortization Period	December 31, 2021	2020
Cost			
Patents	10 years	$ 44,561	$ 50,326
Developed technology	10 years	43,979	44,334
IPR&D	Indefinite	300	300
Customer relationships	7 years	15,621	15,685
License and other	8 years	18,924	16,941
Trademarks—finite lived	10 years	1,839	1,812
	9 years	125,224	129,398
Accumulated amortization			
Patents		$ (41,408)	$ (46,272)
Developed technology		(13,409)	(8,925)
Customer relationships		(4,520)	(2,095)
License and other		(12,528)	(11,006)
Trademarks—finite lived		(693)	(583)
		(72,558)	(68,881)
Intangible assets, net		$ 52,666	$ 60,517

Acquired IPR&D represents the fair value assigned to acquired research and development assets that have not reached technological feasibility. In a business combination, the fair value assigned to acquired IPR&D is determined by estimating the remaining 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.

IPR&D assets 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.

Amortization expense for intangible assets was $9.4 million, $11.2 million and $7.0 million for the years ended December 31, 2021, December 31, 2020, and 2019, respectively. Future amortization expense for intangible assets is estimated as follows:

(U.S. Dollars, in thousands)	Amortization
2022	$ 9,376
2023	8,692
2024	8,254
2025	7,252
2026	6,215
Thereafter	12,577
Total finite-lived intangible assets, net	$ 52,366
Indefinite-lived intangible assets, net	300
Intangible assets, net	$ 52,666

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.

In the fourth quarter of 2021, the Company performed a quantitative assessment of its goodwill. The Company estimated the fair value of each reporting unit using a weighted average of fair value derived from both an income approach and a market approach (all Level 3 fair value measurements). Upon estimating the fair value of each of its reporting units, the Company determined its Global Orthopedics reporting unit's fair value was less than its carrying value of net assets. This resulted in recording a full impairment of the Global Orthopedics goodwill of $11.8 million, which is reflected within Acquisition-related amortization and remeasurement. This amount also represents the total of the Company's accumulated goodwill impairment losses as of December 31, 2021. The assessment concluded there were no indicators of impairment for the Global Spine goodwill.

The following table presents the net carrying value of goodwill, and a rollforward of such balances from December 31, 2020, by reportable segment:

(U.S. Dollars, in thousands)	December 31, 2020	Impairment	Currency Translation Adjustment	December 31, 2021
Global Spine	$ 71,317	$ —	$ —	$ 71,317
Global Orthopedics	12,701	(11,756)	(945)	—
Goodwill	$ 84,018	$ (11,756)	$ (945)	$ 71,317

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. 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 a contractual arrangement qualifies as a lease at inception. The Company's leases primarily relate to facilities, vehicles, and equipment, and certain contract manufacturing agreements. 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 the 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.

A summary of the Company's lease portfolio as of December 31, 2021, and 2020, is presented in the table below:

(U.S. Dollars, in thousands, except lease term and discount rate)	Classification	December 31, 2021	December 31, 2020
Assets			
Operating leases	Other long-term assets	$ 3,155	$ 4,840
Finance leases	Property, plant and equipment, net	18,600	20,552
Total lease assets		$ 21,755	$ 25,392
Liabilities			
Current			
Operating leases	Other current liabilities	$ 1,834	$ 2,092
Finance leases	Current portion of finance lease liability	2,590	510
Long-term			
Operating leases	Other long-term liabilities	1,443	2,946
Finance leases	Long-term portion of finance lease liability	19,890	22,338
Total lease liabilities		$ 25,757	$ 27,886
Weighted Average Remaining Lease Term			
Operating leases		3.3 years	3.6 years
Finance leases		17.0 years	18.1 years
Weighted Average Discount Rate			
Operating leases		2.6%	2.4%
Finance leases		4.2%	4.2%

The components of lease costs were as follows:

(U.S. Dollars, in thousands)	For the Year Ended December 31, 2021	For the Year Ended December 31, 2020	For the Year Ended December 31, 2019
Finance lease costs:			
Amortization of right-of-use assets	$ 2,049	$ 1,766	$ 972
Interest on finance lease liabilities	933	940	919
Operating lease costs	2,234	2,235	2,161
Short-term lease costs	213	230	255
Variable lease costs	815	673	749
Total lease costs	$ 6,244	$ 5,844	$ 5,056

Supplemental cash flow information related to leases was as follows:

(U.S. Dollars, in thousands)	For the Year Ended December 31, 2021	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	$ 4,627	$ 4,299	$ 4,075
Operating cash flows from finance leases	907	689	919
Financing cash flows from finance leases	537	323	365
Right-of-use assets obtained in exchange for lease obligations			
Operating leases	589	959	878
Finance leases	149	1,949	21,179

A summary of the Company's remaining lease liabilities as of December 31, 2021, is included below:

(U.S. Dollars, in thousands)	Operating Leases	Finance Leases
2022	$ 1,883	$ 3,480
2023	614	1,508
2024	211	1,538
2025	192	1,543
2026	189	1,562
Thereafter	330	22,613
Total undiscounted value of lease liabilities	3,419	32,244
Less: Interest	(142)	(9,764)
Present value of lease liabilities	$ 3,277	$ 22,480
Current portion of lease liabilities	$ 1,834	$ 2,590
Long-term portion of lease liabilities	1,443	19,890
Total lease liabilities	$ 3,277	$ 22,480

10. Other current liabilities

(U.S. Dollars, in thousands)	December 31, 2021	December 31, 2020
Accrued expenses	$ 7,151	$ 6,090
Salaries, bonuses, commissions and related taxes payable	23,552	22,362
Accrued distributor commissions	10,787	9,331
Accrued legal and settlement expenses	3,794	5,422
Contingent consideration liability	17,200	14,900
Short-term operating lease liability	1,834	2,092
Non-income taxes payable	4,655	5,509
Accelerated and advance payment program	4,791	9,834
Other payables	3,017	4,731
Other current liabilities	$ 76,781	$ 80,271

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 initial 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, 2021, and 2020, 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 (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 Company is in compliance with all required financial covenants as of December 31, 2021.

In conjunction with obtaining the Facility, the Company paid $1.5 million in debt issuance costs and has capitalized a total of $1.8 million associated with the Facility (inclusive of certain capitalized costs prior to the most recent amendment). 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, 2021, and December 31, 2020, debt issuance costs, net of accumulated amortization, were $1.0 million and $1.4 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, 2021, 2020, and 2019, respectively.

The Company has an unused available Italian line of credit of €5.5 million ($6.3 million and $6.7 million) at December 31, 2021, and 2020, respectively. 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 $1.5 million, $1.9 million, and $0.8 million for the years ended December 31, 2021, 2020, and 2019, 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, 2021	Level 1	Level 2	Level 3
Assets				
Neo Medical convertible loan agreements	$ 7,148	$ —	$ —	$ 7,148
Neo Medical preferred equity securities	5,413	—	5,413	—
Bone Biologics equity securities	309	309	—	—
Other investments	1,505	—	—	1,505
Total	$ 14,375	$ 309	$ 5,413	$ 8,653
Liabilities				
Spinal Kinetics contingent consideration	$ (17,200)	$ —	$ —	$ (17,200)
Other contingent consideration	—	—	—	—
Deferred compensation plan	(1,314)	—	(1,314)	—
Total	$ (18,514)	$ —	$ (1,314)	$ (17,200)

(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)

The fair value of the Company's 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 this liability as a Level 2 financial instrument.

Neo Medical Convertible Loan Agreements 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. 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.

On October 10, 2021, the Company entered into an additional Convertible Loan Agreement (the "Additional Convertible Loan"), separate and distinct from the investment made in 2020, pursuant to which the Company loaned Neo Medical an additional CHF 0.6 million ($0.7 million as of the issuance date). The Company made the election to convert the Additional Convertible Loan into shares of Neo Medical's preferred stock in January 2022.

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. In November 2021, Neo Medical completed a qualified capital increase. As such, the Company adjusted the carrying amount of its equity investment to reflect the change in observable price and recorded a $0.4 million unrealized gain recognized in other income.

The table below presents a reconciliation of the carrying value of the Company's investment in Neo Medical preferred equity securities for the years ended December 31, 2021, and 2020:

(U.S. Dollars, in thousands)	2021	2020
Fair value of Neo Medical preferred equity securities at January 1	$ 5,000	$ —
Additions	—	5,000
Foreign currency remeasurement recognized in other income, net	77	—
Unrealized gain recognized in other income (expense), net	336	—
Fair value of Neo Medical preferred equity securities at December 31	5,413	5,000

Both of the Convertible Loans are recorded in other long-term assets as available for sale debt securities as of December 31, 2021. These Convertible Loans are recorded at fair value, with applicable interest recorded in interest income. The fair value of the Convertible Loans is based upon significant unobservable inputs, including the use of option-pricing models, Monte Carlo simulations for certain periods, and a probability-weighted discounted cash flows model, requiring the Company to develop its own assumptions. Therefore, the Company has categorized these assets as Level 3 financial assets.

Some of the more significant unobservable inputs used in the fair value measurement of the Loans 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 Loans. If the amortized cost of the Convertible Loans exceeds their estimated fair value, the securities are 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 (loss). As of December 31, 2021, the Company has not recognized any credit losses related to the Convertible Loans.

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

(U.S. Dollars, in thousands)	2021	2020
Fair value of Neo Medical Convertible Loans at January 1	$ 7,160	$ —
Additions	671	5,000
Interest recognized in interest income, net	421	103
Foreign currency remeasurement recognized in other income (expense), net	(162)	176
Unrealized gain (loss) recognized in other comprehensive income (loss)	(942)	1,881
Fair value of Neo Medical Convertible Loans at December 31	7,148	7,160
Amortized cost basis of Neo Medical Convertible Loans at December 31	6,209	5,279

The following table provides quantitative information related to certain key assumptions utilized within the valuation of the Convertible Loans as of December 31, 2021:

(U.S. Dollars, in thousands)	Fair Value as of December 31, 2021	Unobservable inputs	Estimate
Neo Medical Convertible Loans	$ 7,148	Cost of equity discount rate	16.1%
		Implied volatility	67.8%

Bone Biologics Equity Securities

The Company holds an investment in common stock of Bone Biologics Inc. ("Bone Biologics"), a developer of orthobiologic products. Prior to 2021, the equity securities were considered an investment that did not have a readily determinable fair value as Bone Biologics was privately held. As such, the Company measured 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 2020, the Company recognized an impairment of $0.2 million as a result of concerns over Bone Biologics' ability to continue as a going concern.

In the fourth quarter of 2021, Bone Biologics completed a public offering of units, with each unit consisting of one share of common stock and one warrant to purchase common shares. As a result of the public offering, Bone Biologics' common stock is now actively traded on the NASDAQ (ticker BBLG). The Company concluded the investment represented a Level 1 fair value measurement subsequent to the public offering as the common shares now have quoted prices in active markets for identical assets. As such, the Company now records the investment at fair value, with changes in fair value recorded within other income (expense), net.

The following table presents the changes in fair value recognized for the equity securities for each of the years ended December 31, 2021, 2020, and 2019:

(U.S. Dollars, in thousands)	2021	2020	2019
Bone Biologics equity securities at January 1	$ —	$ 219	$ 219
Fair value adjustments and impairments recognized in other income (expense), net	309	(219)	—
Bone Biologics equity securities at December 31	$ 309	$ —	$ 219

Other investments

Other investments represent other assets and investments recorded at fair value that are not deemed to be material for disclosure on an individual basis. The fair value of these assets are based upon significant unobservable inputs, such as probability-weighted discounted cash flows models, requiring the Company to develop its own assumptions. Therefore, the Company has categorized these assets as Level 3 financial assets. As of December 31, 2021, this balance was classified within other long-term assets.

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. The

FDA Milestone was achieved and paid in 2019. A second milestone payment, totaling $15.0 million, was achieved and paid in 2021 upon meeting certain net sales targets.

The estimated fair value of the remaining Spinal Kinetics contingent consideration was $17.2 million as of December 31, 2021. The estimated fair value reflects assumptions made by management as of December 31, 2021, such as the expected timing and volume of elective procedures and the impact of these procedures on future revenues. However, the actual amount ultimately paid could be higher or lower than the fair value of the remaining contingent consideration (ultimate payment will either be $30.0 million or the liability will be reversed if the milestone is not met within the required timeline). As of December 31, 2021, the Company has classified the $17.2 million liability within other current liabilities, as the Company currently expects to achieve the remaining milestone in the next twelve months. 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)	2021	2020
Spinal Kinetics contingent consideration at January 1	$ 35,400	$ 42,700
Decrease in fair value recognized in acquisition-related amortization and remeasurement	(3,200)	(7,300)
Payment made	(15,000)	—
Spinal Kinetics contingent consideration at December 31	$ 17,200	$ 35,400

The Company estimated the fair value of the remaining potential future revenue-based milestone payment 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 Motion Preservation 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, 2021:

(U.S. Dollars, in thousands)	Fair Value as of December 31, 2021	Valuation Technique	Unobservable inputs	Range
Spinal Kinetics contingent consideration	$ 17,200	Discounted cash flow	Revenue discount rate	7.13% - 7.55%
			Payment discount rate	3.38% - 3.81%
			Projected year of achievement	2022

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. In October 2019, the Company and eNeura settled the debt security for a $4.0 million cash payment. As such, the Company determined the investment was impaired and adjusted the carrying value of the debt security to 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.

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 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 on a quarterly basis. 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. 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 periodically reassesses this liability based upon current facts and circumstances. As a result of certain temporary relief provided by the Italian National Healthcare System in response to the COVID-19 pandemic through a law enacted on December 30, 2021, the Company recorded a benefit of $1.2 million for the year ended December 31, 2021, and expense of $1.5 million and $1.3 million for the years ended December 31, 2020, and 2019, respectively. As of December 31, 2021, the Company has accrued $5.2 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.

14. Shareholders' equity

Dividends

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

Accumulated Other Comprehensive Income (Loss)

Accumulated other comprehensive income (loss) is comprised of foreign currency translation adjustments and unrealized gains (losses) on available for sale debt securities. 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 Loans	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
Other comprehensive loss	(2,544)	—	(942)	(3,486)
Income taxes	—	—	234	234
Balance at December 31, 2021	$ (711)	$ —	$ 711	$ —

15. Revenue recognition and accounts receivable

Revenue Recognition

The Company accounts for a contract when there is (i) approval and commitment from both parties, (ii) the rights of the parties are identified, (iii) payment terms are identified, (iv) the contract has commercial substance, (v) 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 consideration for 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 December 31, 2032. 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 allografts, 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 and receipt of a confirming purchase order.

Spinal Implants and Global Orthopedics

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

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

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, 2021, 2020, and 2019.

	For the year ended December 31,		
(U.S. Dollars, in thousands)	**2021**	**2020**	**2019**
Product sales	$ 409,554	$ 353,087	$ 397,064
Marketing service fees	54,925	53,475	62,891
Net sales	$ 464,479	$ 406,562	$ 459,955

Product sales primarily consists of the sale of Bone Growth Therapies, Spinal Implants, and Global Orthopedics 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 $54.9 million, or approximately 97% of total Biologics revenues, for the year ended December 31, 2021. As MTF is the single supplier for the allografts in the Company's Biologics portfolio, derived from deceased donors for their bone grafts and living donors for their amnion grafts, any event or circumstance that would impact MTF's continued access to donors 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 $3.5 million, $2.4 million, and $2.8 million for the years ended December 31, 2021, 2020, and 2019, respectively.

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.

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. 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 years ended December 31, 2021, and 2020:

(U.S. Dollars, in thousands)	For the year ended December 31, 2021	2020
Allowance for expected credit losses beginning balance	$ 4,848	$ 3,987
Impact of adoption of ASU 2016-13	—	1,120
Current period provision for expected credit losses	444	199
Writeoffs charged against the allowance and other	(126)	(714)
Effect of changes in foreign exchange rates	(222)	256
Allowance for expected credit losses ending balance	$ 4,944	$ 4,848

The Company will generally sell receivables from certain Italian hospitals each year to accelerate cash collections. During 2021, 2020, and 2019, the Company sold €8.4 million, €8.3 million, and €9.8 million ($9.9 million, $9.6 million, and $10.9 million) of receivables, respectively. The related fees for 2021, 2020, and 2019, were $0.2 million, $0.3 million, and $0.3 million, respectively, which were 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 2020 from the CMS as part of the Accelerated and Advance Payment Program of the CARES Act.

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 Program's recoupment terms for providers and suppliers that received funds from the program. Starting in April 2021, Medicare began to recoup 25% of Medicare payments otherwise owed to the provider or supplier for submitted claims. Beginning March 2022, recoupment increases to 50% for another six 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, 2021, the balance of the contract liability associated with the Accelerated and Advance Payment Program totaled $4.8 million. The Company has classified the entire balance of this contract liability within other current liabilities based upon the Company's estimates of when such funds will be recouped.

The following table provides a detail of changes in the Company's contract liability associated with the Accelerated and Advanced Payment Program for the years ended December 31, 2021, and 2020:

(U.S. Dollars, in thousands)	For the Year Ended December 31, 2021	2020
Contract liability beginning balance	$ 13,851	$ —
Additions	—	13,851
Recoupment recognized in net sales	(9,060)	—
Contract liability ending balance	$ 4,791	$ 13,851

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 totaled $1.4 million and $2.0 million as of December 31, 2021, and 2020, 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 2021 or 2020. 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 has two reporting segments: Global Spine and Global Orthopedics. 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.

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 global network of distributors and sales representatives to sell spine products to hospitals and healthcare providers.

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 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 and also allows the Company to exclusively distribute the Alloquent and fiberFUSE allografts.

Global Orthopedics

The Global Orthopedics 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 Orthopedics distributes its products through a global network of distributors and sales representatives to sell orthopedic products to hospitals, and healthcare providers.

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:

(U.S. Dollars, in thousands)	Year Ended December 31, 2021 Net Sales	2021 Percent of Total Net Sales	2020 Net Sales	2020 Percent of Total Net Sales	2019 Net Sales	2019 Percent of Total Net Sales
Bone Growth Therapies	$ 187,448	40.4%	$ 171,396	42.2%	$ 197,181	42.9%
Spinal Implants	115,094	24.8%	94,857	23.3%	94,544	20.6%
Biologics	56,421	12.1%	55,482	13.6%	65,496	14.2%
Global Spine	358,963	77.3%	321,735	79.1%	357,221	77.7%
Global Orthopedics	105,516	22.7%	84,827	20.9%	102,734	22.3%
Net sales	$ 464,479	100.0%	$ 406,562	100.0%	$ 459,955	100.0%

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

(U.S. Dollars, in thousands)	Year Ended December 31, 2021	2020	2019
Global Spine	$ 58,014	$ 63,036	$ 39,528
Global Orthopedics	3,374	(4,993)	7,496
Corporate	(31,691)	(25,382)	(49,252)
Total EBITDA	29,697	32,661	(2,228)
Depreciation and amortization	(29,599)	(30,546)	(24,699)
Goodwill impairment	(11,756)	—	—
Interest expense, net	(1,837)	(2,483)	(122)
Loss before income taxes	$ (13,495)	$ (368)	$ (27,049)

The following table presents depreciation and amortization by reporting segment:

(U.S. Dollars, in thousands)	Year Ended December 31, 2021	2020	2019
Global Spine	$ 17,548	$ 18,362	$ 14,329
Global Orthopedics	8,233	7,896	5,575
Corporate	3,818	4,288	4,795
Total	$ 29,599	$ 30,546	$ 24,699

Geographical information

The following data includes net sales by geographic destination:

(U.S. Dollars, in thousands)	Year Ended December 31, 2021	2020	2019
U.S.	$ 361,945	$ 327,280	$ 361,939
Italy	20,187	18,733	19,560
Germany	13,716	11,940	12,688
United Kingdom	10,552	7,147	10,090
France	10,475	8,354	8,747
Brazil	5,108	2,347	7,685
Others	42,496	30,761	39,246
Net sales	$ 464,479	$ 406,562	$ 459,955

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)	2021	2020	2019
Global Spine			
U.S.	$ 337,455	$ 304,595	$ 335,410
International	21,508	17,140	21,811
Total Global Spine	358,963	321,735	357,221
Global Orthopedics			
U.S.	$ 24,490	22,685	26,529
International	81,026	62,142	76,205
Total Global Orthopedics	105,516	84,827	102,734
Consolidated			
U.S.	361,945	327,280	361,939
International	102,534	79,282	98,016
Net sales	$ 464,479	$ 406,562	$ 459,955

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

(U.S. Dollars, in thousands)	2021	2020
U.S.	$ 45,090	$ 47,646
Italy	9,412	10,503
Germany	2,544	2,516
United Kingdom	1,193	1,540
Brazil	91	163
Others	922	1,245
Total	$ 59,252	$ 63,613

17. Acquisition-related amortization and remeasurement

Acquisition-related amortization and remeasurement consists of (i) amortization related to intangible assets acquired through business combinations or asset acquisitions, (ii) the remeasurement of any related contingent consideration arrangement, (iii) recognized costs associated with acquired in-process research and development ("IPR&D") assets, which are recognized immediately upon acquisition, and (iv) impairments of goodwill related to previously recognized business combinations. Components of acquisition-related amortization and remeasurement for the years ended December 31, 2021, 2020, and 2019, respectively, are as follows:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2021	2020	2019
Changes in fair value of contingent consideration	$ (3,575)	$ (7,300)	$ 29,140
Amortization of acquired intangibles	7,907	6,801	5,072
Acquired IPR&D	1,500	—	—
Impairment of Global Orthopedics goodwill	11,756	—	—
Total	$ 17,588	$ (499)	$ 34,212

Related Party Asset Acquisition

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 was comprised of $1.0 million due at signing, which was recognized immediately as acquired IPR&D expense within acquisition-related amortization and remeasurement, and $9.0 million in contingent consideration. The contingent consideration is dependent upon multiple milestones, such as receipt of 510(k) clearance and the attainment of certain net sales targets. The Company accounted for this transaction as an asset acquisition. As the transaction is classified as an asset acquisition, the value of the consideration associated with the contingent milestones will be recognized at the time that applicable contingencies are resolved and consideration is paid or becomes payable. In addition, the Company is obligated to pay a royalty of 2% to 4% on net sales, commencing upon commercialization of the assets.

The transaction was approved by the Company's Audit and Finance Committee, with the Audit and Finance Committee directly supervising the negotiations of the transaction. Mr. Serbousek was excluded from such discussions and did not participate in the negotiation or evaluation of the transaction. Mr. Serbousek also continues to be excluded from the 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

IGEA S.p.A Asset Acquisition

On April 7, 2021, the Company entered into an Exclusive License and Distribution Agreement (the "License Agreement") with IGEA S.p.A ("IGEA"), an Italian manufacturer and distributor of bone and cartilage stimulation systems. As consideration for the License Agreement, the Company agreed to pay up to $4.0 million, with certain payments contingent upon reaching an FDA milestone. Of this amount, $0.5 million was paid in 2021, which was recognized as acquired IPR&D costs within acquisition-related amortization and remeasurement. The License Agreement also includes certain minimum purchase requirements.

18. Share-based compensation

At December 31, 2021, and 2020, 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 approved 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, 2021, the Company reserves a total of 7,050,000 shares of common stock for issuance pursuant to the 2012 LTIP, subject to certain adjustments set forth in the 2012 LTIP. At December 31, 2021, there were 1,150,898 options outstanding under the 2012 LTIP, of which 748,539 were exercisable. In addition, there were 13,978 shares of unvested restricted stock awards outstanding and 851,847 restricted stock units outstanding, some of which contain market-based vesting conditions, under the 2012 LTIP as of December 31, 2021.

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, 2021, 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, 2021, there were no remaining options outstanding under the Spinal Kinetics Inducement Plan and 1,284 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, 2021, there were 50,711 options outstanding under this inducement, 25,355 of which were exercisable, and 7,372 unvested restricted stock units outstanding.

In September 2020, the Company appointed a new President of Global Orthopedics. 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, 2021, there were 32,945 options outstanding under this inducement, of which 8,236 were exercisable, and 7,968 unvested restricted stock units 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 expense 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, 2021, the aggregate number of shares reserved for issuance under the Stock Purchase Plan is 2,850,000. As of December 31, 2021, a total of 2,172,134 shares had been issued pursuant to the Stock Purchase Plan.

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 expense by line item in the consolidated statements of income as well as by award type, for the years ended December 31, 2021, 2020, and 2019:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2021	2020	2019
Cost of sales	$ 779	$ 705	$ 715
Sales and marketing	3,385	3,620	2,512
General and administrative	10,289	10,624	16,872
Research and development	979	1,258	1,441
Total	$ 15,432	$ 16,207	$ 21,540

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2021	2020	2019
Stock options	$ 1,893	$ 2,571	$ 4,054
Time-based restricted stock awards and stock units	7,437	8,485	11,084
Performance-based restricted stock awards and stock units	—	—	—
Market-based restricted stock units	4,414	3,509	4,733
Stock purchase plan	1,688	1,642	1,669
Total	$ 15,432	$ 16,207	$ 21,540

The income tax benefit related to this expense was $3.1 million, $3.2 million, and $3.5 million for the years ended December 31, 2021, 2020, and 2019, 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. 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,		
	2021	2020	2019
Assumptions:			
Expected term (in years)	6.0	5.5	5.0
Expected volatility	34.4% – 34.8%	30.2% – 35.1%	29.7% – 31.0%
Risk free interest rate	0.83% – 1.25%	0.28% – 1.65%	1.38% – 2.31%
Dividend yield	—	—	—
Weighted average grant date fair value	$ 12.33	$ 8.74	$ 14.64

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, 2021, and 2020, and changes during the year ended December 31, 2021, are presented below:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term
Outstanding at December 31, 2020	1,491,019	$ 39.56	
Granted	72,995	$ 35.59	
Exercised	(89,151)	$ 36.68	
Forfeited or expired	(77,809)	$ 45.49	
Outstanding at December 31, 2021	1,397,054	$ 39.20	5.04
Vested and expected to vest at December 31, 2021	1,397,054	$ 39.20	5.04
Exercisable at December 31, 2021	944,630	$ 41.10	3.51

As of December 31, 2021, the unamortized compensation expense relating to options granted and expected to be recognized was $2.0 million. This amount is expected to be recognized through December 2025 over a weighted average period of approximately 1.4 years. The total intrinsic value of options exercised was $0.6 million, $0.9 million and $1.4 million for the years ended December 31, 2021, 2020, and 2019, respectively. For the year ended December 31, 2021, we received $3.3 million in cash from stock option exercises, with the tax benefit realized for the tax deductions from these exercises of $0.6 million. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2021, 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 $31.09, the closing price of the Company's stock on December 31, 2021. The aggregate intrinsic value of options outstanding was $1.7 million as of December 31, 2021, whereas the aggregate intrinsic value of options exercisable was $0.5 million as of that date.

Time-based Restricted Stock Awards and Stock Units

During the year ended December 31, 2021, the Company granted to employees and non-employee directors 295,240 shares of time-based restricted stock stock units, which vest at various dates through December 2025. 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, 2021, there were 59,001 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, 2021, 2020, and 2019, was $9.0 million, $6.5 million and $9.5 million, respectively. Unamortized compensation expense related to time-based restricted stock awards and stock units amounted to $15.2 million at December 31, 2021, and is expected to be recognized over a weighted average period of approximately 2.6 years. The aggregate intrinsic value of time-based restricted stock awards and stock units outstanding was $17.4 million as of December 31, 2021.

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, 2021, 2020, and 2019.

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 2021, 2020, or 2019, as the performance targets were obtained in prior years. The fair value of performance-based restricted stock awards that vested and settled during the years ended December 31, 2021, 2020, and 2019, were $0.0 million, $0.0 million, and $3.2 million, respectively. No unamortized compensation expense related to performance-based restricted stock awards remains as of December 31, 2021. There was no intrinsic value of performance-based restricted stock awards outstanding as of December 31, 2021 as the awards were fully settled in 2019.

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. No compensation expense was recorded for these awards in 2021, 2020, or 2019, as the performance targets were obtained in a prior year. The fair value of performance-based restricted stock units that vested and settled during the years ended December 31, 2021, 2020, and 2019, were $0.0 million, $0.0 million, and $2.7 million, respectively. No unamortized compensation expense remains as of December 31, 2021 related to these 2015 performance-based restricted stock units. There was no intrinsic value of performance-based restricted stock units outstanding as of December 31, 2021, as the stock units were fully settled in 2019.

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, 2021, 2020, and 2019, were $0.0 million, $1.4 million, and $0.0 million, respectively. Unamortized compensation expense for market-based restricted stock units amounted to $8.3 million at December 31, 2021, and is expected to be recognized over a weighted average period of approximately 1.7 years. The aggregate intrinsic value of market-based restricted stock units outstanding was $10.0 million as of December 31, 2021.

A summary of the status of our time-based and market-based restricted stock awards and stock units as of December 31, 2021, and 2020, and changes during the year ended December 31, 2021, 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, 2020	493,127	$ 41.13	275,338	$ 54.45
Granted	295,240	$ 41.20	152,575	$ 48.53
Vested and settled	(191,082)	$ 44.50	—	$ —
Cancelled	(37,917)	$ 41.00	(104,832)	$ 63.97
Outstanding at December 31, 2021	559,368	$ 40.03	323,081	$ 48.56

Retirement of the Company's Former 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 former President and Chief Executive Officer, Brad Mason. 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. The Company did not recognize share-based compensation expense related to the Retirement Agreement for the years ended December 31, 2021 and 2020, and recognized approximately $6.5 million in expense during the year ended December 31, 2019.

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, 2021, 2020, and 2019, expenses incurred relating to the 401(k) Plan, including matching contributions, were approximately $2.8 million, $1.1 million, and $2.7 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, 2021, 2020, and 2019, were $1.2 million, $1.1 million, and $1.0 million, respectively.

Deferred Compensation Plans

Under Italian Law, our Italian subsidiary accrues deferred compensation on behalf of its employees, which is paid on termination of employment. The accrual for deferred compensation is based on a percentage of the employee's current annual remuneration plus an annual charge. Deferred compensation is also accrued for the leaving indemnity payable to agents in case of dismissal, which is regulated by a national contract and is equal to approximately 3.5% of total commissions earned from the Company. The Company's relations with its Italian employees, who represent 19.1% of total employees at December 31, 2021, 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, 2021, and 2020 was $1.3 million and $1.4 million, respectively, and represents the amount which would be payable if all the employees and agents had terminated employment at that date.

20. Income taxes

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

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2021	2020	2019
U.S.	$ (5,987)	$ 5,556	$ (24,890)
Non-U.S.	(7,508)	(5,924)	(2,159)
Income (loss) before income taxes	$ (13,495)	$ (368)	$ (27,049)

The provision for income taxes consists of the following:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2021	2020	2019
U.S.			
Current	$ (607)	$ (15,054)	$ (1,911)
Deferred	24,292	(29)	2,008
	23,685	(15,083)	97
Non-U.S.			
Current	1,009	1,382	1,931
Deferred	190	10,816	(615)
	1,199	12,198	1,316
Income tax expense (benefit)	$ 24,884	$ (2,885)	$ 1,413

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, 2021, 2020, and 2019, consist of the following:

	2021		2020		2019	
(U.S. Dollars, in thousands, except percentages)	Amount	Percent	Amount	Percent	Amount	Percent
Statutory U.S. federal income tax rate	$ (2,834)	21.0%	$ (77)	21.0%	$ (5,680)	21.0%
State taxes, net of U.S. federal benefit	(24)	0.2	1,151	(312.8)	1,043	(3.9)
Foreign rate differential, including withholding taxes	480	(3.6)	(147)	39.9	131	(0.5)
Valuation allowances, net	27,819	(206.1)	14,514	(3,944.0)	(165)	0.6
Research credits	(537)	4.0	(982)	266.8	(829)	3.1
Unrecognized tax benefits, net of settlements	(1,363)	10.1	(17,321)	4,706.8	(2,745)	10.1
Equity compensation	1,091	(8.1)	1,657	(450.3)	626	(2.3)
Executive compensation	456	(3.4)	375	(101.9)	1,504	(5.6)
Contingent consideration	(640)	4.7	(1,460)	396.7	5,678	(21.0)
Other, net	436	(3.2)	(595)	161.8	1,850	(6.7)
Income tax expense (benefit) /effective rate	$ 24,884	(184.4)%	$ (2,885)	784.0%	$ 1,413	(5.2)%

The Company paid cash relating to taxes totaling $4.8 million, less than $0.5 million, and $8.1 million for the years ended December 31, 2021, 2020, and 2019, respectively.

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

	December 31,	
(U.S. Dollars, in thousands)	2021	2020
Intangible assets and goodwill	$ 5,245	$ 2,475
Inventories and related reserves	17,097	17,585
Deferred revenue and cost of goods sold	3,888	4,035
Other accruals and reserves	3,082	4,061
Accrued compensation	7,784	8,734
Provision for expected credit losses	1,217	1,178
Net operating loss and tax credit carryforwards	42,546	42,569
Lease liabilities	5,691	6,033
Other, net	1,423	500
Total deferred tax assets	87,973	87,170
Valuation allowance	(76,725)	(50,496)
Deferred tax asset, net of valuation allowance	$ 11,248	$ 36,674
Withholding taxes	(10)	(40)
Property, plant, and equipment	(5,380)	(5,975)
Right-of-use lease assets	(5,165)	(5,617)
Deferred tax liability	(10,555)	(11,632)
Net deferred tax assets	$ 693	$ 25,042
Reported as:		
Deferred income tax assets	1,771	25,042
Deferred income tax liabilities (classified within other long-term liabilities)	(1,078)	—
Net deferred tax assets	$ 693	$ 25,042

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 domestic and certain foreign jurisdictions. The net increase in the valuation allowance of $26.2 million during the year principally relates to recognizing a full valuation allowance against the net deferred tax asset within the Company's U.S. operations as well as an increase in valuation allowance against deferred tax assets within the Company's Italian 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 increase in 2022 due to further losses in certain jurisdictions, offset by decreases related to the expiration of foreign net operating losses.

The Company has federal net operating loss carryforwards of $17.5 million and research and development credits of $2.2 million, including amounts from 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 $32.3 million, of which $20.9 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 $125.0 million that begin to expire in 2022, the majority of which relate to the Company's Italy, Netherlands, and Brazil operations.

Unremitted foreign earnings decreased from $53.7 million at December 31, 2020, to $50.0 million at December 31, 2021. The decrease is due to the impact of currency translation. As a result of the 2017 Tax Act, current year earnings have been deemed to be

repatriated. Those foreign subsidiary earnings that are subject to U.S. taxation as a component of Global Intangible Low Taxed Income (GILTI) under the Tax Act are included as a component of current tax expense. The Company's investment in foreign subsidiaries continues to be indefinite in nature; however, the Company may periodically repatriate a portion of these earnings to the extent that it does not incur significant additional tax liability.

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

The Company's unrecognized tax benefit was $3.5 million and $4.6 million for the years ended December 31, 2021, and 2020, respectively. The Company recorded net interest and penalties expense (benefit) on unrecognized tax benefits of $(0.4) million, $(5.4) million, and $(0.1) million for the years ended December 31, 2021, 2020, and 2019, respectively, and had approximately $0.8 million and $1.2 million accrued for payment of interest and penalties as of December 31, 2021, and 2020, 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 $0.4 million to $1.1 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, 2021, and 2020, is shown below:

(U.S. Dollars, in thousands)	2021	2020
Balance as of January 1,	$ 4,629	$ 16,904
Additions for current year tax positions	45	568
Increases for prior year tax positions	110	84
Settlements of prior year tax positions	—	(29)
Expiration of statutes	(1,322)	(12,898)
Balance as of December 31,	$ 3,462	$ 4,629

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 2017. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to 2015.

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 the 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, 2021, 2020, and 2019, 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,		
	2021	2020	2019
Weighted average common shares-basic	19,690,593	19,267,920	18,903,289
Effect of diluted securities:			
Unexercised stock options and employee stock purchase plan	—	51,951	—
Unvested time-based restricted stock units	—	71,847	—
Weighted average common shares-diluted	19,690,593	19,391,718	18,903,289

There were 1,711,323; 1,499,630; and 1,704,708 weighted average outstanding options, restricted stock, and market-based units not included in the diluted earnings per share computation for the years ended December 31, 2021, 2020, and 2019, respectively, because inclusion of these awards was anti-dilutive or, for market-based units, all necessary conditions had not been satisfied by the end of the respective period.

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Ernst & Young LLP
Dallas, TX

After his injury, professional surfer Koa Rothman was warned by his spine surgeons that he needed to have surgery or he would have to quit surfing. Koa chose to have an artificial cervical disc replacement procedure. His surgeon selected the M6-C artificial cervical disc and now, following his successful surgery, Koa is back surfing, jet skiing, and hiking in Hawaii. Koa states, "The M6-C disc definitely changed my life."

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