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, 2023

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.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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, 2023, as reported by the Nasdaq Global Select Market, was approximately $663.4 million.

As of March 1, 2024, 37,406,644 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. 2024 Annual 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, 2023
Table of Contents

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," "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 intentions, beliefs, and expectations regarding the anticipated benefits of the merger with SeaSpine Holdings Corporation ("SeaSpine"), including the anticipated synergies and cost-savings from the merger;
- 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 credit facilities 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 (including in connection with our merger with SeaSpine in January 2023) and our ability to make future acquisitions and successfully integrate any such future-acquired businesses;
- our anticipated trends and challenges in the markets in which we operate; and
- our expectations and beliefs regarding and the impact of investigations, claims, and litigation.

These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, estimates, and assumptions that are difficult to predict. Any or all forward-looking statements that we make may turn out to be wrong (due to inaccurate assumptions that we make or otherwise) and our actual outcomes and results may differ materially from those expressed in these forward-looking statements. Potential risks and uncertainties that could cause actual results to differ materially include, but are not limited to, those set forth in Part I, Item 1A under the heading "Risk Factors", Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this Annual Report and in any other documents incorporated by reference to this Annual Report. You should not place undue reliance on any of these forward-looking statements. Further, any forward-looking statement speaks only as of the date hereof, unless it is specifically otherwise stated to be made as of a different date. We undertake no obligation to update, and expressly disclaim any duty to update, our forward-looking statements, whether as a result of circumstances or events that arise after the date hereof, new information, or otherwise.

Trademarks

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

PART I

Item 1. Business

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

Company Overview

Orthofix is a leading global spine and orthopedics company with a comprehensive portfolio of biologics, innovative spinal hardware, bone growth therapies, specialized orthopedic solutions, and a leading surgical navigation system. Its products are distributed in more than 60 countries worldwide.

The Company is headquartered in Lewisville, Texas and has primary offices in Carlsbad, CA, with a focus on spine and biologics product innovation and surgeon education, and Verona, Italy, with an emphasis on product innovation, production, and medical education for orthopedics. The combined company's global research and development, commercial and manufacturing footprint also includes facilities and offices in Irvine, CA, Toronto, Canada, Sunnyvale, CA, Wayne, PA, Olive Branch, MS, Maidenhead, UK, Munich, Germany, Paris, France, and São Paulo, Brazil.

The Company was founded in Verona, Italy in 1980 and formally incorporated in 1987 in Curaçao as "Orthofix International N.V." In 2018, we completed a change in our jurisdiction of organization from Curaçao to the State of Delaware (the "Domestication") and changed our name to "Orthofix Medical Inc." As a result, we are a corporation existing under the laws of the State of Delaware.

The merger with SeaSpine was completed on January 5, 2023, via an all-stock merger of equals with SeaSpine continuing as a wholly-owned subsidiary of Orthofix following the transaction (the "Merger"). As a result of the Merger, each share of SeaSpine common stock issued and outstanding immediately prior to the closing of the Merger was converted into the right to receive 0.4163 shares of Orthofix common stock. The shares of common stock of Orthofix, as the corporate parent entity in the combined company structure, continue to trade on NASDAQ under the symbol "OFIX".

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 contained in our website or connected to our website is not incorporated by reference into this Annual Report. Our website is located at www.orthofix.com. Our SEC filings are also available on the SEC website at www.sec.gov.

Business Segments

Orthofix manages the business by two reporting segments, Global Spine and Global Orthopedics, which account for 85% and 15% of our total net sales in 2023, respectively. The chart below presents reported net sales, which includes product sales and marketing service fees, by reporting segment for each of the years ended December 31, 2023, 2022, and 2021.

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, enabling technologies, 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, and partnerships with dedicated and high-performing commercial sales channels. Growth initiatives include:

- A regular cadence of new and differentiated product launches supporting our spine implant and enabling technologies, biologics, and bone growth therapies portfolios
- Ongoing, global sales channel optimization and expansion
- 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 and enhance our spine portfolio
- Invest in the further development of our pre-clinical and clinical programs designed to generate peer-reviewed scientific evidence in support of our products
- Attracting, developing, and retaining key talent

Global Spine Principal Products

The Global Spine reporting segment is largely represented by two principal product categories, (i) Bone Growth Therapies and (ii) Spinal Implants, Biologics, and Enabling Technologies. Each of these product categories, and their significant components, 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"). Several devices in our portfolio 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. A new addition to our stimulation portfolio utilizes our low intensity pulsed ultrasound ("LIPUS"), a technology also supported by strong basic science and published clinical literature. Orthofix is the only manufacturer which offers both PEMF and LIPUS technologies. 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 Spinal Implants, we design, develop, and market a portfolio of motion preservation and fixation implant products for broad spectrum use throughout the entire spinal column. Such products are typically used to facilitate fusion in degenerative, minimally invasive, and complex spinal deformity procedures throughout the lumbar, thoracic, sacral, and cervical regions 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, including hospitals, ambulatory surgery centers ("ASC"), and out-patient hospitals.

Enabling Technologies

Within Enabling Technologies, we design, develop, and market a portfolio of navigation technologies including tracked surgical tools, intelligent software and imaging equipment based on Machine-Vision and optical innovations. Specifically, our 7D FLASH Navigation System with 7D Technology has redefined image guided surgery, delivering a navigation platform with meaningful benefits in spine and cranial procedures. The speed, accuracy, workflow efficiency, and intraoperative radiation-free safety profile of the 7D FLASH Navigation System delivers significant economic value, while eliminating the long-standing frustrations and challenges of traditional image guided navigation systems. We distribute these products globally through a network of direct sales representatives and distributors to facilitate pediatric, adolescent, and adult procedures in hospitals, ASCs, and out-patient facilities.

Biologics

Within the Biologics product category, we offer a portfolio of bone graft substitutes intended to address the key elements of bone regeneration that allow physicians to successfully treat a variety of spinal, orthopedic, and dental conditions. Our Biologics portfolio includes fiber-based and particulate demineralized bone matrices ("DBMs"), cellular bone allografts, collagen ceramic matrices, and synthetic bone void fillers in various forms with supporting graft delivery solutions to address a wide range of clinical applications. Distributed globally through a network of distributors and sales representatives, our portfolio is a mix of internally manufactured tissues and products as well as marketed tissue forms provided by MTF Biologics. The breadth of the product offering and data-supported product lines position us with greater access to facilities, including group purchasing organizations ("GPOs")/integrated delivery networks ("IDNs"), hospitals, and ASCs.

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

Bone Growth Therapies Products	
Product	**Primary Application**
CervicalStim Spinal Fusion Therapy	PEMF non-invasive cervical spinal fusion therapy used to enhance bone growth
SpinalStim Spinal Fusion Therapy	PEMF non-invasive lumbar spinal fusion therapy used to enhance bone growth
PhysioStim Bone Healing Therapy	PEMF non-invasive appendicular skeleton healing therapy used to enhance bone growth in nonunion fractures
AccelStim	LIPUS healing therapy used to enhance bone growth in certain fresh, distal radius, and tibial diaphysis fractures and nonunion fractures

Spinal Implants and Enabling Technologies Products	
Primary Application	**Product**
Posterior Spinal Fixation Procedures	Pedicle screw systems for open and MIS procedures and adult deformity procedures featuring modular technology and accompanying instrumentation designed to reduce the number of trays needed for surgery and that provides surgeons with multiple intra-operative options to facilitate posterior lumbar fixation. We also provide powerful instrumented compression and distraction of the spine. Products include our Mariner, Firebird, Firebird NXG, Janus, Daytona, Newport, and Phoenix product lines. These brands also include several different screw types including, cannulated, fenestrated, HA coated, and cortical cancellous. These options give surgeons a full portfolio of choices for their patients without having to utilize several different screw systems.
Artificial Cervical Disc Replacement Procedures	Our next-generation artificial disc, M6-C artificial cervical disc, developed to replace an intervertebral disc damaged by cervical disc degeneration is 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.

Artificial Lumbar Disc Replacement Procedures	Our next-generation artificial disc, M6-L artificial cervical 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. (Not available in the U.S.)
Anterior Lumbar Interbody Fusion ("ALIF") Procedures	A complete portfolio of ALIF products, including interbody spacers, disc preparation instruments, access systems, and plating/ fixation options. Our spacers come in a variety of material options including PEEK, PEEK Titanium composite ("PTC"), and 3D printed Titanium. Some of our product also contain U.S. Food and Drug Administration ("FDA") cleared Nano surface technology ("Nanovate") that is scientifically proven to upregulate osteogenic factors in vitro. The multiple material types allow surgeons to select the material best for their patients, and they come in a variety of footprints and lordotic options. The interbodies come with a large graft area to accommodate the addition of biologics to aid in the fusion process. Some of our interbodies include integrated fixation to eliminate the need for additional fixation. These options provide a complete list of options for the ALIF procedural category. Our main contributors to this category include Meridian, Waveform A, Reef A, and Pillar SA PTC.
Posterior Cervical Fixation Procedures	We provide spinal fixation systems with novel instrumentation and anatomically designed implants to provide a safe and effective solution designed to improve surgical flow when navigating through complex posterior cervical procedures. These products include a wide array of screws, rods, and instruments to aid surgeons in performing these procedures. Our products include Northstar OCT and Centurion.
Posterior Lumbar Interbody Fusion ("PLIF")/ Transforaminal Lumbar Interbody Fusion ("TLIF") Procedures	Our PLIF/TLIF portfolio includes a variety of interbodies as well as several disc prep and access options. The interbodies come in both straight and curved footprints to accommodate surgeons in placement of the interbodies, and a choice of materials from PEEK, PEEK Titanium Composite and 3D printed Titanium. Some of our product also contain FDA cleared Nanovate that is scientifically proven to upregulate osteogenic factors in vitro. Our main products in the static PLIF/TLIF interbodies are Waveform TA/TO, Reef TA/TO, and Forza. Our straight product category contains both traditional static interbodies as well as expandable options. These options include both our Forza XP and Explorer TO product lines. These expandable options allow surgeons to minimize their exposure and expand the interbody in-situ to the preferred height and lordosis that best suits their patient. To aid in access we also offer several retractor options with our latest screw-based retractor called Fathom. These retractors paired with our posterior disc prep options completes a surgeon’s need for all PLIF/TLIF procedures.
Lateral Lumbar Interbody Fusion ("LLIF") Procedures	The LLIF portfolio includes a full portfolio of interbodies, additional fixation options, retractor access systems and disc prep instrumentation. Our interbodies come in a variety of footprint and lordotic options as well as material types of PEEK, PEEK Titanium composite, and 3D printed Titanium. Our main LLIF interbody brands are Regatta Lateral and Waveform L. These interbodies can be paired with the Regatta plate to provide auxiliary fixation during the LLIF procedure. The Lattus Retractor is our newest market leading access retractor providing surgeons the ability to access the disc space and conduct the LLIF procedure. This pairs seamlessly with several lateral disc prep options that aid surgeons in completing their discectomy prior to interbody placement.
Anterior Cervical Discectomy and Fusion ("ACDF") Procedures	The ACDF portfolio includes interbodies with and without integrated fixation and plating systems to provide fixation of the anterior cervical spine. Like the rest of our portfolio our cervical interbodies come in a wide variety of

	footprints and lordotic options as well as material options giving surgeons the ability of choice to accommodate their patient populations. Our top producing cervical interbodies include, Waveform C, and Construx brands. The Shoreline product brand provides the ability to turn interbodies without integrated fixation into fixated spacers reducing time surgeons spend in the operating room and making it seamless to fixate interbodies into the disc space. When selecting an interbody without fixation an anterior cervical plate is needed. Our top brands of cervical plates are Admiral and Cetra. In addition to these options, we also offer several different disc and endplate preparation options to satisfy the ACDF procedure.
Revision Surgical Procedures	As an adjunct to our posterior lumbar fixation portfolio, we offer two main products, Mariner Outrigger and Connectors, that are designed to help surgeons tackle difficult revision cases. These sets are constructed with an industry leading number of connectors, specially designed rods, and instruments to aid in these cases. Giving surgeons a tremendous number of options is the key to the success of these sets.
SI Fusion Procedures	Firebird SI is a minimally invasive screw system that is intended for fixation of sacroiliac joint disruptions in skeletally mature patients. This has and continues to be a product differentiator as many competitors do not offer SI fixation options. Firebird SI is one of the only 3D printed Titanium products on the market and the only 3D printed product that also has Nanotechnology claims with our Nanovate technology.
Other procedures: Corpectomy, Laminoplasty, Jazz Bands	Outside of the main spinal procedural categories we also offer several products in areas such as corpectomy (VuMesh), laminoplasty (Newbridge), and a unique product, Jazz Bands. Jazz Bands provide a temporary short-term stabilization as a bond anchor to aid in the repair of bone fractures.
7D FLASH Navigation System with 7D Technology (Spine)	A machine-vision navigation platform for use in open and mini-open posterior spinal procedures that uses proprietary visible light technology coupled with advanced software algorithms to deliver a fast, efficient, cost-effective, and radiation free solution for spine surgery.
7D FLASH Navigation System with 7D Technology (Percutaneous)	A valuable enhancement to the 7D FLASH Navigation System to address percutaneous spinal procedures; the camera-based technology coupled with 7D Machine Vision algorithms maintain the same fast, accurate, and efficient surgical workflow as the Spine platform, while also providing an imaging agnostic solution to percutaneous posterior spine surgery.
7D FLASH Navigation System with 7D Technology (Cranial)	A module on the 7D FLASH Navigation System that utilizes 7D Machine Vision Technology for cranial surgery; the visible light technology allows for a completely contactless workflow, acquires hundreds of thousands of virtual fiducials using the patient's own anatomy, and results in nearly instantaneous cranial registrations to the skin or skull in almost any surgical position.
Biologics Technologies	
Product	**Primary Application**
Proprietary Technology	*Accell Bone Matrix ("ABM")* An open structured, dispersed form of DBM, which increases the bioavailability of bone proteins at an earlier time in the healing cascade; when combined with traditional DBM, both fibers and particulate forms, provides a biphasic release of growth factors to promote healing. Accell is a technology featured in several key DBM products.
Cellular Bone Matrixes ("CBM")	*Trinity Elite, Virtuos Lyograft*

	Comprised of demineralized cortical bone fibers and cancellous bone with retained cells, cellular allografts are used during surgery that is designed to aid in the success of a spinal fusion or bone fusion procedure. Provided in either a cryopreserved or shelf-stable form.
Demineralized Bone Fibers ("DBF")	*Strand, Strand Plus, Fiberfuse* DBFs are designed to facilitate and aid in fusion by maximizing osteoinductive content while providing an improved conductive matrix. Multiple compositions include 100% fibers, fibers with Accell Bone Matrix, and fibers mixed with cancellous bone. Provided in both putty and strip formulations.
Synthetics	*Cove, Mozaik* To address the synthetic market segment, this portfolio includes an advanced bioactive synthetic and a value-based offering to meet different customer profiles. Provided in both putty and strip formulations.
Procedure specific solutions	Market differentiated products focused on solving clinical problems tied to specific procedure techniques in spine for fusion. *Ballast, Ballast MT* Resorbable mesh filled with 100% DBM, or provided empty; aids in simplifying graft placement and prevents graft migration for posterolateral fusion. *NorthStar Facet Fusion, Flash Facet Fusion* Novel procedural solution for reproducible biologic placement within the facet joint for cervical and lumbar spine. Kit includes pre-shaped demineralized bone fibers with single-use instrumentation for facet prep and biologic delivery. *RAPID, O-Genesis* Reusable and sterile, single use options to aid in bone graft delivery to the surgical site.
Other	*Versashield* A thin hydrophilic amniotic membrane designed to serve as a wound covering and protective barrier for a variety of surgical demands.

Bone Growth Therapies — Spinal Therapy

Our bone growth therapy devices used in spinal applications are designed to enhance bone growth and improve the success rate of certain spinal fusion procedures 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 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 Android and Apple App Stores.

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.

The AccelStim device provides a safe and effective nonsurgical treatment to improve nonunion fracture healing and accelerate the healing of indicated fresh fractures. The device stimulates the bone's natural healing process through LIPUS waves to the fracture site.

Spinal Implants — Motion Preservation Solutions

Our M6-C cervical and M6-L lumbar artificial discs 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 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. In addition, we have initiated a U.S. 2-level investigational device exemption ("IDE") study for the M6-C artificial cervical disc, which is currently enrolling.

Spinal Implants — Spinal Fixation Solutions

We provide a wide range of implants and fixation products for use in spinal surgery, and we cover the entire spine from occiput to sacrum. See below for a discussion of our portfolio based on the segmentation of our internal franchise groups:

Cervical

Our cervical portfolio includes fixation, interbodies, plates, and motion preservation devices. Our interbody spacer brands and materials include PTC, Waveform, Reef, and Nanovate 3D printed titanium surface technologies. Each coming with different material, clinical, and handling characteristics that can be options for clinicians to make the proper choice for their patients. Some of our spacers also have the option for integrated fixation which eliminates the necessity for additional fixation. In addition to our spacers, our surgical grade titanium plating systems, Admiral and Cetra, allow for anterior fixation of the cervical spine. Lastly, for posterior fixation we offer two systems, Northstar OCT and Centurion, as well as a laminoplasty system, Newbridge. These systems are comprehensive systems comprised of rods, connectors, and screws that are implanted for posterior fixation.

Interbody

Our robust interbody group has options for every approach vector, including anterior lumbar, posterior lumbar, and lateral. Within each group there are several material types, including a thermoplastic compound called PEEK, 3D printed titanium with FDA approved Nanotechnology claims, and two different composites, Nanometalene and PTC, comprised of both PEEK and titanium. Our anterior lumbar portfolio has several different footprints and lordotic options as well as options for integrated fixation or plating. These brands include Waveform A, Reef A, Pillar SA PTC, Unity Lumbosacral Plating, and Meridian. Our lateral portfolio takes full advantage of our top-of-the-line retractor systems to gain access to the disc space. The lateral portfolio is complete with the highly competitive footprints and plating options as well. These brands include Skyhawk, Regatta L, and Waveform L, which are utilized in direct lateral, prone lateral, and anterior to the psoas procedures. Our posterior portfolio, utilized for PLIF and TLIF procedures, has two key segmentations, static and expandable. Our expandable posterior interbodies allow for a smaller incision and smaller exposure that then expands to create or fill the space of the disc space. Our expandable brands are Forza XP, our top performing interbody implant, and Explorer TO. In the static posterior interbodies, we have several brands serving all material types and offering both straight and curved footprints to aid in posterior procedures. Our brands are Forza, Forza PTC, Forza Ti, Waveform TA/TO, and Reef TA/TO.

Thoracolumbar

In our thoracolumbar franchise we have a complete line of fixation products for degenerative spinal conditions, as well as for complex deformity, midline, and revision cases. Our posterior brands are all modular, meaning surgeons have the option to select from several different screw shank varieties including, cannulated, fenestrated, HA coated, cortical cancellous, and a traditional dual lead option. This allows the surgeon to maintain the instrumentation of the parent system, but then select the proper screw shank for the patient, offering maximum clinical value. The Firebird/ Firebird NXG, Phoenix, and Mariner brands are available for open or minimally invasive procedures and have options such as connectors, mono axial screws, and many more instrumentation options to aid in a variety of cases. Also within this franchise group is our SI fixation product, Firebird SI, the first 3D printed SI fixation product and one of the only with Nanotechnology claims.

Enabling Technologies

Our machine vision 7D FLASH navigation platform is used in a variety of posterior spinal procedures, including degenerative, deformity, tumor, trauma, and revision surgery. The platform can be utilized in MIS/percutaneous, mini-open, or open techniques. The technology also offers a comprehensive cranial platform for use in cranial neurosurgery.

Our innovative 7D FLASH Navigation System with 7D Technology delivers a comprehensive navigation platform that utilizes visible light, machine-vision cameras, and intelligent software algorithms to create a 3D image within seconds for surgical navigation. The novel technology allows for a fast image reconstruction for surgical navigation with no disruption to surgeon workflow and eliminates radiation exposure during the procedure to the patient, surgeon, and operating room staff.

Our Spine Module is our leading product in the FLASH Navigation Portfolio with over 130 installations globally. Our recent launch of the FLASH Percutaneous Module has reached over 25 installations in the US. In 2023, we further enhanced the FLASH Percutaneous Module to include preplanning features, as well as integrating fixation systems such as Mariner MIS Posterior Fixation System, Phoenix MIS Posterior Fixation System, and the Fathom Pedicle Based Retractor System. Multiple new spinal reference frame fixation options were also launched in 2023 to accommodate spinal fusion procedures from cervical spine to pelvis. Further enhancements and new features to the Spine Module and Percutaneous Module are in development and are expected to launch in 2024.

In addition to these new products focused on spine, the FLASH Navigation Portfolio also includes our Cranial Module for use in cranial surgeries. The technology uses a completely contactless workflow, acquiring hundreds of thousands of virtual fiducials using the patient’s own anatomy, and results in nearly instantaneous cranial registrations to the skin or skull in almost any surgical position. In 2024, we anticipate the commercial launch of FLASH EVD (“Extra Ventricular Drainage”), a new mobile bed-side navigational system leveraging 7D Technology designed for fast and reliable EVD placement. Initial cadaveric testing has been completed and FLASH EVD is currently under regulatory review.

Biologics — Regenerative Solutions

Our biologics portfolio is focused on best-in-class bone grafting solutions from each of the major bone grafting categories - cellular allografts, DBMs, and synthetics. The breadth of the portfolio within each segment allows for a consultative approach with both physicians and hospitals to determine the best product based on clinical performance and price.

Our largest portfolio of products is within DBMs, which includes both putty and fiber-based forms that provide different handling and performance based on clinical applications. Leading this portfolio are Strand Plus, 100% DMB Fiber with Accell, Evo3/Evo3c, and DBM putty with Accell. ABM is a key differentiator within the DBM market. This internally processed, proprietary technology is an open structured, dispersed form of DBM, which increases the bioavailability of bone proteins at an earlier time in the healing cascade. When combined with traditional DBM, it provides a biphasic release of growth factors to promote healing.

Our cellular allografts portfolio features a market-leading graft with Trinity Elite and our newly released Virtuous Lyograft, both co-branded with MTF biologics. Trinity Elite, an allograft with viable cells, continues to be a market leader due to the long-standing clinical supported through various clinical studies. Virtuous Lyograft is particularly unique in that it is a first-of-its-kind, shelf-stable cellular allograft for spine and orthopedic procedures provided in a room-temperature, ready-to-use, moldable form.

Regarding synthetic solutions, our focus products are Cove and Mozaik. Cove, an advanced bioactive synthetic, is the newest introduction into this segment. Cove has a unique surface topography of the β-TCP and HA granule and has demonstrated the ability to grow bone in a muscle pouch. Additionally, Cove has handling characteristics ideal for ensuring graft placement remains where it is needed. The combination of Cove and Mozaik provides different value options within this portfolio to meet varying customer needs.

In addition to each of the major categories, Orthofix has continued to invest in products that address specific procedural and clinical needs. Our solutions address many of the issues that physicians see with graft delivery and containment within the surgical site. Several of our solutions address this through handling characteristics of product, shape and design, instrumentation to aid delivery, or even added materials to aid in graft containment. All of these solutions are to improve the ease of use and consistency of our products while driving better clinical outcomes.

We receive marketing fees through our collaboration with MTF for the Virtuous, Trinity Elite, FiberFuse, and certain other 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 Virtuous and Trinity Elite, and exclusive rights to market the FiberFuse tissues in the U.S.

Our other leading tissue forms and synthetics such as, Strand Plus, Strand, Evo3, Evo3c, Ballast, Cove, and Mozaik are all processed internally through IsoTis Orthobiologics. This completely integrated business unit allows for a continuous feedback cycle with research and development, marketing, manufacturing, and quality to ensure high-quality products delivered with consistent customer fulfillment.

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 and bovine collagen in certain countries.

Global Spine 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. We expect that the contribution of new, internally developed technologies and undefined external acquisitions will be the primary driver of future growth. In addition, we also have initiated a U.S. 2-Level IDE study for the M6-C artificial cervical disc.

Regarding our Bone Growth Therapy business, we have participated in research at the Wake Forest University Health Sciences, Chinese University of Hong Kong, 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, cartilage, meniscus, nerve, and efficacy of healing. From these efforts, some studies have been published in peer-reviewed journals. Among other insights, the studies illustrate positive effects of PEMF on callus formation and bone strength, meniscus and nerve injury repair, as well as proliferation and differentiation of cells involved in tissue regeneration and healing. Furthermore, we believe that the previous research work with Cleveland Clinic, the Chinese University of Hong Kong, and the University of Pennsylvania, allowing for characterization and demonstration of the Orthofix new 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.

Global Orthopedics

The Global Orthopedics reporting segment offers products and solutions for limb deformity correction and complex limb reconstruction with a focus on use in trauma, adult and pediatric limb reconstruction, and foot and ankle procedures. This reporting segment specializes in the design, development, and marketing of external and internal fixation orthopedic products that are

coupled with enabling digital technologies to serve the complete patient treatment pathway. We sell these products through a global network of distributors and sales representatives to hospitals, healthcare organizations, and healthcare providers.

Global Orthopedics Strategy

Our strategy for the Global Orthopedics reporting segment is to continue to offer pioneering limb reconstruction and deformity correction procedural solutions that address the entire patient treatment pathway.

Our key strategies in this segment are:

- 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 expansive pediatric product portfolio and support tools
- Leverage our cross-product OrthoNext digital platform, a uniquely developed pre and post planning software that allows our clinicians to pre-plan surgery for patients so they can start surgeries with a greater degree of confidence, reduce surgical times, enable better outcomes, and follow up post operatively to evaluate the success of their chosen surgical plan
- Expand our foot and ankle portfolio by building on our historical position as a company highly focused on addressing complex and challenging conditions and remaining at the forefront of innovation in helping surgeons and patients alike in the management of Charcot foot and ankle
- Promote and invest in our Fitbone intermedullary limb lengthening platform, which together with our external fixation products, offers surgeons internal and external solutions for limb lengthening and deformity correction
- Within the orthopedic trauma segment, continue to focus on open and complex fracture management, with a focus on providing single use sterile pack procedural solutions to reduce costs and drive surgical efficiencies
- Collaborate with physicians and healthcare partners to improve patients' lives through technology, digital transformation, clinical evidence, and our industry-leading medical education program, 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 patients' 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 and 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
TrueLok EVO	A modular circular external fixation system, available pre-assembled in sterile kits that features both radiolucent rings and struts to enable clear radiographic visualization and allow physicians to better assess bone anatomy both during surgery and in post-operative care
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, and is the only intramedullary limb lengthening system with an FDA-cleared pediatric indication
Pediatric Portfolio	Our pediatric solutions include a range of products and resources dedicated to pediatrics and young adults with bone fractures and deformities. With our 360° approach to the patient journey we provide dedicated tools to treat all stages of the healing process: collaterals, educational games, software applications, and patient apps for post-operative management Our pediatric solutions 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 first and market leading system for gradual correction of the growth plate; - The JuniOrtho Plating System; - The Rodeo Telescopic Nail to provide bone fixation in patients suffering from osteogenesis imperfecta
Galaxy Fixation System	A pin-to-bar system for temporary and definitive fracture fixation, in the upper and lower limbs. Available in sterile kits, 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. The latest version, Galaxy Gemini, includes a universal clamp and other updates to better streamline surgical procedures
Galaxy Fixation Shoulder	A unique solution for the treatment of proximal humeral fractures
Ankle Hindfoot Nail ("AHN")	A differentiated solution for hindfoot fusions that includes a revision option to address larger bone defects and more complex hindfoot pathologies
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 hip and knee arthroplasty
External Fixators	External fixation, including our limb-lengthening systems, ProCallus, XCaliber, Pennig, Radiolucent Wrist Fixators, and Calcaneal Fixator

LRS advanced Limb Reconstruction System	An external fixation solution for limb lengthening and deformity corrections, 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 and Fitbone Intramedullary Limb Lengthening System, enabling surgeons to accurately plan the deformity correction and osteotomy position as well as visualize the implant in relation to the anatomy

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 correct bone deformities, 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 or fusion 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, TrueLok Evo, the Galaxy and Galaxy Gemini Fixation Systems, 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.

The Fitbone Intramedullary Limb Lengthening System provides an internal option for limb lengthening of the femur and tibia and together with our external fixation solutions, provides Orthofix with the most complete limb reconstruction portfolio on the market. We are continuing to invest in the Fitbone technology platform in order to offer surgeons more solutions for deformity correction and bone defect management.

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 eight-Plate Plus.

Product Development

Our primary research and development facilities are located in Lewisville, Texas, Carlsbad, California, Toronto, Canada, and Verona, Italy.

We have a research and development organization dedicated to advancing our portfolio of spinal implants, biologics, orthopedic devices, and machine vision image guidance innovations through product development and clinical affairs programs. Our product development efforts employ an integrated team approach that involves collaboration between surgeons, our engineers, our machinists, and our regulatory personnel. We also work with leading hospital research institutions, surgeons, consultants, and certain non-profit organizations, such as MTF Biologics, 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.

For our spine and orthopedics products, our product development teams, in consultation with design surgeons, formulate a design for the product and then our machinists build prototypes for testing our prototyping development and testing operation at our facilities. We use a broad scope of technologies designed to allow us to meet the complex engineering requirements of customers. As part of the development process, surgeons test the implantation of the products in our in-house cadaveric laboratories, which aids in the design of new products intended to meet the needs of both the surgeon, the patient, and the healthcare ecosystem. Our team refines or redesigns the prototype as necessary based on the results of the product testing, allowing our team to perform rapid iterations of the design-prototype-test development cycle. Our clinical and regulatory personnel work in parallel with our product engineering personnel to facilitate regulatory clearances of our products. We believe that these product development efforts allow our team to provide solutions that respond to the needs of our surgeon customers and their patients.

Similar to the spine and orthopedics product development process, our software engineers, product managers, and design surgeons are working towards the full integration of our spinal implants and biologics product lines with our machine vision 7D FLASH Navigation System. This includes the design of specific software modules, features and tracked instruments designed to meet the needs of a wide range of procedures including, degenerative, complex, revision, minimally invasive and deformity spine procedures. In addition, we are also exploring opportunities to integrate the 7D FLASH Technology into a variety of adult and pediatric orthopedic applications.

For biologics, we plan to develop line extensions for our innovative biologics technologies that will continue to improve bone forming potential while addressing specific procedural requirements both in the spine field and in general orthopedic applications. We are investigating new product formulations in DBM, while continuously looking at process improvements within tissue processing. Our Biologics research and development team has experience in biomaterial sciences and bringing next generation technologies to market.

In 2023, 2022, and 2021, we incurred research and development expenses of $80.2 million, $49.1 million, and $49.6 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. Many of our products are covered by patents 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 found by a court to 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 the 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 a 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 March 2023)), the Office of Inspector General (HCCA-OIG “General Compliance Program Guidance” (November 2023)), 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; and
- Risk assessments to identify areas of compliance risk.

Government Regulation

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

Our research, development, 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 (the “FDCA”) 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, devices deemed 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, classified as class II devices and the instruments used with these products are generally classified as class I. Our 7D FLASH Navigation System is classified as class II and certain accessories thereto are classified as class I. Our Bone Growth Therapies products and the M6-C artificial cervical disc are currently classified as class III, and have been approved for commercial distribution in the U.S. through the PMA process. However, an FDA panel 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 (“MDR”) (Council Regulations 2017/745), which imposes strict requirements for the marketing and sale of medical devices, including new quality system and post-market surveillance requirements. The regulation, as amended in March 2023, provides a transition period for all currently approved medical devices prior to May 2021 (under the European Medical Device Directive) to meet the additional requirements, and for higher risk devices, this transition period was extended until December 2027 and until December 2028 for medium-and-lower risk devices. After this transition period, all medical devices marketed in the E.U. will require certification according to these new requirements. This regulation has required us to incur, and we expect to continue to incur, significant costs through the transition period and beyond to maintain compliance with the additional requirements. 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.

In the E.U., our products that contain human-derived tissue, including demineralized bone material, are not medical devices as defined in the MDR. They are also not medicinal products as defined in Directive 2001/83/EC of the European Parliament and of the Council of the E.U. Today, the regulations in the E.U. governing products that contain human-derived tissue, if applicable, vary from one E.U. member state to the next. Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the E.U., the approval process for human-derived cell or tissue-based medical products in the E.U. may be extensive, lengthy, expensive, and unpredictable.

Certain countries, as well as the E.U., have issued regulations that govern products that contain materials derived from animal sources. Regulatory authorities are particularly concerned with materials infected with the agent that causes bovine spongiform encephalopathy ("BSE"). These regulations affect our biomaterial products for the spine, which contain material derived from bovine tissue. Although we take steps designed to provide that our products are safe and free of agents that can cause disease, products that contain materials derived from animals, including our products, may become subject to additional regulation, or even be banned in certain countries, because of concern over the potential for prion transmission. Significant new regulations, a ban of our products, or a movement away from bovine-derived products because of an outbreak of BSE could have a material and adverse effect on our business or our ability to expand our business.

Within our Biologics product category, we market tissue for bone repair and reconstruction under the brand name Trinity ELITE, our allogeneic bone matrix comprised of cancellous bone containing viable cells and a demineralized cortical bone component. In addition, we provide demineralized cortical fiber technologies under the brand name FiberFuse, structural allografts for spinal fusion, and an amniotic membrane, which is a natural tissue barrier. These allografts are regulated under the FDA’s Human Cell, Tissues and Cellular and Tissue-Based Products ("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 Opus BA and the Opus MG lines 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 maintain an adequate inventory to avoid disruptions in product supply.

We also manufacture products derived from human tissue (demineralized bone tissue). Internally produced HCT/Ps may fall within the definition of a biological product, medical device, or drug regulated under the FDCA. These biologic, device, or drug HCT/Ps must comply both with the requirements exclusively applicable to HCT/Ps and with requirements applicable to biologics, devices or drugs, including premarket clearance or approval from the FDA.

Section 361 of the Public Health Service Act authorizes the FDA to issue regulations to prevent the introduction, transmission, or spread of communicable disease. HCT/Ps regulated as 361 HCT/Ps are subject to requirements relating to registering facilities and listing products with the FDA, screening and testing for tissue donor eligibility, Good Tissue Practice when processing, storing, labeling, and distributing HCT/Ps, including required labeling information, stringent record keeping, and adverse event reporting.

The American Association of Tissue Banks ("AATB") has issued operating standards for tissue banking. Accreditation is voluntary, but compliance with these standards is a requirement to become an AATB-accredited tissue establishment. In addition, some states in the U.S. have their own tissue banking regulations. We are AATB-accredited and licensed or have permits for tissue banking in California, Florida, New York, Maryland, and other states that require specific licensing or registration.

Procurement of certain human organs and tissue for transplantation is subject to the restrictions of the National Organ Transplant Act ("NOTA"), which prohibits the transfer of certain human organs, including skin and related tissue for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human tissue and skin. We reimburse tissue banks for their expenses associated with the recovery, storage, and transportation of donated human tissue they provide to us for processing. We include in our pricing structure amounts paid to tissue banks to reimburse them for their expenses associated with the recovery and transportation of the tissue, in addition to certain costs associated with the processing, preservation, quality control and storage of the tissue, marketing and medical education expenses, and costs associated with development of tissue processing technologies. NOTA payment allowances may be

interpreted to limit the amount of costs and expenses that we may recover in our pricing for our products, thereby reducing our future revenue and profitability.

For a further description of some of the risks associated with matters described above, 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. 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 the risks associated with the regulatory requirements described above, 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 9001:2015 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 each 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 were 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 the transparency laws of Massachusetts and Vermont.

Sales, Marketing and Distribution

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. Our products are distributed in more than 60 countries worldwide.

Reporting Segments and Product Categories

Orthofix manages the business by two reporting segments, Global Spine and Global Orthopedics, which account for 85% and 15%, respectively, of our total net sales in 2023.

Sales Network

Our U.S. sales network is generally comprised of a mix of direct sales representatives and independent distributors, dependent upon each product category. An increasing number of these independent distributors sell products for more than one product category. Our Bone Growth Therapies product category is largely supported by a hybrid distribution network of direct sales representatives and independent distributors, whereas our Spinal Implants, Biologics, and Orthopedics sales organizations primarily consist of regional and territory business managers who oversee a broad network of independent distributors and sales agents.

We market our Enabling Technologies portfolio through a direct sales force in the U.S. who collaborate with our independent sales agents to generate either a capital sale or to place systems and components in an account in a capital efficient manner in return for a long-term revenue commitment for our Spinal Implants and/or Biologics products.

In the U.S., we typically consign our Biologics products and consign or loan our Spinal Implants and Orthopedics implant sets to hospitals and independent sales agents, who in turn deliver them to the hospital for a single surgical procedure. In other instances, we leave sets with hospitals that are high volume users for use in multiple procedures. These sets typically contain the instruments, including disposables, and implants required to complete a surgery. Our Orthopedics business provides a wide array of single use pack procedural solutions, alleviating the burden of instrument sets.

We focus on entering distribution relationships in territories with a high potential for growth, where our partner will carry our products exclusively, except with respect to clinical markets that our products do not address. We believe these more exclusive relationships allow us to grow faster and in a more cost-effective manner in these territories over the long term. We also plan to continue to invest in additional instrument sets and marketing and education efforts to support the expansion of our independent sales agent footprint.

Outside the U.S., we employ direct sales representatives in certain markets and also contract with independent stocking distributors, who purchase our products directly from us and independently sell them. 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 and sales expansion efforts through comprehensive and specialized training workshops for physicians and sales specialists 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. To this end, we leverage the capacity of our hands-on cadaveric training laboratories located at our Lewisville, Texas, Carlsbad, California, and Wayne, Pennsylvania facilities to increase the number of training opportunities for surgeons and sales agents. In-person trainings are also held at our facility in Verona, Italy, and in various locations in Latin America. We believe training and education will help surgeons become adept with our products and techniques, thereby improving outcomes for their patients. 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.

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.

Competition

The global spine, biologics, orthopedics, and image guided surgery markets are highly competitive. We face significant competition in these markets from the spine and orthopedic divisions of large multinational medical device companies, established companies focused solely or primarily on spine and orthopedics, and from smaller, emerging companies focused on product innovation. These competitors are focused on bringing new technologies to market and acquiring technologies and technology licenses that directly compete with our products or that have potential product advantages that could render our products obsolete or noncompetitive.

Our Bone Growth Therapies product category competes principally with similar products marketed by Zimmer Biomet, DJO Global, and Bioventus. Our primary competitors in the Biologics, Enabling Technologies, and Spinal Implants markets include Alphatec Spine, Baxter, B. Braun, Brainlab, Bioventus, Cerapedics, DePuy Synthes Spine (a Johnson & Johnson company), Globus Medical, Medtronic, Stryker, XTANT Medical, ZimVie and various smaller public and private companies. For Global Orthopedics devices, our principal competitors include DePuy Synthes, Stryker, Smith & Nephew, Globus Medical, Enovis, Paragon 28, and OrthoPediatrics.

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

In general, raw materials essential to our businesses are readily available from multiple sources. For reasons of quality assurance, availability, or cost effectiveness, certain components and raw materials are available only from one supplier. Our relationships with suppliers that cannot be replaced without a material expense or delay are governed by written contracts, which are generally supply agreements. These agreements set forth the process by which we order components or raw materials, as applicable, from such suppliers (which process is either on a purchase order basis or based on quarterly or annual forecasts and in some cases require us to purchase minimum amounts) and the related fees for purchasing such components or raw materials. These agreements outline the rights of each party with respect to quality assurance, inspection, and compliance with applicable law and contain what we believe to be customary indemnification provisions for commercial agreements. Each of these agreements is entered into in the ordinary course of our business, is immaterial in amount and significance, and not a contract upon which our business is substantially dependent. In addition, we endeavor to maintain sufficient inventory of components and raw materials so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time.

Bone Growth Therapies, Spinal Implants, Enabling Technologies, and Global Orthopedic Products

We generally design, develop, assemble, test, and package our Bone Growth Therapies, Spinal Implants, Enabling Technologies, and Global Orthopedic products, and subcontract the manufacturing of a substantial portion of the component parts and instruments. Although certain aspects 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.

Our products are currently manufactured and assembled in the U.S., Canada, Germany, Spain, China, 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.

Biologics

Most of our Biologics products contain material derived from human or bovine tissue. We only source our raw materials from tissue banks registered with the FDA and accredited by the AATB. The donors are screened, tested, and processed by the tissue banks in accordance with FDA and AATB requirements. Additionally, each donor must pass FDA-specified bacterial and viral testing before raw material is distributed to us for further processing. We receive with each donor lot a certification of the safety of the raw material from the tissue bank’s medical director. As an added safety assurance, each lot of bone is released into the manufacturing process only after our quality assurance microbiologists screen the incoming bone and serology test records. During our manufacturing process, the bone particles are subjected to our proprietary process and terminally sterilized. This process is designed to support the safety and effectiveness of our DBM products.

The collagen used in our collagen ceramic matrix products is derived only from the deep flexor tendon of cattle less than 24 months old from New Zealand. The World Health Organization classifies different types of cattle tissue for relative risk of BSE transmission. Deep flexor tendon is in the lowest-risk category for BSE transmission (the same category as milk, for example) and is therefore considered to have a negligible risk of containing the agent that causes BSE (an improperly folded protein known as a prion).

We also 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. Our partnership with MTF allows us to exclusively market the Virtuos Lyograph, Trinity ELITE, FiberFuse and FiberFuse Strip, and certain other tissue forms and we have a non-exclusive marketing rights for our Opus BA and Opus MG Set synthetic, biologic offerings.

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

As of December 31, 2023, we had 1,634 employees worldwide. Of these, 1,271 were employed in the U.S. and 363 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 221 at December 31, 2023, 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 agreements.

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 of 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, a Company-provided basic life insurance and disability benefits, a corporate wellness program, an onsite fitness center for certain locations, 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 have developed a robust onboarding program for our newly hired associates that provides a comprehensive overview of our product portfolio and company history. 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 2023, we launched the second cohort of our Leadership Excellence and Acceleration Program ("LEAP") dedicated to fostering a culture of excellence and innovation through continued development of our key talent. All of our employees are encouraged to work with their managers to create individual plans to guide their career progression, taking advantage of learning curriculum and training opportunities to support their growth and continued success.

Diversity and Inclusion

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, Mental Health and Awareness Month, Diwali, Ramadan, Kwanzaa, Juneteenth, and Hispanic and Native American Heritage Months among others. 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, we incorporate into our new hire orientation, a training titled, "Hiring, Leading and Fostering Diverse and Inclusive Teams" for all hiring managers, leaders, and interviewers.

Health and Safety

Promoting and protecting the health and safety of our workforce is a top priority. Health and safety matters are responsibilities that we share throughout our organization. Employees' safety risks vary depending on the roles they perform, and we seek to tailor our safety efforts accordingly. Key areas of focus include corporate compliance with responsible hazardous waste management, recycling, emergency preparedness, and other safety programs aimed at reducing and eliminating serious injuries. We periodically measure employee sentiment through engagement surveys and share results and action plans with employees.

Community

We support a variety of charitable organizations through monetary and product donations, fundraising efforts, educational partnerships with colleges and universities, and local community development. Over the years, we have raised funds and awareness for disaster response organizations, veteran support groups, food and shelter insecurity groups, and health-related institutions among others. In 2023, we continued our corporate objective to measure our community outreach as part of our annual incentive program to encourage volunteerism. Under our "Orthofix Gives Back" initiative, our employees contributed 2,755 hours to programs, which exceeded our communicated goal. We proudly supported Steps2Walk, Ronald McDonald House, American Red Cross Disaster Relief, The Trevor Project, Boys & Girls Club, Toys for Tots, Meals on Wheels, Texas Scottish Rite Hospital for Children, SickKids Hospital, and various blood drives, food pantries and other charitable initiatives in the communities we live and work in around the world.

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. The disclosures in this Item 1A of this Annual Report under the heading "Risk Factors" relate to the combined company subsequent to the merger unless otherwise noted.

Summary of Risk Factors

The section provides a summary of many of the risks we are exposed to in the normal course of our business activities. The summary does not contain all of the information that may be important to you, and you should read the summary together with the more detailed discussion of risks set forth following this section as well as elsewhere in this report.

- Integration of the Orthofix and SeaSpine businesses is expected to be expensive and time-intensive and we may not be able to successfully integrate the businesses and/or realize anticipated synergies and benefits in a timely manner, if at all.
- We are subject to a wide range of requirements, regulations, and laws due to our international operations and related to the medical device industry in which we operate, the violation of any of which could subject us to adverse consequences.
- Ongoing healthcare reform initiatives and changes in third-party reimbursement policies and in the healthcare industry aimed at cost containment may adversely impact our business.
- We and certain of our suppliers are subject to extensive government regulation that increases our costs and could limit our ability to market or sell our products.
- Oversight of the medical device industry might affect the way we sell medical devices and compete in the marketplace.
- A FDA panel 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 are subject to requirements relating to hazardous materials which may impose significant compliance or other costs on us.
- The COVID-19 pandemic or other such global events, and the related effects thereof, could materially adversely affect, our operations, supply chain, manufacturing, product demand, product distribution, customers, and other business activities.
- Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if a GPO or similar entity excludes us from being a supplier.
- The industry in which we operate is highly competitive. New product developments and improvements by our competitors could make our products or technologies non-competitive or obsolete. Similarly, unless clinical studies demonstrate the safety and efficacy of our products, alone and relative to competitive products, our sales may be adversely affected.
- 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, including physicians, hospitals, and third-party payors.
- Clinical development is a lengthy and expensive process with an inherently uncertain outcome. Failure to successfully complete clinical trials and obtain regulatory approval for our product candidates on our anticipated timelines at reasonable costs to us, or at all, could have a material adverse effect on our business, operating results, and financial condition.
- If the third parties on which we rely to conduct our clinical studies do not perform as contractually required or expected, we may not obtain required approvals for or commercialize our products.
- Unfavorable negative publicity concerning both alleged improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of some of our products.
- We may not be able to successfully introduce new products to the market and, if we do, market acceptance or the market

size for our products may not be as we expect.

- There is no guarantee that regulatory authorities, U.S. or foreign, will grant clearance or premarket approval of our future products.
- Our success depends on our ability to successfully educate and train surgeons and their staff on the benefits, safety, cost-effectiveness, and proper use of our products.
- Security breaches, cyber-attacks, loss of data, and other disruptions to our information technology systems could compromise sensitive information and/or adversely affect our business.
- Our business could be harmed if any of our manufacturing, development, or research facilities are damaged and/or our manufacturing processes are interrupted.
- We depend on a limited number of third-party manufacturers and suppliers for manufacturing and processing activities, components, and raw materials. Failure of these third parties to perform as expected could result in substantial delays, increased costs or failures of our product development programs, or delayed or unsuccessful commercialization of our products.
- We may not maintain or grow our revenue if we are unable to maintain and expand our network of independent sales representatives and distributors.
- Our success depends on the services of key members of our senior management and other key employees.
- Our business is subject to economic, political, regulatory, and other risks associated with international sales and operations.
- Our failure to adequately protect or enforce our intellectual property rights could harm our position in the marketplace or prevent or impede the commercial protection of our products.
- We may be subject to third parties claims for infringement or misappropriation of their intellectual property.
- There have been substantial intellectual property disputes in our industry, which are inherently costly, divert significant time and other resources, and have unpredictable outcomes.
- We may have significant product or other liability exposure, some of which may not be covered by insurance, and if covered by insurance, such coverage may not cover all claims, which could require us to pay substantial sums.
- Our efforts to identify, pursue, and implement new business opportunities (including acquisitions) may be unsuccessful.
- We have invested in and provided loans to privately-held companies and if they are unsuccessful, we may lose all of our investment and our loans may not be repaid.
- Our sales volumes and our operating results may fluctuate.
- Our goodwill, intangible assets, and fixed assets are subject to potential impairment which could adversely affect our future financial results.
- We maintain a $150.0 million financing agreement secured by a pledge of substantially all of our property. Our failure to comply with the facility’s covenants could result in an event of default, which could adversely affect our future.
- We must maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows.
- Our future capital needs are uncertain and we may need to raise additional funds in the future, and such funds may not be available on acceptable terms or at all.
- Our business could be negatively impacted by corporate citizenship and environmental, social, and governance ("ESG") matters and/or our reporting of such matters.

Risks Related to our Merger with SeaSpine

The combined company may be unable to successfully integrate the Orthofix and SeaSpine businesses and realize the anticipated benefits of the merger.

The success of the merger will depend, in part, on our ability to successfully combine and integrate the Orthofix and SeaSpine businesses, and realize the anticipated benefits, including synergies, cost savings, innovation and technological opportunities, and operational efficiencies from the merger in a manner that does not materially disrupt existing customer, supplier, and employee relations and does not result in decreased revenues due to losses of, or decreases in orders by, customers. If we are unable to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits may not be realized fully or at all, or may take longer to realize than expected, and the value of our common stock may decline. Integration may result in additional and unforeseen expenses, and we may fail to realize some or all of the anticipated benefits of the merger on a timely basis or at all.

While we have successfully completed a number of integration activities since the closing of merger, the remainder of our integration activities may not be completed smoothly or successfully. The integration of the two companies may result in material challenges, including, without limitation:

- managing a larger, more complex combined medical device business;
- maintaining employee morale and retaining key management and other employees;
- retaining existing business and operational relationships, including customers, suppliers, and employees and other counterparties, as may be impacted by contracts containing consent and/or other provisions that may be triggered by the merger, and attracting new business and operational relationships;
- unanticipated issues in integrating the numerous systems involved in operating our businesses, including information technology, communications, purchasing, accounting, and finance, including integrating different accounting policies, sales, billing, payroll, employee benefits, regulatory compliance, and other systems;
- successfully addressing inconsistencies in standards, controls, procedures, or policies that could affect our ability to maintain relationships with customers and employees or to achieve the anticipated benefits of the merger;
- consolidating corporate and administrative infrastructures and eliminating duplicative operations;
- coordinating geographically separate organizations, systems, and facilities and addressing possible differences in business backgrounds, corporate cultures, and management philosophies; and
- unforeseen expenses or delays associated with the merger.

Many of these factors will be outside of our control, and any one of them could result in delays, increased costs, decreases in the amount of expected revenues, and other adverse impacts, which could materially affect our financial position, results of operations, and cash flows. In addition, the integration of certain operations requires the dedication of significant management resources, which may temporarily distract management's attention from our day-to-day business. Employee uncertainty and lack of focus during the integration process may also disrupt our business.

Our future results may be adversely impacted if we do not effectively manage our complex operations following the completion of the merger.

Following the merger, the size of our business has become significantly larger. Our ability to successfully manage this expanded business will depend, in part, upon our ability to design and implement strategic initiatives that address not only the integration of the Orthofix and SeaSpine businesses, but also the increased scale and scope of the combined business with its associated increased costs and complexity. There can be no assurances that we will be successful in integrating the businesses or that we will realize the expected operating efficiencies, cost savings, and other benefits as originally anticipated from the merger.

We have incurred substantial expenses related to the merger and we expect to incur substantial additional expenses related to the integration of the Orthofix and SeaSpine businesses.

We incurred substantial expenses in connection with the completion of the merger and we have incurred substantial expenses related to integration activities performed to date in order to integrate a large number of processes, policies, procedures, operations, technologies, and systems of Orthofix and SeaSpine. These activities remain ongoing for certain integration areas, thus

we expect to continue to still incur significant expenses associated with these activities in the future. The substantial majority of these costs are believed to be non-recurring expenses related to the transaction, our facilities, our personnel, and systems consolidation costs. We may incur additional costs or suffer loss of business under third-party contracts that are terminated or that contain change in control or other provisions that may be triggered by the completion of the merger, and/or losses of, or decreases in orders by, customers, and may also incur costs to (i) retain certain key management personnel and employees or (ii) associated with restructuring activities following the merger. These incremental transaction-related and integration costs may exceed the savings the combined company expects to achieve from the elimination of duplicative costs and the realization of other efficiencies related to the integration of the businesses, particularly in the near term and in the event there are material unanticipated costs. Factors beyond our control could affect the total amount or timing of these expenses, many of which, by their nature, are difficult to estimate accurately.

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. Also, previously effective internal controls may become inadequate over time because of changes in our business or operating structure, and we may fail to take measures to evaluate the adequacy of and update these controls, as necessary. 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 recently identified a material weakness in our internal control over financial reporting, and our business and stock price may be adversely affected if our internal control over financial reporting is not effective.

During the financial close for the quarter ended December 31, 2023, we identified a material weakness in our internal controls over financial reporting related to the operation of certain management review controls pertaining to business combinations and goodwill. A more complete description of this material weakness is included in Item 9A, "Controls and Procedures" in this Form 10-K.

As previously discussed, 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.

In recent years, both the U.S. and non-U.S. regulators have increased regulation, enforcement, inspections, and governmental investigations of the medical device industry, including increased U.S. government oversight and enforcement of the FCPA. Despite implementation of a comprehensive global healthcare compliance program, we may be subject to more regulation, enforcement, inspections, and investigations by governmental authorities in the future.

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, suspension or withdrawal of CE Certificates of Conformity, 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.

Federal and state government agencies, as well as private whistleblowers, have significantly increased investigations and enforcement activity under these laws. Violations of these laws are punishable by 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. Although we exercise care in structuring our sales and marketing practices, customer discount arrangements, and interactions with healthcare professionals to comply with these laws and regulations, we cannot provide assurance that government officials will not assert that our practices are not in compliance or that government regulators or courts will interpret those laws or regulations in a manner consistent with our interpretation. Even if an investigation is unsuccessful or is not fully pursued, we may spend considerable time and resources defending ourselves and the adverse publicity surrounding any assertion that we may have engaged in violative conduct could have a material and adverse effect on our reputation with existing and potential customers and on our business, financial condition, and results of operations.

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.

Maintaining and growing sales of our products depends on the availability of adequate coverage and reimbursement from third-party payors, both within and outside the U.S. 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, managed care organizations, and healthcare networks. Major third-party payors for medical services in the U.S. and internationally continue to work to contain health care costs, are increasingly challenging the policies and the prices charged for medical products and services, and have or may implement initiatives to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments, and managed-care arrangements. 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 continually review and revise their coverage and reimbursement policies for procedures involving the use of our products and can, without notice, eliminate or reduce coverage or 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.

For example, in the past, a major national third-party insurer in the U.S. reduced coverage (from all or most cases to limited indications) for biomechanical devices (e.g., spine cages) used in cervical fusion procedures, stating that the devices had not been shown to be more effective than bone graft. In addition, certain insurers have limited coverage for vertebral fusions in the lumbar spine and other insurers may adopt similar coverage decisions in the future. 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, and 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.

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.

With respect to international sales, market acceptance may depend, in part, upon the availability of coverage and reimbursement within prevailing healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country. As in the U.S., our products may not obtain coverage and reimbursement approvals in a timely manner, if at all, in a particular international market. In addition, even if we obtain country-specific coverage and reimbursement approvals, we could incur considerable expense to do so. Our failure to obtain such coverage and approvals would negatively affect market acceptance of our products in the international markets in which such failure occurs and the expenses incurred in connection with obtaining such coverage and approvals could outweigh the benefits of obtaining them.

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.

If governmental agencies and other third-party payors reduce coverage of and/or reimbursement for procedures using our products, our business, results of operations, and financial condition could be materially and adversely affected. Further, we cannot be certain that, under current and future payment systems, the cost of our products will be adequately incorporated into the overall cost of the procedure and, accordingly, we cannot be certain that the procedures performed with our products will be reimbursed at a cost-effective level, or at all.

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 must engage in extensive recordkeeping and reporting. For example, the Federal Medical Device Reporting regulation requires us to provide information to the FDA whenever there is evidence that reasonably suggests that a device may have caused or contributed to a death or serious injury or that a malfunction occurred that would be likely to cause or contribute to a death or serious injury upon recurrence.

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. Allegations may be made against us or against our suppliers, including donor recovery groups or tissue banks, claiming that the acquisition or processing of biomaterials products does not comply with applicable FDA regulations or other relevant statutes and regulations. Allegations like these could cause regulators or other authorities to investigate or take other action against us or our suppliers, or could cause negative publicity for us or our industry generally. If the FDA were to investigate us, because of an allegation or otherwise, and if the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, 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. The FDA may also recommend prosecution to the U.S. DOJ. Any notice or communication from the FDA regarding a failure to comply with applicable requirements, or negative publicity or product liability claims resulting from any adverse regulatory action, could have a material adverse effect on our development of new laboratory tests, business strategy, financial condition, results of operations, or cash flows.

We have little control over the ongoing compliance of our suppliers with applicable regulations. Their failure to comply may expose us to regulatory action and other liability, including fines and civil penalties, suspension of production, suspension or delay in new product approval or clearance, product seizure or recall, or withdrawal of product approval or clearance.

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.

In addition, until a completed mutual recognition agreement exists between Switzerland and the E.U., Switzerland will be considered a Third Country. The company has, however, pursued registration of certain key products in Switzerland under their new laws. Similar activities have been pursued in the United Kingdom in relation to Brexit.

Oversight of the medical device industry might affect the way we sell medical devices and compete in the marketplace.

The FDA, the U.S. Office of the Inspector General for the U.S. Department of Health and Human Services, the U.S. DOJ, and other regulatory agencies actively enforce regulations prohibiting the promotion of a medical device for a use that has not been cleared or approved by the FDA. Use of a device outside its cleared or approved indications is known as "off-label" use. Physicians may prescribe our products for off-label uses, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. However, if a regulatory agency determines that our promotional materials, training, or activities constitute improper promotion of an off-label use, the regulatory agency could request that we modify our promotional materials, training, or activities, or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine, and/or criminal penalties. Although our policy is to refrain from statements and activities that could be considered off-label promotion of our products, any regulatory agency could disagree and conclude that we have engaged in off-label promotion and, potentially, caused the submission of false claims. Moreover, the off-label use of our products may increase the risk of injury to patients, and, in turn, the risk of product liability claims. In addition, we may be subject to compliance actions, penalties, or injunctions if the FDA challenges one or more of our determinations that a product modification did not require new approval or clearance by the FDA.

A FDA panel 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 as the only company to provide both PEMF and LIPUS bone healing solutions. 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 Orthopedic 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. Persisting uncertainty with respect to the scope and effect of certain provisions of the ACA have made compliance costly. Any future changes to the ACA or other such legislation, depending on their nature, could affect rebates, prices, or the rate of price increases for health care products and services, or required reporting and disclosure, and could have an adverse effect on our ability to maintain or increase sales of any of our products and achieve profitability. We cannot predict the timing or impact of any future rulemaking or changes in the law. However, any changes that have the effect of reducing reimbursements for our products or reducing medical procedure volumes could have a material and adverse effect on our business, financial condition, and results of operations.

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. Foreign governmental regulations have become increasingly stringent and more common, and we may become subject to even more rigorous regulation by foreign governmental authorities. Numerous laws restrict, and in some cases prohibit, U.S. companies from directly or indirectly selling goods, technology, or services to people or entities in certain countries. In addition, these laws require that we exercise care in structuring our sales and marketing practices and effecting product registrations in foreign countries. Compliance with these regulations is costly.

The import and export of our products 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.

The sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies.

AdvaMed (U.S.), MedTech Europe (Europe), MEDEC and MedTech Canada (Canada), and MTAA (Australia), some of the principal trade associations for the medical device industry, have promulgated model codes of ethics that set forth standards by which its members should (and non-member companies may) abide in the promotion of their products in various regions. We have implemented policies and procedures for compliance consistent with the standards promulgated by these associations, and we train our sales and marketing personnel on our policies regarding sales and marketing practices. Nevertheless, the sales and marketing practices of our industry have been the subject of increased scrutiny from federal and state government agencies. We believe this trend will continue and that it could affect our ability to retain customers and other relationships important to our business.

For example, prosecutorial scrutiny and governmental oversight, at both the state and federal levels, over some major device companies regarding the retention of healthcare professionals have limited how medical device companies may retain healthcare professionals as consultants. Various hospital organizations, medical societies, and trade associations are establishing their own practices that may require detailed disclosures of relationships between healthcare professionals and medical device companies, or ban or restrict certain marketing and sales practices, such as gifts and business meals. In addition, the ACA, as well as certain state laws, require detailed disclosure of expenses incurred on behalf of and remuneration made to certain healthcare professionals and teaching hospitals, the publicity surrounding which could have a negative impact on our relationships with our customers and ability to seek input on product design or involvement in research. As a result of laws, rules, and regulations, or our own or third-party policies that prohibit or restrict interactions, or the growing perception that any interaction between healthcare professionals and industry are tainted, we may be unable to engage with our healthcare professional customers in the same manner or to the same degree, or at all, as would otherwise be the case, which may adversely affect our ability to understand our customer's needs and to incorporate into our development programs feedback that addresses these needs. If we are unable to develop and commercialize new products that address the needs of our physician customers and their patients, our products may not be broadly accepted in the marketplace, or at all, which would have a negative effect on our business, results of operations, and financial condition.

We are subject to requirements relating to hazardous materials which may impose significant compliance or other costs on us.

Our research, development, and manufacturing processes involve the controlled use of certain hazardous materials. For example, our allograft bone tissue processing may generate waste materials that in the U.S. are classified as medical waste. In addition, we lease facilities at which hazardous materials could have been used. Because of the foregoing, we are subject to federal, state, foreign, and local laws and regulations governing the use, manufacture, storage, handling, treatment, remediation, and disposal of hazardous materials and certain waste products.

Although we believe that our procedures for handling and disposing of hazardous materials comply with applicable laws as currently in effect, we cannot eliminate the risk of accidental contamination or injury from these materials. In addition, under some environmental laws and regulations, we could also be held responsible for all of the costs relating to any contamination at our past or present facilities and at third-party waste disposal sites, even if such contamination was not caused by us. If an accident occurs, state or federal or other applicable authorities may curtail our use of these materials and interrupt our business operations. In addition, if an accident or environmental discharge occurs, or if we discover contamination caused by prior operations, including by prior owners and operators of properties we acquire, we could be liable for cleanup obligations, damages, and fines. Any related liability could exceed our resources. If such unexpected costs are substantial, this could significantly harm our financial condition and results of operations. We carry no insurance specifically covering environmental claims relating to the use of hazardous materials.

Risks Related to our Business and Industry

The COVID-19 pandemic and related supply chain and raw material disruptions previously had material adverse impacts to our global operations and financial condition. Other such global events could similarly have a 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 temporarily led to a global shortage of semiconductor chips, which are used in certain of our products. This shortage was primarily caused by manufacturers experiencing shutdowns or slowdowns during the pandemic, and it took several fiscal quarters for normalized capacity to return. In addition, limitations in key raw material supplies could also cause semiconductor chip and other component shortages potentially in the future. To the extent such shortages are experienced, particularly on a longer-term basis, this could adversely affect our ability to procure key 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 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 trend toward healthcare cost containment through aggregating purchasing decisions and industry consolidation, along with the growth of managed care organizations, all of which has placed increased emphasis on the delivery of more cost-effective medical therapies. For example:

- There has been consolidation among healthcare facilities and purchasers of medical devices, particularly in the U.S. One of the results of such consolidation is that GPOs, IDNs, and large single accounts use their market power to consolidate purchasing decisions, which intensifies competition to provide products and services to healthcare providers and other industry participants, resulting in greater pricing pressures and the exclusion of certain suppliers from important market segments. For example, some GPOs negotiate pricing for its member hospitals and require us to discount, or limit our ability to increase, prices for certain of our products. In particular, certain of our DBM products are priced at a premium to competitors' DBM products and a significant price reduction could result in a material adverse effect on our profitability.
- Physicians increasingly have moved from independent, out-patient practice settings toward employment by hospitals and other larger healthcare organizations, which align physicians’ product choices with their employers’ price sensitivities and adds to pricing pressures. Hospitals have introduced and may continue to introduce new pricing structures into their contracts to contain healthcare costs, including fixed price formulas and capitated and construct pricing.
- Certain hospitals provide financial incentives to doctors for reducing hospital costs (known as gainsharing), rewarding physician efficiency (known as physician profiling), and encouraging partnerships with healthcare service and goods providers to reduce prices.
- Existing and proposed laws, regulations, and industry policies, in both domestic and international markets, regulate or seek to increase regulation of sales and marketing practices and the pricing and profitability of companies in the healthcare industry.

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, IDNs, 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.

In addition, the largest device companies with multiple product franchises have increased their effort to leverage and contract broadly with customers across franchises by providing volume discounts and multi-year arrangements that could prevent our access to these customers or make it difficult (or impossible) to compete on price.

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. Our competitors may also have: stronger intellectual property portfolios; broader spine surgery product offerings and products supported by more extensive clinical data; more established distribution networks; entrenched relationships with physicians; significantly greater name recognition and more recognizable trademarks for products similar to the products we sell; more established relationships with healthcare providers and payors; greater experience in obtaining and maintaining FDA and other regulatory clearances or approvals for products and product enhancement; and greater experience in launching, marketing, and selling products than we do. Many of our competitors specialize in a specific product or focus on a particular market segment, making it more difficult for us to increase our overall market position.

The frequent introduction by competitors of products that are, or claim to be, superior to our products, or that are alternatives to our existing or planned products may also create market confusion that may make it difficult to differentiate the benefits of our products over competing products. In addition, the entry of multiple new products and competitors may lead some of our competitors to employ pricing strategies that could adversely affect the pricing of our products and pricing in the spine market generally.

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. Market acceptance for any of our products requires, among other things, that we timely secure regulatory clearance and/or approval; demonstrate the value of our products, both to our physician customers and payors, which may require that we collect clinical data and/or conduct clinical studies; effectively educate and train our physician customers and their staff on the proper use of our products; obtain and maintain coverage and adequate reimbursement for our products, both within and outside the U.S., including under Medicare and Medicaid and from private payors; attract and retain a network of independent sales agents and stocking distributors focused on neurophysicians and orthopedic spine physicians; develop and execute effective marketing strategies; protect the proprietary positions of our products, including through patent protection; and consistently produce quality products in sufficient quantities to meet demand. Significant risks are associated with each of these activities and other activities required to achieve market acceptance of both our current and future products, including risks inherent in collaborations, or use of nascent manufacturing or imaging techniques, such as additive processing (more commonly known as 3D printing) or advanced optical technologies and machine version-based registration algorithms. 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.

Clinical studies are expensive and subject to extensive regulation and their results may not support our product candidate claims or may result in the discovery of adverse effects.

In developing new products or new indications for, or modifications to, existing products, we may conduct or sponsor pre-clinical testing, clinical studies, or other clinical research. We are conducting post-market clinical studies of some of our products to gather information about their performance or optimal use. The data collected from these clinical studies may ultimately be used to support additional market clearance or approval for these products or future products. If any of our new products require premarket clinical studies, these studies are expensive, the outcomes are inherently uncertain, and they are subject to extensive regulation and review by numerous governmental authorities, both in the U.S. and abroad, including by the FDA and, if federal funds are involved or if an investigator or site has signed a federal assurance, are subject to further regulation by the Office for Human Research Protections and the National Institutes of Health. For example, clinical studies must be conducted in compliance with FDA regulations, local regulations, and according to principles and standards collectively called “Good Clinical Practices.” Failure to comply with applicable regulations could result in regulatory and legal enforcement action, including fines, penalties, suspension of studies, and also could invalidate the data and make it unusable to support an FDA submission. Even if any of our future premarket clinical studies are completed as planned, we cannot be certain that their results will support our product candidates and/or proposed claims or that the FDA or foreign authorities and Notified Bodies will agree with our interpretation and conclusions regarding the data they generate. Success in pre-clinical studies and early clinical studies does not ensure that later clinical studies will succeed, and we cannot be sure that the results of later studies will replicate those of earlier or prior studies. The clinical study process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product candidate and may delay development of others. Any delay or termination of our clinical studies will delay the filing of our product submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patient subjects enrolled in our clinical studies of our marketed products will experience adverse

side effects that are not currently part of the product candidate's profile and, if so, these findings may result in lower market acceptance, which could have a material and adverse effect on our business, results of operations, and financial condition.

If the third parties on which we rely to conduct our clinical studies and to assist us with pre-clinical development do not perform as contractually required or expected, we may not obtain regulatory clearance, approval, or a CE Certificate of Conformity for our products or be able to successfully commercialize our products.

We often must rely on third parties, such as contract research organizations, medical institutions, clinical investigators, and contract laboratories, to assist in conducting our clinical studies and other development activities. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory obligations, or meet expected deadlines, or if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to failing to adhere to clinical protocols, to applicable regulatory requirements or otherwise, our pre-clinical development activities and clinical studies may be extended, delayed, suspended, or terminated. Under these circumstances, we may not be able to obtain regulatory clearance/approval or a CE Certificate of Conformity for our products or be able to successfully commercialize our products on a timely basis, if at all, and our business, operating results, and prospects may be materially and adversely affected.

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

A portion of 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.

In addition, procurement of certain human organs and tissue for transplantation is subject to the NOTA, which prohibits the transfer of certain human organs, including skin and related tissue, for valuable consideration, but permits the reasonable payment associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of human tissue and skin. If we were to be found to have violated NOTA's prohibition on the sale or transfer of human tissue for valuable consideration, we would potentially be subject to criminal enforcement sanctions, which could materially and adversely affect our results of operations.

Because of the absence of a harmonized regulatory framework and the proposed regulation for advanced therapy medicinal products in the E.U., as well as for other countries, the approval process in the E.U. for human-derived cell or tissue-based medical products could be extensive, lengthy, expensive, and unpredictable. Among others, some of our Biologics products are subject to E.U. member states' regulations that govern the donation, procurement, testing, coding, traceability, processing, preservation, storage, and distribution of HCT/Ps. These E.U. member states' regulations include requirements for registration, listing, labeling, adverse-event reporting, and inspection and enforcement. Some E.U. member states have their own tissue banking regulations, including new requirements related to COVID-19 and donor screening. Non-compliance with various regulations governing our products in any E.U. member state could result in the banning of our products in such member state or enforcement actions being brought against us, which could have a material and adverse effect on our business, results of operations, and financial condition.

Unfavorable media reports or other negative publicity concerning both alleged improper methods of tissue recovery from donors and disease transmission from donated tissue could limit widespread acceptance of some of our products.

Unfavorable reports of improper or illegal tissue recovery practices, both in the U.S. and internationally, as well as incidents of improperly processed tissue leading to the transmission of disease, may affect the rate of future tissue donation and market acceptance of technologies incorporating human tissue. In addition, negative publicity could cause the families of potential donors to become reluctant to donate tissue to for-profit tissue processors. For example, the media has reported examples of alleged illegal harvesting of body parts from cadavers and resulting recalls conducted by certain companies selling human tissue-based products affected by the alleged illegal harvesting. These reports and others could have a negative effect on our tissue regeneration business.

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.

To be and remain competitive, we need to continue to make improvements in our products, develop new products, introduce our products into new markets, and successfully respond to technological advances. Doing so is technologically challenging and involves

significant risks and uncertainty. Despite our planning, the process of developing and introducing new products (including product enhancements) is inherently complex, uncertain, and involves risks. The success of any of our new product offerings or enhancement or modification to our existing products will depend on several factors, including our ability to:

- properly identify and anticipate physician and patient needs;
- develop new products, enhancements, or modifications in a timely manner;
- obtain regulatory clearance and/or approvals for new products or product enhancements or modifications in a timely manner;
- achieve timely alpha and/or full commercial launches of new products;
- provide adequate training to potential users of new products and product enhancements or modifications;
- receive adequate reimbursement approval of third-party payors such as Medicaid, Medicare, and private insurers;
- gain broad market acceptance (including by physicians); and
- develop an effective marketing and distribution network.

In addition, competitors could develop products that are more effective, less expensive to manufacture, priced more competitively, or that are ready for commercial introduction before our products. The introduction of new products by our competitors may lead us to reduce the prices of our products, result in reduced margins or loss of market share, and/or render our products obsolete or noncompetitive.

These risks make it inherently difficult to forecast and predict the future net sales of our products. If we cannot develop technically and commercially viable new products and enhancements or modifications to our existing products on a consistent basis and before our competitors, our prospects could be materially and adversely affected. In addition, 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.

It is also important that we carefully manage our introduction of new products and enhancements or modifications to our existing products. If potential customers delay purchases until new or enhanced or modified products are available, it could negatively impact our sales. In addition, to the extent we have excess or obsolete inventory as we transition to new or enhanced or modified products, it would result in margin reducing write-offs for obsolete inventory, and our results of operations may suffer.

There is no guarantee that the FDA will grant 510(k) clearance or premarket approval, or that equivalent foreign regulatory authorities will grant the foreign equivalent, of our future products, and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

In general, unless an exemption applies, a medical device and modifications to the device or its indications must receive either premarket approval or premarket clearance from the FDA before it can be marketed in the U.S. While in the past we have received such clearances, we may not succeed in the future in receiving approvals and clearances in a timely manner, or at all. The process of obtaining approval or clearance from the FDA and comparable foreign regulatory agencies for new products, or for enhancements or modifications to existing products, could:

- take significant time;
- require the expenditure of substantial resources;
- involve rigorous and expensive pre-clinical and clinical testing, as well as post-market surveillance;
- involve modifications, repairs, or replacements of our products; and
- result in limitations on the indicated uses of our products.

Some of our new products will require FDA 510(k) clearance or approval of a PMA prior to being marketed. Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. Similarly, modifications to PMA-approved products may require submission and approval of a PMA supplement. The FDA requires every manufacturer to determine whether a new 510(k) or PMA is needed in the first instance, and the FDA has issued guidance on assessing modifications to 510(k)-cleared and PMA-approved devices to assist manufacturers with

making these determinations. However, the FDA may review any such determination and the FDA may not agree with our determinations regarding whether new clearances or approvals are necessary. We have modified some of our 510(k)-cleared products and have determined, based on our understanding of FDA guidance, that certain changes did not require new 510(k) clearances. If the FDA disagrees with our determination and requires us to seek new 510(k) clearances, or PMA approval, for modifications to our cleared products, we may have to stop marketing or distributing our products, we may need to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. Significant delays in receiving clearance or approval, or failing to receive clearance or approval for our new products would have a material and adverse effect on our ability to expand our business.

Outside the U.S., clearance or approval procedures can vary among countries and can involve additional product testing and validation and additional administrative review periods. The time required to obtain clearance or approval in other countries might differ from that required to obtain FDA clearance or approval. The regulatory process in other countries may include all of the risks to which we are exposed in the U.S., as well as other risks. Favorable regulatory action in one country does not ensure favorable regulatory action in another, but a failure or delay in obtaining regulatory clearance or approval in one country may have a negative effect on the regulatory process in others. Failure to obtain clearance or approval in other countries or any delay or setback in obtaining such clearance or approval have a material and adverse effect on our business, including that our products may not be cleared or approved for all indications requested, which could limit the uses of our products and have an adverse effect on product sales.

In the European Economic Area ("EEA"), we must inform the Notified Body that carried out the conformity assessment of the medical devices we market or sell in the EEA of any planned substantial change to our quality system or any significant change to our devices. The Notified Body will then assess the change and verify whether it affects the products' conformity with the Essential Requirements or the conditions for the use of the device. If the assessment is favorable, the Notified Body may issue a new CE Certificate of Conformity or an addendum to the existing CE Certificate of Conformity. If it is not, we may not be able to continue to market and sell the applicable product in the EEA, which could have a material and adverse effect on our business, results of operations and financial condition.

We cannot be certain that we will receive required approval or clearance from the FDA and foreign regulatory agencies for new products, including modifications to existing products, on a timely basis, or at all. Failing to receive approval or clearance for new products on a timely basis would have a material and adverse effect on our financial condition and results of operations.

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 physicians 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 physicians, consistent with the AdvaMed Code and the MedTech Code, we organize regular multilingual teaching seminars in multiple locations. However, convincing physicians to dedicate the time and energy necessary for adequate training is challenging, and we may not be successful in our efforts to educate the medical community and properly train physicians. Physicians who do not use our products may be hesitant to do so for the following or other reasons:

- lack of experience with our products, techniques, or technologies, or with the equipment necessary to use any of the foregoing;
- existing relationships with those who sell competitive products;
- the time required for physician and medical staff education and training on new products, techniques, and equipment and technologies;
- lack or perceived lack of clinical evidence supporting patient benefit relative to competing products;
- our products not being included on hospital formularies, in IDNs, or on GPO preferred vendor lists;
- less attractive coverage and/or reimbursement within healthcare payment systems for our products and procedures compared to other products and procedures;

- other costs associated with introducing new products and the equipment necessary to use new products; and
- perceived risk of liability that could be associated with the use of new products, techniques, or technologies.

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.

In addition, we believe recommendations and support of our products by influential physicians are essential for market acceptance and adoption. If we do not receive support from such physicians or long-term data does not show the benefits of using our products, physicians may not use our products. If we are not successful in convincing physicians of the merits of our products, we may not maintain or grow our sales or achieve or sustain profitability.

Relatedly, although we believe our training methods for physicians are conducted in compliance with FDA and other applicable regulations developed both nationally and in third countries, if the FDA or other regulatory agency determines that our training constitutes promotion of an unapproved use or promotion of an intended purpose not covered by the CE mark affixed to our products or FDA approved labeling, they could request that we modify our training or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine, and/or criminal penalty.

Sales of, or the price at which we sell, our products may be adversely affected unless the safety and efficacy of our products, alone and relative to competitive products, is demonstrated in clinical studies.

Generally, we have obtained 510(k) clearance to manufacture, market, and sell the products we market in the U.S. and the right to affix the CE mark to the products we market in the EEA. To date, we have not been required to generate new clinical data to support our 510(k) clearances, CE marks, or product registrations in other countries. However, the E.U. Medical Device Regulations, which replaced the prior medical device directives in May 2021, require submission of certain pre- and post-market data to maintain our CE marks. Additionally, we recently completed an analysis of which of our product systems will require submission of clinical data pursuant to MEDDEV 2.7.1 rev 4, which sets forth the EC’s guidance on the clinical evaluation of medical devices. Accordingly, and in line with our vision to deliver clinical value, we have commenced clinical data collection activities for certain of our marketed products as more fully described elsewhere in this "Risk Factors" section.

In part due to the increased emphasis on the delivery of more cost-effective treatments, purchasing decisions of our customers increasingly will be based on clinical data that demonstrates the value of our products or the effectiveness of our products relative to others. Conducting clinical studies is expensive and time-consuming and outcomes are uncertain. See “Clinical studies are expensive and subject to extensive regulation and their results may not support our product candidate claims or may result in the discovery of adverse effects,” above. We may elect not to, or may be unable to, fund the clinical studies necessary to generate the data required for all of our products to compete effectively, in part due to the breadth of our product portfolio. Currently, we do not expect to undertake such clinical studies for all of our products and only expect to do so where we anticipate the benefits will outweigh the costs on a risk-adjusted basis. However, even when we elect and are able to fund such clinical studies on one or more of our products, such studies may not succeed. Data we generate may not be consistent with our existing data and may demonstrate less favorable safety or efficacy, which could reduce demand for our products and negatively impact future sales. Neurophysicians and orthopedic spine physicians may be less likely to use our products if more robust, or any, clinical data supporting the safety and efficacy of competing products is available. If we are unable to or unwilling to generate clinical data supporting the safety and effectiveness of our products, our business, results of operations and financial condition could be materially and adversely affected. Further, future patient studies or clinical experience may indicate that treatment with our products does not improve patient outcomes.

With the passage of the American Recovery and Reinvestment Act of 2009, funds have been appropriated for the U.S. Department of Health and Human Services’ Healthcare Research and Quality to conduct comparative effectiveness research to determine the effectiveness of different drugs, medical devices, and procedures in treating certain conditions and diseases. Some of our products or procedures performed with our products could become the subject of such research. It is unknown what effect, if any, this research may have on our business. Further, future research or experience may indicate that treatment with our products does not improve patient outcomes or improves patient outcomes less than we initially expected. Such results would reduce demand for our products, affect sustainable reimbursement from third-party payors, significantly reduce our ability to achieve expected revenue, and could cause us to withdraw our products from the market and could prevent us from sustaining or increasing profitability. Moreover, if future results and experience indicate that our products cause unexpected or serious complications or other unforeseen negative effects, we could be subject to significant legal liability, negative publicity, and damage to our reputation, and we could experience a dramatic reduction in sales of our products, all of which would have a material adverse effect on our business, financial condition, and results of operations. The spine medical device market has been particularly prone to potential

product liability claims that are inherent in the testing, manufacture, and sale of medical devices and products for spine surgery procedures.

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, fill and ship customer orders on a timely basis, coordinate our sales activities across all of our products and services, and 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 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 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 information technology systems and infrastructure while maintaining the reliability and integrity of our information technology systems and infrastructure. An expansion of our information technology 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 information technology 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 integrating such upgrades or new technology. 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 and could have a material adverse effect on our business, financial condition, and results of 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 the greater of 20 million Euros or 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 are also subject to the California Consumer Privacy Act (the "CCPA"), which went into effect in January 2020. In November 2020, California passed the California Privacy Rights Act (the "CPRA"), which builds on the CCPA and expands consumer privacy rights to more closely align with the GDPR. The CPRA went into effect on January 1, 2023, and applies to information collected on or after January 1, 2022. The CCPA and CPRA, among other things, create new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also created a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. It remains unclear what, if any, additional modifications will be made to the CPRA by the California legislature or how it will be interpreted. 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 have seen 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 hospitals 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.

If any of our manufacturing, development, or research facilities are damaged and/or if our manufacturing processes are interrupted, we could experience supply disruptions and/or lost revenues and our business could be seriously harmed.

Damage to our manufacturing, development, or research facilities, or disruption to our business operations for any reason, including due to natural disaster (such as earthquake, wildfires, and other fires or extreme weather), power loss, communications failure, unauthorized entry, or other events, such as a flu or other health epidemic (such as the result of the COVID-19 pandemic), could cause us to discontinue development and/or manufacturing of some or all of our products for an undetermined period of time. The property damage and business interruption insurance coverage on these facilities that we maintain might not cover all losses under such circumstances, and we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs. If our facilities were damaged, they could be difficult to replace and could require substantial lead time to repair or replace. In particular, we manufacture certain of our biologics products in one facility in Irvine, California, and any damage to that facility could adversely affect our ability to timely satisfy demand for those products. Out of an abundance of caution, in October 2020, we relocated part of our Biologics finished goods inventory from our Irvine facility to our Carlsbad office due to the threat of the Silverado Fire that was causing evacuations throughout Orange County, California. Disruptions to our business operations may result from damage to the facilities of, or disruption to the business operations of our suppliers. For example, if we are unable to obtain disposables or other materials required to maintain "clean room" sterility in our Irvine facility, we may be unable to continue to manufacture products at that facility, which products accounts for a significant amount of our total

revenue. Any significant disruption to our manufacturing operations and to our ability to meet market demand likely would have an adverse impact on our sales and revenues as key stakeholders, including our independent sales agents and stocking distributors and physician customers, transition to what they perceive as more reliable sources of products.

We depend 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.

We depend on a limited number of third-party suppliers for processing activities, components and raw materials and losing any of these suppliers, or their inability to provide us with an adequate supply of materials that meet our quality and other requirements, could harm our business.

Outside suppliers, some of whom are sole-source suppliers, provide us with products, raw materials, and components used in manufacturing our products. We strive to maintain sufficient inventory of products, raw materials, and components so that our production will not be significantly disrupted if a particular product, raw material, or component is not available to us for a period of time, including as a result of a supplier's loss of its ISO or other certification or as a result of any of the disruptions described below under the risk factor titled “If any of our manufacturing, development, or research facilities are damaged and/or if our manufacturing processes are interrupted, we could experience supply disruptions and/or lost revenues and our business could be seriously harmed.” For example, a certain number of our products require titanium, which is sourced from third party suppliers. While the titanium required for such products is not directly sourced from Russia, the current geopolitical events involving Russia and Ukraine is negatively impacting the wider titanium supply chain and such geopolitical events and factors relating thereto or resulting therefrom, including the imposition of sanctions, may negatively impact the ability of our local supply sources to timely supply titanium to us. In addition, some of our suppliers may choose to discontinue making their products available in the E.U. rather than follow MDR, which would require us to identify alternate supply sources for those products. Any such disruption in our production could harm our reputation, business, financial condition, and results of operations.

Although we believe there are alternative supply sources, replacing our suppliers may be impractical or difficult in many instances. For example, we could have difficulty obtaining similar services or products from other suppliers that are acceptable to the FDA or other foreign regulatory authorities and who are able to provide the appropriate supply volumes at an acceptable cost. In addition, if we are required to transition to new suppliers for certain services or components of our products, the use of services, components, or materials furnished by these alternative suppliers could require us to alter our operations, and if we are required to change the manufacturer of a critical component of our products, we will have to verify that the new manufacturer maintains facilities, procedures, and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner. Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products, or could require that we modify the design of those systems.

If we are unable to obtain sufficient quantities of products, raw materials, or components that meet our quality and other requirements on a timely basis for any reason, we may not produce sufficient quantities of our products to meet market demand until a new or alternative supply source is identified and qualified and, as a result, we could lose customers, our reputation could be harmed and our business could suffer. Furthermore, an uncorrected defect or supplier’s variation in a component or raw material that is incompatible with our manufacturing, or unknown to us, could harm our ability to manufacture products.

Further, under the Food and Drug Administration Safety and Innovation Act ("FDASIA"), which includes the Medical Device User Fee Amendments of 2012, as well as other medical device provisions, all U.S. and foreign manufacturers must have a FDA Establishment Registration and complete Medical Device listings for sales in the U.S. While we believe that our facilities materially comply with these requirements, we also source products from foreign contract manufacturers. It is possible that some of our foreign contract manufacturers will not comply with applicable requirements and choose not to register with the FDA. In such an event, we will need to determine if there are alternative foreign contract manufacturers who comply with the applicable requirements. If such a foreign contract manufacturer is a sole supplier of one of our products, there is a risk that we may not be able to source another supplier.

Furthermore, we rely on a small number of tissue banks accredited by the AATB for the supply of human tissue, a crucial component of our biologics products that serve as bone graft substitutes. Any failure to obtain tissue from these sources or to have the tissue

processed by these sources for us in a timely manner will interfere with our ability to meet demand for our biologics products effectively. The processing of human tissue into biologics products is labor intensive and maintaining a steady supply stream is challenging. In addition, due to seasonal changes in mortality rates, some scarce tissues used for our biologics products are at times in particularly short supply. If governments require additional donor testing due to COVID-19, this could also strain the supply of tissue. We cannot be certain that our supply of human tissue from our suppliers will be available at current levels or will meet our needs or that we will be able to successfully negotiate commercially reasonable terms with other accredited tissue banks.

If we are unable to maintain and expand our network of independent sales representatives and distributors, we may not maintain or grow our revenue.

We sell our products in many countries through independent sales representatives and distributors. Frequently, our independent sales representatives and our distributors have the exclusive right to sell our products in their respective territories. If any of our independent sales representatives or distributors fail to adequately promote, market, and sell our products, our sales could significantly decrease. The terms of our agreements with our independent sales representatives and distributors 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.

Further, we face significant challenges and risks in managing our geographically dispersed distribution network and retaining the independent sales representatives and distributors who make up that network, and as we launch new products and increase our marketing efforts with respect to existing products, we plan to expand the reach of our marketing and sales efforts and may need to hire new independent sales representatives and distributors. Independent sales representatives and distributors require significant technical expertise in various areas such as spinal care practices, spine injuries and disease, and spinal health and they require training and time to achieve full productivity. We may not attract or retain qualified independent sales representatives and distributors or enter into agreements with them on favorable or commercially reasonable terms, if at all. This could be due to a number of factors, including, but not limited to, perceived deficiencies, or gaps, in our existing product portfolio, intense competition for services of independent sales representatives and distributors, or because of the disruption associated with restrictive covenants to which representatives or distributors may be subject and potential litigation and expense associated therewith. We may also experience unforeseen disengagement from independent sales representatives and distributors who have worked with us for many years. Even if we enter into agreements with additional qualified independent sales representatives or distributors, it often takes 6 to 12 months for new sales representatives or distributors to reach full operational effectiveness and they may not generate revenue as quickly as we expect them to, commit the necessary resources to effectively market and sell our products, or ultimately succeed in selling our products. Our success will depend largely on our ability to continue to hire, train, retain, and motivate qualified independent sales representatives and distributors. If we cannot expand our sales and marketing capabilities domestically and internationally, if we fail to train new independent sales representatives and distributors adequately, or if we experience high turnover in our sales network, we may not commercialize our products adequately, or at all, which would adversely affect our business, results of operations and financial condition.

Moreover, because our independent sales representatives and distributors are not our employees, we have limited control over their activities and, generally, we do not enter into exclusive relationships with them. If one or more of them were to be retained by a competitor, whether or an exclusive or non-exclusive basis, they may divert business from us to our competitor, which could materially and adversely affect our sales.

In order to compete, we must attract, retain, and motivate executives and 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.

Moreover, replacing key employees may be a difficult, costly, and protracted process, and we may not have other personnel with the capacity to assume all of the responsibilities of a departing employee. Competition for qualified personnel, particularly for key positions, is intense among companies in our industry, and many of the organizations against which we compete for qualified personnel have greater financial and other resources and different risk profiles than us, which may make them more attractive employers. All of our employees, including our management personnel, may terminate their employment with us at any time without notice. If we cannot attract and retain highly qualified personnel, as needed, we may not achieve our financial and other goals.

To attract, retain, and motivate qualified executives and key employees, we utilize stock-based incentive awards, such as employee stock options and restricted stock units. Certain awards vest based upon the passage of time while others vest upon the achievement of certain performance-based and/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.

In addition, future internal growth could impose significant added responsibilities on our management, and we will need to identify, recruit, maintain, motivate, and integrate additional employees to manage growth effectively. If we do not effectively manage such growth, our expenses may increase more than expected, we may not achieve our goals, and our ability to generate and/or grow revenue could be diminished.

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, social, or economic conditions;
- difficulties in staffing and managing widespread operations;
- having to comply with export control laws, including, but not limited to, the Export Administration Regulations and trade sanctions against embargoed countries, which are administered by the Office of Foreign Assets Control within the Department of the Treasury, as well as the laws and regulations administered by the Department of Commerce;
- complex data privacy requirements, including, but not limited to, the GDPR;
- differing regulatory requirements for obtaining clearances or approvals to market our products, and unexpected changes in regulatory requirements;
- changes in, or uncertainties relating to, foreign rules and regulations that may impact our ability to sell our products, perform services or repatriate profits to the U.S.;
- tariffs, trade barriers, export regulations, and other regulatory and contractual limitations that may adversely impact our ability to sell our products in certain foreign markets, the scope and consequences of which are subject to changing agendas of political, business, and environmental groups;
- consequences from changes in tax or customs laws;
- fluctuations in foreign currency exchange rates;
- limitations on or increase of withholding and other taxes on remittances and other payments by foreign subsidiaries or joint ventures;
- differing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- differing labor laws and standards;
- an inability, or reduced ability, to protect our intellectual property, including any effect of compulsory licensing imposed by government action;
- availability of government subsidies or other incentives that benefit competitors in their local markets that are not available to us; and

- having to comply with various U.S. and international laws, including the FCPA and anti-money laundering laws, and violation by our independent sales representatives or distributors of such 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. Further, there is a substantial backlog of patent applications at the U.S. Patent and Trademark Office, and the approval or rejection of patent applications may take several years. 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. Moreover, 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.

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.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, adequately protect our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable.

We may face claims by third parties that our agreements with employees, consultants, or advisors obligating them to assign intellectual property to us are ineffective or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such intellectual property. Litigation may be necessary to resolve an ownership dispute, and if we are unsuccessful, we may be precluded from using certain intellectual property or may lose our exclusive rights in that intellectual property. Either outcome could harm our business and competitive position.

Furthermore, the laws of some foreign countries may not protect our intellectual property rights to the same extent as the laws of the U.S., if at all. Since certain of our issued patents and pending patent applications are for the U.S. only, we lack a corresponding scope of patent protection in other countries. Thus, we may not be able to stop a competitor from marketing products in other countries that are similar to some of our products.

If we are unable to obtain, protect, and enforce patents on our technology and to protect our trade secrets, such inability could have a material and adverse effect on our business, results of operations, and financial condition.

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

Our success will depend in part on our ability, both in the U.S. and in foreign countries, to operate without infringing upon the patents and proprietary rights of others, and to obtain appropriate licenses to patents or proprietary rights held by third parties if infringement would otherwise occur.

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. Accordingly, an adverse determination in a judicial or administrative proceeding, or a failure to obtain necessary assignments or licenses, could result in us having to pay substantial damages (which may be increased up to three times of awarded damages) and/or substantial royalties, and could prevent us from manufacturing or selling some products or increase our costs to market these products unless we obtain a license or are able to redesign our products to avoid infringement. Any such license may not be available on reasonable terms, if at all, and there can be no assurance that we would be able to redesign our products in a way that would not infringe the intellectual property rights of others. If we fail to obtain any required licenses or make any necessary changes to our products or technologies, we may have to withdraw existing products from the market or may be unable to commercialize one or more of our products, all of which could have a material adverse effect on our business, results of operations, and financial condition.

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

If we seek to protect or enforce our intellectual property rights through litigation or other proceedings, it could require us to spend significant time and money, the results of which are uncertain.

To protect or enforce our intellectual property rights, we may have to initiate or defend litigation against or by third parties, such as infringement suits, opposition proceedings, or seeking a court declaration that we do not infringe the proprietary rights of others or that their rights are invalid or unenforceable. We may not have sufficient resources to enforce our intellectual property rights or to defend our intellectual property rights against a challenge. Even if we prevail, the cost of litigation, including the diversion of management and other resources, could affect our profitability and could place a significant strain on our financial resources.

Our ability to enforce our intellectual property rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components used in their products. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor’s or potential competitor’s product. The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. It is not unusual for parties to exchange letters surrounding allegations of intellectual property infringement and licensing arrangements. In addition, the patent positions of medical device companies, including our patent position, may involve complex legal and factual questions, and, therefore, the scope, validity, and enforceability of any patent claims we have or may obtain cannot be predicted with certainty.

We may be subject to claims that we, our employees, or our independent sales agents or stocking distributors have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were employed at other medical device companies, including our competitors or potential competitors, and in some cases, were employed at such medical device companies immediately prior to joining us. In addition, many of our independent sales representatives and distributors sell, or in the past have sold, products of our competitors. We may be subject to claims that we, our employees, or our independent sales representatives or distributors intentionally, inadvertently, or otherwise used or disclosed trade secrets or other proprietary information of former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee, or encouraged/assisted an independent sales agent, to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Litigation is expensive and time-consuming, and could divert management attention and resources away from our business. Even if we prevail, the cost of litigation could affect our profitability. If we do not prevail, in addition to any damages we might have to pay, we may lose valuable intellectual property rights or employees, independent sales representatives, or distributors. There can be no assurance that this type of litigation or the threat thereof will not adversely affect our ability to engage and retain key employees, sales representatives, or distributors.

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.

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. Spine surgery involves significant risk of serious complications, including bleeding, nerve injury, paralysis and even death. In addition, if neurosurgeons and orthopedic spine surgeons are not sufficiently trained in the use of our products, they may misuse or ineffectively use our products, which may result in unsatisfactory patient outcomes or patient injury. We could become the subject of product liability lawsuits alleging that component failures, malfunctions, manufacturing flaws, design defects, or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition or injury to patients. In addition, the development of allograft implants and technologies for human tissue repair and treatment may entail particular risk of transmitting diseases to human recipients, and any such transmission could result in the assertion of product liability claims against us.

Product liability claims are expensive to defend, divert our management’s attention and, if we are not successful in defending the claim, can result in substantial monetary awards against us or costly settlements. Further, successful product liability claims made against one or more of our competitors could cause claims to be made against us or expose us to a perception that we are vulnerable to similar claims. Any product liability claim brought against us, with or without merit and regardless of the outcome or whether it is fully pursued, may result in: decreased demand for our products, injury to our reputation, significant litigation costs, product recalls, loss of revenue, the inability to commercialize new products or product candidates, and adverse publicity regarding our products. Any of these may have a material and adverse effect on our reputation with existing and potential customers and on our business, financial condition, and results of operations. In addition, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

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, a recall of some of our products, whether or not the result of a product liability claim, could result in significant costs and loss of customers.

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

We do not carry insurance for all categories of risk to which our business is or may be exposed. Some of the policies we maintain include product liability insurance, directors’ and officers’ liability insurance, property insurance, cybersecurity insurance, general liability insurance, and workers’ compensation insurance. We do not know, however, if we will be able to maintain insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against losses. If the costs of maintaining adequate insurance coverage should increase significantly in the future, our operating results could be materially adversely impacted. Even if we have insurance, a claim could exceed the amount of our insurance coverage or it may be excluded from coverage under the

terms of the policy. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

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 stockholders. 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 stockholders.

Furthermore, as a result of acquisitions of other healthcare businesses, we may be subject to the risk of unanticipated business uncertainties, regulatory and other compliance matters, or legal liabilities relating to those acquired businesses for which the sellers of the acquired businesses may not indemnify us, for which we may not be able to obtain insurance (or adequate insurance) or for which the indemnification may not be sufficient to cover the ultimate liabilities.

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 ASCs. 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. In October 2021, the Company entered into an additional Convertible Loan Agreement (the “Additional Convertible Loan”), pursuant to which the Company loaned Neo Medical an additional CHF 0.6 million ($0.7 million as of the issuance date). In January 2022, the Company elected to convert the Additional Convertible Loan into shares of Neo Medical’s preferred stock.

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, many of which are outside our control. Such factors include:

- economic conditions worldwide, which could affect the ability of hospitals and other customers to purchase our products and could result in a reduction in elective and non-reimbursed operative procedures;
- increased competition;
- market acceptance of our existing products, as well as products in development, and the demand for, and pricing of, our products and the products of our competitors;
- costs, benefits, and timing of new product introductions;
- the timing of or failure to obtain regulatory clearances or approvals for new products;
- lost sales and other expenses resulting from stoppages in our production or from third parties supplying our business, including as a result of product recalls or field corrective actions;
- the availability and cost of components and materials, including raw materials such as human tissue;
- accurate predictions of product demand and production capabilities sufficient to meet that demand;
- our ability to realize expected yield improvements and scrap reduction initiatives that we have undertaken;
- higher than anticipated independent sales representatives and distributors commissions;
- our ability to purchase or manufacture and ship our products efficiently and in sufficient quantities to meet sales demands;
- the timing of our research and development expenditures;
- expenditures for major initiatives;
- the timing and level of reimbursement, changes in reimbursement or denials in coverage for our products by third-party payors, such as Medicare, Medicaid, private and public health insurers, and foreign governmental health systems;
- the ability of our independent sales representatives and distributors to achieve expected sales targets and for new agents and stocking distributors to become familiar with our products in a timely manner;
- the timing of and our ability to successfully onboard and/or hire new sales agents and distributors;
- the loss of certain customers, sales agents, or distributors, or the removal of our contractual ability to sell to certain customers, hospitals, or healthcare providers;
- peer-reviewed publications discussing the clinical effectiveness of our products;
- inspections of our manufacturing facilities for compliance with the FDA’s Quality System Regulations (Good Manufacturing Practices), which could result in Form 483 observations, warning letters, injunctions, or other adverse findings from the FDA or equivalent foreign regulatory bodies, and corrective actions, procedural changes, and other actions, including product recalls, that we determine are necessary or appropriate to address the results of those

inspections, any of which may affect production and our ability to supply our customers with our products;

- the costs to comply with new regulations from the FDA or equivalent foreign regulatory bodies, such as the requirements to establish a unique device identification system to adequately identify medical devices through their distribution and use;
- the increased regulatory scrutiny of certain of our products, including products we manufacture for others, which could result in them being removed from the market;
- fluctuations in foreign currency exchange rates; and
- the impact of acquisitions, including the impact of goodwill and intangible asset impairment charges, if future operating results of the acquired businesses are significantly less than the results anticipated at the time of the acquisitions.

In addition, we may experience meaningful variability in our sales and gross profit among quarters, as well as within each quarter, as a result of several factors, including but not limited to (and in addition to those listed above):

- the number of products sold in the quarter;
- the unpredictability of sales of full sets of spinal implants and instruments to our international stocking distributors; and
- the number of selling days in the quarter.

Our goodwill, intangible assets, and fixed assets are subject to potential impairment; we have recorded significant goodwill impairment charges in the past 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 2023 had a favorable impact of $2.3 million on net sales outside of the U.S. Although we seek to manage our foreign currency exposure by matching non-dollar revenues and expenses, exchange rate fluctuations could have a material adverse effect on our results of operations in the future. To minimize such exposures, we may enter into currency hedges from time to time.

In addition, for those foreign customers who purchase our products in U.S. Dollars, currency exchange rate fluctuations between the U.S. Dollar and the currencies in which those customers do business may have a negative effect on the demand for our products in foreign countries where the U.S. Dollar has increased in value compared to the local currency. Converting our earnings from international operations to U.S. Dollars for use in the U.S. can also raise challenges, including problems moving funds out of the countries in which the funds were earned and difficulties in collecting accounts receivable in foreign countries where the usual accounts receivable payment cycle is longer.

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, vesting of equity awards at a price below the original valuation, historical entity classification elections, and the resolution of matters arising from tax audits.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures immediately in the year incurred and requires taxpayers to amortize such expenditures over five years, or 15 years for such expenditures incurred outside of the U.S. This requirement may have a significant impact on our cash tax liability and our effective tax rate as we perform research and development in the U.S., Italy, and Canada.

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 and operating cash flow.

We maintain a $150.0 million financing agreement secured by a pledge of substantially all of our property.

On November 6, 2023, we, as borrower, and certain of our subsidiaries, as guarantors, entered into a Financing Agreement (the “Financing Agreement”) with Blue Torch Finance LLC, as administrative agent and collateral agent, and certain lenders party thereto. The Financing Agreement provides for a $100.0 million senior secured term loan (the “Initial Term Loan”), a $25.0 million senior secured delayed draw term loan facility (the “Delayed Draw Term Loan”), and a $25.0 million senior secured revolving credit facility (the “Revolving Credit Facility,” and together with the Initial Term Loan and the Delayed Draw Term Loan, the “Credit Facilities”), each of which mature on November 6, 2027. In connection with entering into the Financing Agreement, we repaid in full amounts outstanding and terminated all commitments under our prior credit agreement (which had a maturity date of October 25, 2024). The Initial Term Loan was fully funded on November 6, 2023. As of the date of this filing (March 5, 2024), we had not made any borrowings under the Delayed Draw Term Loan, but had borrowed $15.0 million under the Revolving Credit Facility.

Borrowings under the Financing Agreement were and may be used for, among other things, (i) the repayment in full of amount that we had outstanding under our prior credit agreement, (ii) working capital and (iii) other general corporate purposes. Borrowings under the Credit Facilities bear interest at a floating rate, which will be, at our option, either the three-month SOFR rate (subject to a floor of 3.00% and a credit spread adjustment of 0.26161%) (the “Adjusted Term SOFR Rate”) plus an applicable margin of 7.25%, or a base rate plus an applicable margin of 6.25%. A revolving unused line fee of 2.00% is payable monthly in arrears based on the average amount of the undrawn portion of each lender’s revolving credit commitments under the Revolving Credit Facility for the preceding month. A delayed draw unused fee equal to the Adjusted Term SOFR Rate plus a margin of 1.00% is payable monthly in arrears based on the average amount of the undrawn portion of each lender’s delayed draw term loan commitments in respect of the Delayed Draw Term Loan for the preceding month. Certain of our existing and future material subsidiaries (collectively, the “Guarantors”) are required to guarantee the repayment of our obligations under the Financing Agreement. Our obligations and each of the Guarantors with respect to the Financing Agreement are secured by a pledge of substantially all of our assets and the assets of each of the Guarantors, including, without limitation, accounts receivables, deposit accounts, intellectual property, investment property, inventory, equipment, and equity interests in their respective subsidiaries.

The Financing Agreement contains customary affirmative and negative covenants, including limitations on our and our 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 Financing Agreement contains financial covenants requiring us to maintain a minimum level of liquidity at all times, a maximum consolidated leverage ratio (measured on a quarterly basis), and a minimum asset coverage ratio (measured on a monthly

basis). The Financing 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 Credit Facilities may be accelerated and/or the lenders' commitments terminated.

We believe that we will be in compliance with the covenants in future fiscal quarters. However, there can be no assurance that we will be in such compliance, and if we are not, the failure to do so could result in an event of default, which could have a material adverse effect on our financial position in the event that we continue to have significant amounts drawn under the facility at such time.

We must maintain high levels of inventory, which could consume a significant amount of our resources and reduce our cash flows.

Because we maintain substantial inventory levels to meet the needs of our customers, we are subject to the risk of inventory excess, obsolescence, and shelf-life expiration. Many of our spinal implant products come in sets. Each set includes a significant number of components in various sizes so that the physician may select the appropriate spinal implant based on the patient's needs. In a typical surgery, not all of the implants in the set are used, and therefore certain sizes of implants placed in the set or that we purchase for replenishment inventory may become obsolete before they can be used. In addition, to market our products effectively, we often must provide hospitals and independent sales agents with consigned sets that typically consist of spinal implants and instruments, including products to ensure redundancy and products of different sizes. Further, our biologics products have expiration dates, which range from one to five years, and these products may expire before they can be used. If a substantial portion of our inventory is deemed excess, becomes obsolete, or expires, it could have a material adverse effect on our earnings and cash flows due to the resulting costs associated with the inventory impairment charges and costs required to replace such inventory. Further, as we increasingly launch new products and product systems, we may cannibalize older products and product systems, which could exacerbate excess and obsolete charges.

We may need additional financing in the future to meet our capital needs or to make opportunistic acquisitions, and such financing may not be available on favorable terms, if at all.

We may need additional financing in the future to meet our capital needs or to make opportunistic acquisitions. The capital and credit markets may experience extreme volatility and disruption, which may lead to uncertainty and liquidity issues for both borrowers and investors, and we may be unable to obtain any desired additional financing on favorable terms, if at all. If adequate funds are not available to us on acceptable terms, we may be unable to successfully develop or enhance products, or respond to competitive pressures, any of which could negatively affect our business, results of operations, and financial condition. If we raise capital by issuing debt or entering into credit facilities, we may be subject to limitations on our operations due to restrictive covenants.

We hold our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.

We hold our cash and cash equivalents used to meet our working capital and operating expense needs in deposit accounts at multiple financial institutions. The balance held in these accounts typically exceeds the Federal Deposit Insurance Corporation ("FDIC") standard deposit insurance limit or similar government guarantee schemes. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

For example, on March 10, 2023, Silicon Valley Bank ("SVB"), and Signature Bank, were closed by state regulators and the FDIC was appointed receiver for each bank. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the United States Department of Treasury, the Federal Reserve, and the FDIC. If financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits in a similar manner.

General Risks

Our stock price has fluctuated and may continue to fluctuate, which may make future prices of our stock difficult to predict.

Investors should not rely on recent or historical trends to predict future stock prices, financial condition, results of operations, or cash flows. Our stock price, like that of other medical device companies, can be volatile and can be affected by, among other things: speculation, coverage, or sentiment in the media or the investment community; the announcement of new, planned or

contemplated products, services, technological innovations, acquisitions, divestitures, or other significant transactions by us or our competitors; our quarterly financial results and comparisons to estimates by the investment community or financial outlook provided by us; the financial results and business strategies of our competitors; publication of research reports about us or our industry or changes in recommendations or withdrawal of research coverage by securities analysts; changes in laws or regulations affecting our business, including tax legislation; changes in accounting standards, policies, guidance, interpretations, or principles; threatened or actual litigation or governmental investigations; and inflation; market volatility or downturns caused by outbreaks, epidemics, pandemics, geopolitical tensions or conflicts, or other macroeconomic dynamics. General or industry specific market conditions or stock market performance or domestic or international macroeconomic and geopolitical factors unrelated to our performance also may affect the price of our stock.

In addition, the stock market in general, and the stocks of medical device companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. This could limit or prevent investors from readily selling their shares and may otherwise negatively affect the liquidity of our common stock. Securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company's securities. This litigation, if instituted against us, could result in very substantial costs, divert our management's attention and resources, and harm our business, financial condition, and results of operations.

We expend substantial resources to comply with laws and regulations relating to public companies, and any failure to maintain compliance could subject us to regulatory scrutiny and cause investors to lose confidence in our company, which could harm our business and have a material adverse effect on our stock price.

Laws and regulations affecting public companies, including provisions of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the Sarbanes-Oxley Act of 2002, and the related rules and regulations adopted by the SEC, and by the Nasdaq Stock Market increase our accounting, legal, and financial compliance costs and make some activities more time-consuming and costly. We cannot predict or estimate with any reasonable accuracy the total amount or timing of the costs we may incur to comply with these laws and regulations.

We are also subject to SEC regulations that require us to determine whether our products contain certain specified minerals, referred to under the regulations as "conflict minerals," and, if so, to perform an extensive inquiry into our supply chain, to determine whether such conflict minerals originate from the Democratic Republic of Congo or an adjoining country. Compliance with these regulations has increased our costs and has been time-consuming for our management and our supply chain personnel (and time-consuming for our suppliers), and we expect that continued compliance will continue to require significant money and time. In addition, to the extent any of our disclosures are perceived by the market to be "negative," it may cause customers to refuse to purchase our products. Further, if we determine to make any changes to products, processes, or sources of supply, it may result in additional costs, which may adversely affect our business, financial condition, and results of operations.

Our amended and restated bylaws designates certain courts as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by applicable law: (A) the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, the Superior Court of the State of Delaware, or, if both the Court of Chancery of the State of Delaware and the Superior Court of the State of Delaware lack subject matter jurisdiction, the United States District Court for the District of Delaware) and any state (or, if applicable, federal) appellate court therefrom shall be the sole and exclusive forum for (i) any derivative action, suit, or proceeding brought on behalf of our company, (ii) any action, suit, or proceeding asserting a claim of breach of fiduciary duty owed by any current or former director, officer, or other employee, or stockholder of ours to our company or our stockholders or any action asserting a claim for aiding and abetting any such breach of fiduciary duty, (iii) any action, suit, or proceeding asserting a claim against us or any of our directors, officers, or other employees arising pursuant to, or seeking to enforce any right, obligation, or remedy under, any provision of the General Corporation Law of Delaware (the "DGCL") or our (certificate of incorporation or bylaws, (iv) any action, suit, or proceeding as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware, or (v) any action, suit, or proceeding asserting a claim against us or our current or former directors, officers, employees, or stockholders governed by the internal affairs doctrine, in all cases subject to the court's having personal jurisdiction over the indispensable parties named as defendants (including personal jurisdiction by reason of any such indispensable party's consent to personal jurisdiction in the State of Delaware or such court); and (B) the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. These provisions may limit a stockholder's ability to obtain a judicial forum that such stockholder may prefer for disputes governed by these provisions.

Environmental, social, and corporate governance ("ESG") regulations, policies and provisions may make our supply chain more complex and may adversely affect our relationships with customers.

There is an increasing focus on the governance of environmental and social risks. A number of our customers who are payors or distributors have adopted, or may adopt, procurement policies that include ESG provisions that their suppliers or manufacturers must comply with, or they may seek to include such provisions in their terms and conditions. An increasing number of participants in the medical device industry are also joining voluntary ESG groups or organizations, such as the Responsible Business Alliance. These ESG provisions and initiatives are subject to change, can be unpredictable, and may be difficult and expensive for us to comply with, given the complexity of our supply chain and the outsourced manufacturing of certain components of our products. If we are unable to comply, or are unable to cause our suppliers to comply, with such policies or provisions, a customer may stop purchasing products from us, and may take legal action against us, which could harm our reputation, revenue, and results of operations.

Our business could be negatively impacted by corporate citizenship and ESG matters and/or our reporting of such matters.

There is an increasing focus from certain investors, customers, consumers, and other stakeholders concerning corporate citizenship and sustainability matters. We could be perceived as not acting responsibly in connection with these matters. Our business could be negatively impacted by such matters. Any such matters, or related corporate citizenship and sustainability matters, could have a material adverse effect on our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We have implemented cybersecurity programs designed to maintain and protect our information technology systems and the confidentiality, integrity, and availability of our data. These programs serve to maintain compliance with applicable laws and regulations governing ethical business practices, including our relationships with suppliers, customers, and business partners.

We maintain formal processes for our cybersecurity program and incident response procedures, which are updated at least annually and reviewed by external legal and cybersecurity advisors. These processes include, among other things, detailed steps on how we assess cyber risks, identify threats, and determine the materiality of cyber incidents. These processes also designate certain roles within the company to execute these policies and certain leadership roles to manage material risk escalation. These processes endeavor to follow the National Institute of Standards and Technology ("NIST") Cybersecurity Framework and are tested at least annually.

Our Information Security team uses automated technology, third-party partners, and direct review of system indicators to monitor and implement the prevention, detection, mitigation, and remediation of cybersecurity incidents, and to stay current with the changing threat landscape. We also leverage encryption technologies and other measures to safeguard systems. We engage third parties as part of our cyber program, including external security firms that provide security technology, conduct regular security audits, and conduct penetration testing. We also engage third parties to conduct regular drills, such as tabletop exercises, to help with our overall preparedness.

We also engage third-party service providers to assist with managing various other aspects of our business. We have implemented processes designed to both assess and maintain oversight of third-party service providers with regards to cybersecurity risks. These service providers are subject to due diligence reviews of their information security programs during our vendor evaluation process.

Our employees are responsible for complying with our data security standards and are required to complete annual training to understand the behaviors and technical requirements necessary to keep data secure. We also require that cybersecurity training be part of the onboarding process for new hires.

As of December 31, 2023, cybersecurity risks have not materially affected our business strategy, results of operations, or financial condition.

Governance

Cybersecurity is an important component of our enterprise risk management program. While the full Board of Directors has primary responsibility for risk oversight, the Board of Directors utilizes its committees, as appropriate, to monitor and address the risks that

may be within the scope of a particular committee's expertise or charter. The Board of Directors receives updates at quarterly board meetings on committee activities from each committee Chair.

The Audit and Finance Committee has oversight over and regularly reviews our cybersecurity, including IT risks, controls, procedures, and plans to mitigate cybersecurity risks and respond to security incidents. The Audit and Finance Committee receives reports on at least a quarterly basis from the Chief Information Officer and the Vice President, Information Security, on, among other issues, our cyber risks and threats, the status of projects, management's strategies to strengthen our IT systems, assessments of our security program, third-party assessments and testing, our emerging threat landscape, and the review of our cybersecurity insurance policy. Pursuant to our incident response procedures, material cyber incidents will be reported to the Chair of the Audit and Finance Committee upon a determination of material status. Due to the importance of cybersecurity, the full Board of Directors also receives updates on cybersecurity matters from management at least annually.

Management is responsible for our company's day-to-day risk management activities. Our cybersecurity program is led by our Chief Information Officer, who is responsible for assessing and managing cybersecurity risks. He has 25 years of experience in both military and corporate leadership roles, including 12 years of experience in CIO-level leadership roles, including consulting with major firms, covering technology and security operations responsibility.

Our Vice President, Information Security, who reports to our Chief Information Officer, is responsible for cybersecurity program execution, risk management, and oversight of information security staff and consultants. She has 20 years of experience in IT roles, including 13 years in IT leadership roles and 5 years in cybersecurity program execution and oversight of information security.

Our Manager, Information Security, who reports to our Vice President, Information Security, is responsible for managing our security analyst team and the tactical execution of security operations. He has nine years of experience in security roles, including seven years in technical system administration roles. He also has the following certifications: ISC2 CCSP, ISC2 SSCP, CompTIA Security+, EC-Council Certified Encryption Specialist ("ECES"), EC-Council Certified Incident Handler ("ECCIH").

As cybersecurity risks arise, our Information Security team executes the incident response procedure and communicates the appropriate details to management in alignment with the escalation steps in the procedure. In addition, our Chief Information Officer, Vice President, Information Security, and Manager, Information Security, conduct monthly cybersecurity program status reviews with the Information Security team that includes KPI tracking, risk assessment, escalation actions, and project status.

Item 2. Properties

We lease or own real property to support our business. The following lists those properties that we believe are material to our business. We believe that our facilities meet our current needs and that we will be able to renew any such leases when needed on acceptable terms or find alternative facilities.

Facility	Location	Approx. Square Feet	Ownership
Manufacturing, warehousing, distribution, research and development, location of a cadaveric training laboratory, and administrative facility for corporate functions and all reporting segments	Lewisville, TX	140,000	Leased
Design, development, marketing, and inspection for biologics and spinal implant products, distribution of certain Spinal Implant products, location of a cadaveric training laboratory, and administrative facility	Carlsbad, CA	82,000	Leased
Manufacturing and distribution for certain Biologics products	Irvine, CA	70,000	Leased
Manufacturing, warehousing, distribution, research and development, and administrative facility for Motion Preservation	Sunnyvale, CA	25,000	Leased
Design of Spinal Implants and location of a cadaveric training laboratory	Wayne, PA	3,700	Leased
Design, development, and marketing for Enabling Technologies products	Toronto, Canada	9,200	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 Orthopedics products	Verona, Italy	18,000	Leased
Mechanical workshop for Orthopedics 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	Munich, Germany	18,300	Leased

Our manufacturing facilities are registered with the FDA. Our facilities are subject to FDA inspection to ensure compliance with its Quality System Regulations. For further information regarding the status of FDA inspections, see the "Item 1. Business - Government Regulation."

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 March 1, 2024, we had 456 holders of record of our common stock. A substantially greater number of holders of our common stock are "street name" or beneficial holders, whose shares are held by banks, brokers and other financial institutions. The closing price of our common stock on March 1, 2024, was $13.00. 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
2022		
First Quarter	$ 36.13	$ 28.66
Second Quarter	35.34	23.17
Third Quarter	26.35	18.97
Fourth Quarter	21.12	13.76
2023		
First Quarter	$ 23.19	$ 15.09
Second Quarter	20.65	16.27
Third Quarter	21.60	12.25
Fourth Quarter	14.39	9.57

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 Financing 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.

Equity Compensation Plan Information

Information about our equity compensation plan is incorporated herein by reference to Part III, Item 12 of this report.

Recent Sales of Unregistered Securities

During the fourth quarter of 2023, we did not issue any securities that were not registered under the Securities Act of 1933, as amended (the "Securities Act").

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, 2018, 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.

Item 6. **Reserved**

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 2023 and 2022 financial results, including comparisons of our year-over-year performance between these years. Discussion and analysis of our 2021 fiscal year specifically, as well as the year-over-year comparison of our 2022 financial performance to 2021, 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, 2022, filed with the SEC on March 6, 2023, which is available on our website at www.orthofix.com and the SEC's website at www.sec.gov.

Executive Summary

Orthofix is a leading global spine and orthopedics company with a comprehensive portfolio of biologics, innovative spinal hardware, bone growth therapies, specialized orthopedic solutions and a leading surgical navigation system. Its products are distributed in more than 60 countries worldwide.

We are headquartered in Lewisville, Texas, and have primary offices in Carlsbad, CA, with a focus on spine and biologics product innovation and surgeon education, and Verona, Italy, with an emphasis on product innovation, production, and medical education for orthopedics. Our global R&D, commercial and manufacturing footprint also includes facilities and offices in Irvine, CA, Toronto, Canada, Sunnyvale, CA, Wayne, PA, Olive Branch, MS, Maidenhead, UK, Munich, Germany, Paris, France, and São Paulo, Brazil.

The merger with SeaSpine was completed on January 5, 2023, with SeaSpine continuing as a wholly-owned subsidiary of Orthofix following the transaction. For additional discussion of the merger with SeaSpine, see Note 4 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report. The shares of common stock of Orthofix, as the corporate parent entity in the combined company structure, continue to trade on NASDAQ under the symbol "OFIX".

Notable financial results in 2023 include the following:

- Net sales were $746.6 million, an increase of 62.1% on a reported basis and 61.6% on a constant currency basis
- Bone Growth Therapies growth of 13.5%, with of each the last four consecutive quarters exhibiting double-digit net sales growth
- U.S. Spinal Implants, Biologics, and Enabling Technologies growth of 7.6% on a pro forma basis over 2022
- Global Orthopedics net sales growth of 7.2% on a reported basis and 5.2% on a constant currency basis
- Adjusted EBITDA of $46.3 million compared to pro forma adjusted EBITDA in 2022 of $27.4 million

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,		
	2023 (%)	2022 (%)	2021 (%)
Net sales	100.0	100.0	100.0
Cost of sales	34.9	26.8	24.7
Gross profit	65.1	73.2	75.3
Sales and marketing	51.7	49.7	47.6
General and administrative	19.4	17.4	14.9
Research and development	10.7	10.6	10.7
Acquisition-related amortization and remeasurement	1.9	(1.6)	3.9
Operating loss	(18.6)	(2.9)	(1.8)
Net loss	(20.3)	(4.3)	(8.3)

Net Sales by Reporting Segment

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

				Percentage Change			
				2023/2022	2023/2022	2022/2021	2022/2021
(U.S. Dollars, in thousands)	2023	2022	2021	Reported	Constant Currency	Reported	Constant Currency
Bone Growth Therapies	$ 212,530	$ 187,247	$ 187,448	13.5%	13.5%	-0.1%	-0.1%
Spinal Implants, Biologics, and Enabling Technologies	418,789	165,927	171,515	152.4%	152.4%	-3.3%	-2.7%
Global Spine	631,319	353,174	358,963	78.8%	78.7%	-1.6%	-1.4%
Global Orthopedics	115,322	107,539	105,516	7.2%	5.2%	1.9%	11.0%
Net sales	$ 746,641	$ 460,713	$ 464,479	62.1%	61.6%	-0.8%	1.5%

Global Spine

Global Spine offers the following products categories:

- Bone Growth Therapies, which manufactures, distributes, sells, and provides support services for market-leading devices used adjunctively in high-risk spinal fusion procedures and to treat both nonunion and acute fractures in the orthopedic space. Bone Growth Therapies uses distributors and a direct sales channel to sell its devices and provide associated support services to hospitals, healthcare providers, and patients in the U.S.
- Spinal Implants, Biologics, and Enabling Technologies is comprised of a broad portfolio of spine fixation and motion preservation implant products used in surgical procedures of the spine, one of the most comprehensive biologics portfolios in both the demineralized bone matrix and cellular allograft market segments, and image-guided surgical solutions to facilitate degenerative, minimally invasive, and complex surgical procedures. Spinal Implants, Biologics, and Enabling Technologies products are sold through a network of distributors and sales representatives to hospitals and healthcare providers on a global basis for Spinal Implants and Enabling Technologies, primarily within the U.S. for Biologics.

2023 Compared to 2022

Net sales increased $278.1 million or 78.8%

- Bone Growth Therapies net sales increased $25.3 million or 13.5%, with above market performance in both the spine and fracture channels, largely driven by (i) an increase in complex spine procedures, which are typically paired within our CervicalStim and SpinalStim devices, (ii) increased reimbursement rates that Medicare approved for 2023, (iii) growth in our spine and fracture sales channels as a result of investments made in the commercial channel in the prior year, and (iv) the launch of AccelStim for the healing of fresh and nonunion fractures
- Spinal Implants, Biologics, and Enabling Technologies net sales increased $252.9 million or 152.4%, primarily due to the contribution of SeaSpine net sales and growth driven by the onboarding of new, high-volume distribution partners along with multiple recent product launches

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.

2023 Compared to 2022

Net sales increased $7.8 million, or 7.2% on a reported basis and 5.2% on a constant currency basis

- U.S. growth of 11.1% largely due to investments made in recent product launches, commercial execution within our sales channel, and from our best in class surgeon education programs

- International growth of 3.3% on a constant currency basis, largely due to an increase in stocking distributor orders and as a result of recent product launches
- Increase of $2.2 million due to movement in foreign current exchange rates, which had a favorable impact on net sales in 2023

Gross Profit

				Percentage Change	
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**	**2023/2022**	**2022/2021**
Net sales	$ 746,641	$ 460,713	$ 464,479	62.1%	-0.8%
Cost of sales	260,368	123,544	114,914	110.7%	7.5%
Gross profit	$ 486,273	$ 337,169	$ 349,565	44.2%	-3.5%
Gross margin	65.1%	73.2%	75.3%	-8.1%	-2.1%

2023 Compared to 2022

Gross profit increased $149.1 million, or 44.2%

- Gross profit largely increased due to the contribution of SeaSpine results in 2023, as SeaSpine contributed approximately $258.9 million in net sales
- Partially offset by $36.0 million in amortization of the inventory fair value step up at acquisition, which is being recognized over the expected sales cycles of the acquired inventory
- Further offset by approximately $6.0 million in charges due to inventory rationalization decisions related to the Merger

Sales and Marketing Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**	**2023/2022**	**2022/2021**
Sales and marketing	$ 385,736	$ 228,810	$ 221,318	68.6%	3.4%
As a percentage of net sales	51.7%	49.7%	47.6%	2.0%	2.1%

2023 Compared to 2022

Sales and marketing expense increased $156.9 million

- Increase largely due to the contribution of SeaSpine results in 2023 and the overall increase in net sales as compared to the prior year period, which resulted in increased variable expenses, such as commissions and bonus expenses associated with the achievement of certain sales objectives
- Included within sales and marketing expenses for 2023 are integration-related expenses of $4.5 million, which are mainly related to severance and retention costs

General and Administrative Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**	**2023/2022**	**2022/2021**
General and administrative	$ 144,659	$ 79,966	$ 69,353	80.9%	15.3%
As a percentage of net sales	19.4%	17.4%	14.9%	2.0%	2.5%

2023 Compared to 2022

General and administrative expense increased $64.7 million

- Increase largely due to the contribution of SeaSpine results in 2023 and resulting integration costs incurred as a result of the Merger, partially offset by a reduction in due diligence and transaction costs incurred prior to the closing of the Merger
- Included within general and administrative expenses for 2023 are merger and integration related expense of $22.7 million, which are mainly comprised of (i) professional fees totaling $11.5 million, inclusive of a $5.5 million payment to Orthofix's financial advisor for the Merger upon closing of the transaction, and (ii) severance and retention costs totaling $10.5 million

- Increase of $8.8 million in share-based compensation expense as a result of a larger employee base post-Merger and from accelerated vesting of certain equity-based awards as a result of the Merger, partially offset by a recognized benefit related to the forfeiture of outstanding equity grants due to executive leadership changes

- Increases of approximately $10.0 million in costs associated with the Board of Directors' independent investigation conducted by independent outside legal counsel, which resulted in the termination of three former executives, and other resulting activities

Research and Development Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**	**2023/2022**	**2022/2021**
Research and development	$ 80,231	$ 49,065	$ 49,621	63.5%	-1.1%
As a percentage of net sales	10.7%	10.6%	10.7%	0.1%	-0.1%

2023 Compared to 2022

Research and development expense increased $31.2 million

- Increase largely due to the contribution of SeaSpine results in 2023 and resulting integration costs incurred as a result of the Merger
- Included within research and development expenses for 2023 are merger and integration-related expenses of $2.8 million, which are mainly comprised of severance and retention costs
- Increase of $0.8 million related to the attainment of a development milestone with MTF Biologics achieved in the first quarter of 2023
- Partially offset by a decrease of $1.5 million in costs to comply with the European Union Medical Device Regulations

Acquisition-related Amortization and Remeasurement

				Percentage Change	
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**	**2023/2022**	**2022/2021**
Acquisition-related amortization and remeasurement	$ 14,757	$ (7,404)	$ 17,588	-299.3%	-142.1%
As a percentage of net sales	1.9%	-1.6%	3.9%	3.5%	-5.5%

2023 Compared to 2022

Acquisition-related amortization and remeasurement increased $22.2 million

- Increase of $17.2 million related to a benefit recognized in 2022 from the remeasurement of potential revenue-based milestone payments associated with the Spinal Kinetics acquisition; we did not achieve the remaining milestone prior to April 30, 2023, the end of the measurement period for achieving such milestone
- Increase in amortization expense of $9.4 million during 2023 associated with intangible assets recognized as a result of the Merger
- Partially offset by a benefit of $2.7 million recognized in 2023 associated with the remeasurement of a contingent consideration obligation with Lattus Spine LLC assumed in the Merger
- Further offset by $1.6 million in costs recognized in 2022 associated with the acquisition of in-process research and development assets, recognized immediately upon acquisition

Non-operating Income (Expense)

				Percentage Change	
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**	**2023/2022**	**2022/2021**
Interest expense, net	$ (8,631)	$ (1,288)	$ (1,837)	570.1%	-29.9%
Other expense, net	(938)	(3,150)	(3,343)	-70.2%	-5.8%

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.

2023 Compared to 2022

Interest expense, net, increased $7.3 million

- Increase of $5.0 million attributable to an increase in outstanding indebtedness in 2023, either under our prior Credit Agreement or in relation to our new Financing Agreement, as no such balance was outstanding in the prior year
- Increase of $2.2 million associated with the amortization of capitalized debt issuance costs and lenders fees
- Increase of $0.6 million attributable to an early termination prepayment penalty associated with the payoff of the assumed indebtedness of SeaSpine as of the close of the Merger
- Partially offset by $0.6 million of interest income recognized on third-party notes receivable

Other expense, net, decreased $2.2 million

- Favorable change of $4.9 million associated with changes in foreign currency exchange rates, as we recorded a non-cash remeasurement gain of $1.6 million in 2023 compared to a loss of $3.3 million in 2022
- Partially offset by an increase in impairment losses on held-for-sale investment securities of $2.0 million as compared to the prior year

Income Tax Expense

				Percentage Change	
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**	**2023/2022**	**2022/2021**
Income tax expense	$ 2,716	$ 2,043	$ 24,884	32.9%	-91.8%
Effective tax rate	-1.8%	-11.5%	-184.4%	9.7%	172.9%

2023 Compared to 2022

Income tax expense increased by $0.7 million

- Increase of $8.4 million associated with financial statement expenses not deductible for tax, including executive compensation and Merger-related deal costs
- Increase of $1.3 million associated with foreign income inclusion, largely driven by research and development expenses outside of the U.S.
- Decrease of $10.1 million associated with higher financial statement losses offset by valuation allowances

2022 Compared to 2021

- Decrease of $20.2 million related to changes in valuation allowances recorded in 2021 versus 2022
- Decrease of $2.7 million related to the change in fair value of contingent consideration
- Partially offset by $1.0 million U.S. tax expense on foreign income inclusion

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

The Company has two reporting segments: Global Spine and Global Orthopedics. The primary metric used in managing the Company is adjusted earnings before interest, tax, depreciation, and amortization ("Adjusted EBITDA", a non-GAAP financial measure) (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 presents adjusted EBITDA by segment and reconciles consolidated adjusted EBITDA to loss before income taxes:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**
Adjusted EBITDA by reporting segment			
Global Spine	$ 91,115	$ 62,692	$ 71,086
Global Orthopedics	442	5,267	9,260
Corporate	(45,272)	(19,406)	(19,084)
Consolidated adjusted EBITDA	$ 46,285	$ 48,553	$ 61,262
Reconciling items:			
Interest expense, net	$ 8,631	$ 1,288	$ 1,837
Depreciation and amortization	53,063	29,019	41,355
Share-based compensation expense	35,707	18,443	15,432
Foreign exchange impact	(1,581)	3,291	3,981
SeaSpine merger-related costs	36,623	12,010	—
Strategic investments	2,272	4,018	5,700
Acquisition-related fair value adjustments	33,393	(15,595)	(2,014)
(Gain) loss on investments	1,781	187	(644)
Litigation and investigation costs	14,453	803	33
Medical device regulation	9,446	10,261	8,018
Business interruption - COVID-19	—	2,387	320
Succession charges	1,176	147	739
Loss before income taxes	$ (148,679)	$ (17,706)	$ (13,495)

Liquidity and Capital Resources

Cash, cash equivalents, and restricted cash at December 31, 2023, was $37.8 million compared to $50.7 million at December 31, 2022.

	Year Ended December, 31,		
(U.S. Dollars, in thousands)	**2023**	**2022**	**Change**
Net cash from operating activities	$ (45,753)	$ (11,538)	$ (34,215)
Net cash from investing activities	(33,131)	(24,534)	(8,597)
Net cash from financing activities	65,322	(78)	65,400
Effect of exchange rate changes on cash and restricted cash	619	(997)	1,616
Net change in cash, cash equivalents, and restricted cash	$ (12,943)	$ (37,147)	$ 24,204

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

	Year Ended December, 31,		
(U.S. Dollars, in thousands)	**2023**	**2022**	**Change**
Net cash from operating activities	$ (45,753)	$ (11,538)	$ (34,215)
Capital expenditures	(62,050)	(23,160)	(38,890)
Free cash flow	$ (107,803)	$ (34,698)	$ (73,105)

Operating Activities

Cash flows from operating activities decreased $34.2 million

- Unfavorable change in net loss of $24.4 million, excluding the impact of non-cash adjustments to net loss
- Unfavorable change of $9.8 million relating to changes in working capital accounts, primarily attributable to changes in inventory levels, partially offset by recoupment activities associated with the CMS Accelerated and Advance Payment

Program in prior year and favorable changes in accounts payable and other current liabilities

Two of our primary working capital accounts are accounts receivable and inventory. Day’s sales in receivables were 59 days at December 31, 2023, compared to 62 days at December 31, 2022 (calculated using fourth quarter net sales and ending accounts receivable). Inventory turns were consistent at 1.2 times as of December 31, 2023, and December 31, 2022, respectively.

Investing Activities

Cash flows from investing activities decreased $8.6 million

- Primarily driven by an increase of $38.9 million in capital expenditures, largely due to the inclusion of SeaSpine's financial results within the 2023 financial results
- Partially offset by an increase of $29.4 million attributable to cash acquired as a result of the Merger
- Further offset by a favorable change of $0.9 million associated with certain asset acquisitions and other investing activities

Financing Activities

Cash flows from financing activities increased $65.4 million

- Increase of $95.5 million in net borrowings associated with proceeds from our new Financing Agreement during 2023, borrowings made under our Prior Credit Agreement, and the repayment of our Prior Credit Agreement upon execution of the Financing Agreement
- Increase of $2.0 million related to the conclusion of the Fitbone Contract Manufacturing and Supple Agreement with Wittenstein in 2022, which was accounted for as a finance lease obligation
- Partially offset by a decrease of $26.9 million associated with the termination and repayment of SeaSpine's credit facility
- Further offset by a decrease of $2.7 million for tax withholdings obligations from shares traded and a decrease in other financing activities of $2.3 million

Credit Facilities

On November 6, 2023, we entered into a Financing Agreement (the "Financing Agreement") with Blue Torch Finance LLC and certain lenders party thereto, which provides for a $100.0 million senior secured term loan (the "Initial Term Loan"), a $25.0 million senior secured delayed draw term loan facility (the "Delayed Draw Term Loan") which, subject to certain conditions specified in the Financing Agreement, may be drawn on or prior to March 30, 2024, and a $25.0 million senior secured revolving credit facility (the "Revolving Credit Facility", and together with the Initial Term Loan and the Delayed Draw Term Loan, the "Credit Facilities"), each of which mature on November 6, 2027. In connection with entering into the Financing Agreement, we repaid in full amounts outstanding and terminated all commitments under the prior $175.0 million senior secured revolving credit facility evidenced by that certain Second Amended and Restated Credit Agreement (the "Prior Credit Agreement"), dated as of October 25, 2019.

Borrowings under the Financing Agreement were and may be used for, among other things, the repayment in full of the Prior Credit Agreement, working capital and other general corporate purposes of the Company.

As of December 31, 2023, we have $100.0 million outstanding borrowings under the Financing Agreement related to the Initial Term Loan. As of December 31, 2023, we have not made any borrowings under the Delayed Draw Term Loan or the Revolving Credit Facility. However, on January 10, 2024, we borrowed $15.0 million under the $25.0 million secured revolving credit facility for working capital purposes. In addition, we intend to utilize the Delayed Draw Term Loan following the completion of the audit of financial statements for the year ended December 31, 2023. 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.

We have no outstanding borrowings on our Italian line of credit of €5.5 million ($6.1 million) as of December 31, 2023. 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.

Lattus Spine LLC ("Lattus") Contingent Consideration

In connection with the Merger, we assumed a contingent consideration obligation under a purchase agreement between

SeaSpine and Lattus executed in December 2022. Under the terms of the agreement, we may be required to make installment payments at

certain dates based on future net sales of certain products (the "Lateral Products"). The estimated fair value of the contingent consideration arrangement as of December 31, 2023, was $8.5 million; however, the actual amount ultimately paid could be higher or lower than the estimated fair value of the contingent consideration. As of December 31, 2023, we classified the remaining contingent consideration liability within other long-term liabilities. For additional discussion of this matter, see Note 12 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

Legion Innovations, LLC Asset Acquisition

On December 29, 2022, we entered into a technology assignment and royalty agreement with Legion Innovations, LLC, a U.S.-based medical device technology company, whereby we acquired intellectual property rights to certain assets. As consideration, we paid $0.2 million in January 2023, with additional payments contingent upon reaching future commercialization and revenue-based milestones.

IGEA S.p.A Exclusive License and Distribution Agreement

In April 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 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.

In May 2022, we achieved FDA approval pertaining to the acquired technology, triggering a contingent consideration milestone obligation of $3.5 million. Of this amount, $1.5 million was paid in 2022, $1.0 million was paid in May 2023, and $1.0 million was accrued within other current liabilities as of December 31, 2023.

Unremitted Foreign Earnings

Unremitted foreign earnings were $33.6 million as of December 31, 2023. 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.

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 under a purchase agreement between SeaSpine and Lattus assumed in the Merger, (ii) contingent consideration arrangements associated with certain asset acquisitions or business combinations, of which material obligations are described above, (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 12 and 17), lease obligations (Note 9), and uncertain tax positions (Note 20).

Off-balance Sheet Arrangements

As of December 31, 2023, 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, adjusted 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 Bone Growth Therapies 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 Therapies products 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 mostly processed from within our Irvine facility. In addition, we have a long-standing collaborative arrangement with MTF that provides exclusive global marketing rights to MTF's Trinity and FiberFuse product families. We receive marketing fees from MTF based on sales of products covered under the collaborative arrangement. 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. 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, 2023, would result in an increase or decrease to sales and marketing expense of $0.7 million. Additionally, we believe our estimate to establish contractual allowances is sufficient to cover customer credit risks; however, a 10% change in our reserve for contractual allowances as of December 31, 2023, 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, adjusted 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, adjusted 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 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 and net income.

In the fourth quarter of 2021, we performed a quantitative assessment for our annual goodwill impairment analysis. Upon estimating the fair value of each of reporting unit, 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 was reflected within Acquisition-related amortization and remeasurement for the year ended December 31, 2021. The assessment concluded there were no indicators of impairment for the Global Spine goodwill.

In the fourth quarter of 2022, we performed a qualitative assessment for our annual goodwill impairment analysis, which did not result in an impairment charge. This qualitative analysis considered all relevant factors specific to the reporting units, including macroeconomic conditions, industry and market considerations, overall financial performance, and relevant entity-specific events.

In the third quarter of 2023, we announced the termination of the former President and Chief Executive Officer, former Chief Financial Officer, and former Chief Legal Officer, from their respective roles. Immediately following the announcement, our market capitalization decreased by approximately 30%, indicating that an impairment may exist. As a result, we performed an interim quantitative assessment of our goodwill as of September 30, 2023. Upon performing our assessment, we determined the Global Spine reporting unit's fair value exceeded its carrying value as of September 30, 2023.

In the fourth quarter of 2023, we performed a qualitative assessment for our goodwill impairment analysis, which did not result in an impairment charge. This quantitative 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.

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 impaired.

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, 2023, and 2022, include (i) contingent consideration attributable to Lattus and (ii) our convertible loan agreements with Neo Medical.

The contingent consideration obligation consists of future installment payments at certain dates based on future net sales of Lateral Products. The estimated fair value of the contingent consideration arrangement as of December 31, 2023, was $8.5 million; however, the actual amount ultimately paid could be higher or lower than the estimated fair value of the contingent consideration.

The estimated fair value of the Lattus contingent consideration is determined using a Monte Carlo simulation and a discounted cash flow model requiring significant inputs which are not observable in the market. The significant inputs include assumptions related to the timing and probability of certain product launch dates, estimated future sales of the products, revenue risk-adjusted discount rate, revenue volatility, and discount rates matched to the timing of payments.

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 of the present value factor by 5% would have resulted in a decrease in the fair value of the convertible loan of $0.5 million, whereas a decrease of the present value factor by 5% would have resulted in an increase in the fair value of the convertible loan by $0.2 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 and net income.

Other Fair Value Measurements Utilized in Purchase Accounting

Assets acquired and liabilities assumed in a business combination or asset acquisition are recorded at fair value as of the date of acquisition. Common adjustments to historical carrying values recognized for such assets or liabilities include (i) adjusting the basis of acquired inventory from net realizable value to fair value, (ii) adjusting acquired plant, property, and equipment, net of any historical accumulated depreciation, to the asset’s estimated fair value, and (iii) the remeasurement of right-of-use assets and assumed lease liabilities. The determination of the acquisition date fair value of the assets acquired and liabilities assumed requires management's judgment and involves the use of significant estimates and assumptions, especially with respect to future expected cash flows, useful lives, and discount rates.

As part of the Merger, we acquired SeaSpine's inventory, including raw materials, work-in-process ("WIP"), and finished goods. Raw materials had not been subjected to any manufacturing processes that would add additional value, therefore we determined book value is representative of fair value. We assessed the fair value of the WIP and finished goods inventory using the comparative sales method. The estimated step-up in fair value on acquired inventory recognized in connection with the Merger was $48.2 million. As of December 31, 2023, the unamortized step-up in fair value on acquired inventory remaining was $12.2 million.

We estimated the fair value of the various classes of property, plant, and equipment acquired using the income approach, sales comparison approach, and the cost approach. The estimated fair value of property, plant, and equipment acquired in connection with the Merger was $68.9 million.

Intangible assets primarily included customer relationships, developed technology, and in-process research and development. Determining the fair value of intangible assets acquired as part of purchase accounting requires us to make significant estimates. These estimates include the amount and timing of projected future cash flows, royalty savings, and the discount rate used to discount those cash flows to present value.

We estimated the fair value of acquired right-of-use assets and assumed lease liabilities acquired in connection with the Merger using the yield capitalization method of the income approach. Acquired right-of-use assets and assumed lease liabilities are measured based on the remaining lease payments over the remaining portion of the lease term. As our leases do not provide an

implicit rate, our incremental borrowing rate is used as a discount rate, based on the information available as of the acquisition date, in determining the present value of lease payments.

These 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 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, adjusted 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, with any discounts for post-vesting restrictions estimated using the Chaffe Model. 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 units is calculated based upon (i) the closing stock price at the date of grant and (ii) the number of stock units expected to vest at the conclusion of the performance period. 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 financial results metrics or applicable milestones associated with the grant and requires significant judgment.

As part of the Merger, our Board of Directors determined to treat the transaction as a "Change in Control" under applicable agreements and equity plans. As a result, all outstanding and previously granted performance-based and market-based restricted stock units were converted to time-based restricted stock units. We used the Monte Carlo valuation methodology to calculate the fair value of the performance-based and market-based restricted stock units. The value is recognized as expense over the requisite service period and adjusted for forfeitures as they occur.

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, 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.

Adjusted EBITDA

Adjusted EBITDA represents earnings before interest income (expense), income taxes, depreciation, and amortization and excludes the impact of share-based compensation, gains and losses related to changes in foreign exchange rates, charges related to the SeaSpine merger and other strategic investments, acquisition-related fair value adjustments, interest and gains and losses on investments, litigation and investigation costs, charges related to initial compliance with regulations set forth by the European Union Medical Device Regulation, charges related to business interruption resulting from the COVID-19 pandemic, and succession charges. Adjusted 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 the outstanding debt related to our Initial Term Loan, which bears interest at floating rates based on a three-month Secured Overnight Financing Rate, or SOFR, plus an applicable borrowing margin or at a base rate (as defined in the Financing 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.

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 Dollar, Swiss Franc, British Pound, or Canadian Dollar. 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, 2023, we recorded a foreign currency gain of $1.6 million on the statement of operations and comprehensive loss resulting from gains and losses in foreign currency transactions.

We are also subject to currency exposure from translating the results of our global operations into the U.S. Dollar at exchange rates that fluctuate during the period. The U.S. Dollar equivalent of international sales denominated in foreign currencies was favorably impacted during the year ended December 31, 2023, and unfavorably impacted during the year ended December 31, 2022, 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 $9.4 million and an increase in operating income of $0.6 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 $9.4 million and a decrease in operating income of $0.6 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 not effective due to a material weakness in the Company's internal control over financial reporting related to management's review activities for business combinations and goodwill as disclosed below.

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, 2023, 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 our internal control over financial reporting was not effective as of December 31, 2023, due to a material weakness in the design and operation of certain management review controls pertaining to business combinations and assessing recoverability of goodwill, resulting from insufficient evidence supporting the precision over the determination of certain estimates and insufficient evidence supporting the operating effectiveness of the associated review controls. This material weakness did not result in any misstatements to the consolidated financial statements or disclosures.

Notwithstanding the material weaknesses, management has concluded that the financial statements included elsewhere in this Annual Report present fairly, in all material respects, our financial position, results of operations, and cash flows in conformity with GAAP.

As permitted by the SEC Staff interpretive guidance for recently acquired businesses, management's assessment and conclusion on the effectiveness of the Company's disclosure controls and procedures as of December 31, 2023, excludes an assessment of the internal control over financial reporting of the SeaSpine business acquired on January 5, 2023. SeaSpine represents approximately 52% of consolidated total assets and approximately 35% of consolidated revenues as of and for the year ended December 31, 2023.

Ernst & Young LLP, an independent registered public accounting firm, has issued an audit report on the effectiveness of our internal control over financial reporting as of December 31, 2023, which follows this report.

Plan to Remediate Material Weakness

In order to address and resolve the identified material weakness, management, with oversight from our Audit Committee, is in process of developing a detailed plan for remediation, which will include:

- Evaluating skill set gaps and hiring additional accounting, finance, and/or financial reporting personnel, as needed, with relevant public company accounting and financial reporting experience to develop and implement additional policies, procedures, and controls as it pertains to business combinations, asset acquisitions, and/or other processes heavily dependent on the usage of prospective financial information;
- Providing ongoing training for key personnel responsible for internal control over financial reporting; and
- Enhancing or designing and implementing controls over the completeness and accuracy of information used in financial reporting and forecasted financial results, particularly as it relates to the accounting for business combinations and goodwill.

We are committed to remediating the material weaknesses and we are making progress in that effort. The actions we are taking are subject to ongoing senior management review, as well as oversight from the Audit Committee. When fully implemented and operational, we believe the measures described above will remediate the underlying causes of the control deficiencies that gave rise to the material weakness and will strengthen our internal control over financial reporting. However, remediation efforts are expected to continue beyond the fiscal year ending December 31, 2023. Further, we will not be able to fully remediate this material weakness until these steps have been completed and have been operating effectively for a sufficient period of time. We may also identify additional measures that may be required to remediate the material weakness in our internal control over financial reporting, necessitating further action.

Changes in Internal Control over Financial Reporting

We are working towards implementing processes and procedures to address the material weakness noted above. However, none of these efforts have resulted in the remediation of the material weaknesses noted above as of December 31, 2023. There have been no changes in our internal control over financial reporting during the fourth quarter of 2023 other than the identification of the material weakness and the remediation plan disclosed above that have materially affected, or that 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, 2023, 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, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Orthofix Medical Inc. (the Company) has not maintained effective internal control over financial reporting as of December 31, 2023, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management identified a material weakness in its review controls over business combinations and assessment of the recoverability of goodwill.

As indicated in the accompanying Management's Annual Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of SeaSpine Holdings Corporation, which is included in the 2023 consolidated financial statements of the Company and constituted 52% of total assets as of December 31, 2023 and 35% of revenues for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of SeaSpine Holdings Corporation.

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, 2023, and 2022, 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, 2023, and the related notes. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2023 consolidated financial statements, and this report does not affect our report dated March 5, 2024, which 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
March 5, 2024

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 Schedule

(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, dated as of October 10, 2022, by and among Orthofix Medical Inc., Orca Merger Sub Inc. and SeaSpine Holdings Corporation (filed as an exhibit to the Company's Current Report on Form 8-K dated October 11, 2022 and incorporated herein by reference).
2.2	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	Amended and Restated Certificate of Incorporation (filed as an exhibit to the Company's Current Report on Form 8-K dated June 20, 2023 and incorporated herein by reference).
3.2	Amended and Restated Bylaws, as amended (filed as an exhibit to the Company's Current Report on Form 8-K dated June 20, 2023 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	Financing Agreement, dated as of November 6, 2023, among Orthofix Medical Inc., certain subsidiaries of Orthofix Medical Inc. from time to time party thereto as guarantors, the lenders from time to time party thereto, and Blue Torch Finance LLC, as administrative agent and collateral agent (filed as an exhibit to the Company's Current Report on Form 8-K dated November 8, 2023 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. (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference).
10.3†	Supply Agreement between SeaSpine Orthopedics Corporation and PcoMed, LLC, dated March 1, 2021 (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.4	Lease Agreement between AR Industrial No. 1 Ltd. and Orthofix Inc. dated February 10, 2009 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference).

10.5	First Amendment to the Lease Agreement between AR Industrial No. 1 Ltd. and Orthofix Inc. dated April 13, 2009 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference).
10.6	Second Amendment to the Lease Agreement between AR Industrial No. 1 Ltd. and Orthofix Inc. dated May 12, 2010 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference).
10.7	Third Amendment to the Lease Agreement between AR Industrial No. 1 Ltd. and Orthofix Inc. dated December 21, 2017 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference).
10.8	Fourth Amendment to the Lease Agreement between AR Industrial No. 1 Ltd. and Orthofix Inc. dated March 13, 2018 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference).
10.9	Fifth Amendment to the Lease Agreement between AR Industrial No. 1 Ltd. and Orthofix Inc. dated January 3, 2019 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference).
10.10	Standard Lease Agreement between Lake Midas LLC and Spinal Kinetics, Inc. dated April 16, 2015 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference).
10.11	First Amendment to the Standard Lease Agreement between Lake Midas LLC and Spinal Kinetics LLC (formerly known as Spinal Kinetics, Inc.) dated March 4, 2022 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference).
10.12	Sublease Agreement between SeaSpine Orthopedics Corporation and SkinMedica, Inc., dated July 8, 2015 (filed as an exhibit to the Current Report on Form 8-K dated September 8, 2015 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.13	Standard Industrial/Commercial Single-Tenant Lease–NET between Monarch RRC Properties, LP and Isotis Orthobiologics, Inc., dated June 1, 2022 (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.14	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).
10.15	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).
10.16*	Amendment No. 3 to the Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan.
10.17	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).
10.18	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).
10.19	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).
10.20	Amendment No. 3 to 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 June 7, 2022 and incorporated by reference).
10.21*	Amendment No. 4 to the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan.
10.22	Form of Employee Performance Stock Unit Agreement (2022 grant) 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, 2022 and incorporated herein by reference).

10.23	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).
10.24	Form of Time-Based Vesting Employee Restricted Stock Unit Grant Agreement (2023 grant) 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).
10.25	Form of Time-Based Vesting Employee Restricted Stock Unit Grant Agreement (2018 – 2022 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 fiscal year ended December 31, 2022 and incorporated herein by reference).
10.26	Form of Time-Based Vesting Employee Non-Qualified Stock Option Agreement (2023 grant) 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).
10.27	Form of Time-Based Vesting Employee Non-Qualified Stock Option Agreement (July 2016 – 2022 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).
10.28	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).
10.29	Form of Non-Employee Director Restricted Stock Unit Agreement (2023 grant) 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, 2022 and incorporated herein by reference).
10.30	Form of Non-Employee Director Restricted Stock Unit Agreement (2017 - 2022 grants) 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).
10.31	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).
10.32	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).
10.33	Form of Time-Based Vesting Employee Restricted Stock Unit Grant Agreement (October 2023 grant) under the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 and incorporated herein by reference).
10.34	Form of Time-Based Vesting Employee Restricted Stock Unit Grant Agreement (October 2023 Cathy Burzik grant) under the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 and incorporated herein by reference).
10.35	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).
10.36	Orthofix Medical Inc. Inducement Plan for SeaSpine Employees (filed as exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration No. 333-269116) filed January 4, 2023 and incorporated herein by reference).
10.37	Orthofix Medical Inc. Inducement Plan for SeaSpine Employees – Stock Unit Grant Agreement (filed as exhibit 4.4 to the Company's Registration Statement on Form S-8 (Registration No. 333-269116) filed January 4, 2023 and incorporated herein by reference).
10.38	Orthofix Medical Inc. Inducement Plan for SeaSpine Employees – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-8 (Registration No. 333-269116) filed January 4, 2023 and incorporated herein by reference).

10.39	SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan (As Amended and Restated as of March 30, 2016) (filed as an exhibit to the Company's Form S-8 filed on January 10, 2023 and incorporated herein by reference).
10.40	First Amendment to the SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan (filed as an exhibit to the Company's Form S-8 filed on January 10, 2023 and incorporated herein by reference).
10.41	Second Amendment to the SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan (filed as an exhibit to the Company's Form S-8 filed on January 10, 2023 and incorporated herein by reference).
10.42	Amendment to the SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan (filed as an exhibit to the Company's Form S-8 filed on January 10, 2023 and incorporated herein by reference).
10.43	Form of Stock Option Grant Notice and Stock Option Agreement under SeaSpine Holdings Corporation 2015 Incentive Award Plan (three-month exercise period post-termination) (filed as an exhibit to the Registration Statement on Form S-8 filed with the Commission on June 7, 2016 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.44	Form of Stock Option Grant Notice and Stock Option Agreement under SeaSpine Holdings Corporation 2015 Incentive Award Plan (one-year exercise period post-termination) (filed as an exhibit to Amendment No. 2 to Form 10 filed with the Commission on June 1, 2015 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.45	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under SeaSpine Holdings Corporation 2015 Incentive Award Plan (grants awarded after January 1, 2020) (filed as an exhibit to the Annual Report on Form 10-K for the year ended December 31, 2019 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.46	Form of Stock Option Grant Notice and Stock Option Agreement under SeaSpine Holdings Corporation 2015 Incentive Award Plan (grants to Senior Leadership Team Members awarded after June 6, 2018) (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.47	Form of Stock Option Grant Notice and Stock Option Agreement under SeaSpine Holdings Corporation 2015 Incentive Award Plan (grants to Non-Senior Leadership Team Members awarded after June 6, 2018) (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.48	SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan (filed as an exhibit to the Company's Form S-8 filed on January 10, 2023 and incorporated herein by reference).
10.49	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.50	Form of Stock Option Grant Notice and Stock Option Agreement under SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan (grants to Senior Leadership Team Members) (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.51	Form of Stock Option Grant Notice and Stock Option Agreement under SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan (grants to Non-Senior Leadership Team Members) (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.52	SeaSpine Holdings Corporation 2020 Employment Inducement Incentive Award Plan (filed as an exhibit to the Company's Form S-8 filed on January 10, 2023 and incorporated herein by reference).
10.53	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under SeaSpine Holdings Corporation 2020 Employment Inducement Incentive Award Plan (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 by SeaSpine Holdings Corporation and incorporated herein by reference).

10.54	Form of Stock Option Grant Notice and Stock Option Agreement under SeaSpine Holdings Corporation 2020 Employment Inducement Incentive Award Plan (grants to Senior Leadership Team Members) (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.55	Form of Stock Option Grant Notice and Stock Option Agreement under SeaSpine Holdings Corporation 2020 Employment Inducement Incentive Award Plan (grants to Non-Senior Leadership Team Members) (filed as an exhibit to the Quarterly Report on Form 10-Q for the quarter ended June 30, 2020 by SeaSpine Holdings Corporation and incorporated herein by reference).
10.56	Form of Indemnification Agreement between Orthofix Medical Inc. and its directors and officers (filed as an exhibit to the Company's Current Report on Form 8-K filed January 5, 2023 and incorporated herein by reference).
10.57	Form of Indemnification Agreement between Orthofix Medical Inc. and its directors and officers (filed as an exhibit to the Company's Registration Statement on Form S-4 (Registration No. 333-224407) filed April 23, 2018).
10.58	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).
10.59	Transition Agreement, dated March 3, 2023, between Orthofix Medical Inc. and Jon Serbousek (filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2022 and incorporated herein by reference).
10.60	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).
10.61	Letter Agreement, dated April 4, 2023, between the Company and Kevin Kenny (filed as an exhibit to the Company's Current Report on Form 8-K dated April 4, 2023 and incorporated herein by reference).
10.62	Change in Control and Severance Agreement, date June 19, 2023, between the Company and Kevin Kenny (filed as an exhibit to the Company's Current Report on Form 8-K dated June 21, 2023 and incorporated herein by reference).
10.63	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).
10.64	Transition Agreement, dated March 3, 2023, between Orthofix Medical Inc. and Doug Rice (filed as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2022 and incorporated herein by reference).
10.65	Change in Control and Severance Agreement, dated November 1, 2016, between Orthofix International N.V. and Kimberley Elting (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and incorporated herein by reference).
10.66	Change in Control and Severance Agreement, date June 19, 2023, between the Company and Kimberley A. Elting (filed as an exhibit to the Company's Current Report on Form 8-K dated June 21, 2023 and incorporated herein by reference).
10.67	Offer Letter between the Company and Keith C. Valentine (filed as an exhibit to the Company's Current Report on Form 8-K filed on January 5, 2023 and incorporated herein by reference).
10.68	Change in Control and Severance Agreement, dated June 19, 2023, between the Company and Keith C. Valentine (filed as an exhibit to the Company's Current Report on Form 8-K dated June 21, 2023 and incorporated herein by reference).
10.69	Offer Letter between the Company and John J. Bostjancic (filed as an exhibit to the Company's Current Report on Form 8-K filed on January 5, 2023 and incorporated herein by reference).
10.70	Change in Control and Severance Agreement, dated June 19, 2023, between the Company and John J. Bostjancic (filed as an exhibit to the Company's Current Report on Form 8-K dated June 21, 2023 and incorporated herein by

reference).

10.71 Offer Letter between the Company and Patrick L. Keran (filed as an exhibit to the Company's Current Report on Form 8-K filed on January 5, 2023 and incorporated herein by reference).

10.72	Change in Control and Severance Agreement, dated June 19, 2023, between the Company and Patrick L. Keran (filed as an exhibit to the Company's Current Report on Form 8-K dated June 21, 2023 and incorporated herein by reference).
10.73	Change in Control and Severance Agreement, dated October 2, 2023, between Orthofix Medical Inc. and Geoffrey Gillespie (filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 and incorporated herein by reference).
10.74	Letter agreement, entered into on November 27, 2023, between Orthofix Medical Inc. and Massimo Calafiore (filed as an exhibit to the Company's Current Report on Form 8-K dated December 1, 2023 and incorporated herein by reference).
10.75	Orthofix Medical Inc. 2024 CEO Inducement Plan (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration no. 333-276433) filed January 8, 2024 and incorporated herein by reference).
10.76	Orthofix Medical Inc. 2024 CEO Inducement Plan – Performance Stock Unit Grant Agreement (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration no. 333-276433) filed January 8, 2024 and incorporated herein by reference).
10.77	Orthofix Medical Inc. 2024 CEO Inducement Plan – Stock Unit Grant Agreement (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-8 (Registration no. 333-276433) filed January 8, 2024 and incorporated herein by reference).
10.78	Orthofix Medical Inc. 2024 CEO Inducement Plan – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-8 (Registration no. 333-276433) filed January 8, 2024 and incorporated herein by reference).
10.79	Change in Control and Severance Agreement, dated as of January 8, 2024, between Orthofix Medical Inc. and Massimo Calafiore (filed as an exhibit to the Company's Current Report on Form 8-K dated January 9, 2024 and incorporated herein by reference).
10.80	Letter agreement, dated as of January 4, 2024, between Orthofix Medical Inc. and Julie Andrews (filed as an exhibit to the Company's Current Report on Form 8-K dated January 9, 2024 and incorporated herein by reference).
10.81	Orthofix Medical Inc. 2024 CFO Inducement Plan (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration no. 333-276506) filed January 8, 2024 and incorporated herein by reference).
10.82	Orthofix Medical Inc. 2024 CFO Inducement Plan – Performance Stock Unit Grant Agreement (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration no. 333-276506) filed January 8, 2024 and incorporated herein by reference).
10.83	Orthofix Medical Inc. 2024 CFO Inducement Plan – Stock Unit Grant Agreement (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-8 (Registration no. 333-276506) filed January 8, 2024 and incorporated herein by reference).
10.84	Orthofix Medical Inc. 2024 CFO Inducement Plan – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-8 (Registration no. 333-276506) filed January 8, 2024 and incorporated herein by reference).
10.85	Change in Control and Severance Agreement, dated as of January 15, 2024, between Orthofix Medical Inc. and Julie Andrews (filed as an exhibit to the Company's Current Report on Form 8-K dated January 17, 2024 and incorporated herein by reference).
10.86	Cooperation Agreement, dated December 11, 2023, by and among Orthofix Medical Inc. Engine Capital, L.P., Engine Jet Capital, L.P., Engine Lift Capital LP, Engine Capital Management, LP, Engine Capital Management GP, LLC, Engine Investments, LLC, Engine Investments II, LLC and Arnaud Ajdler (filed as an exhibit to the Company's Current Report on Form 8-K dated December 15, 2023 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.
97.1*	Incentive Compensation Recovery Policy
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.
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: March 5, 2024

By: /s/ MASSIMO CALAFIORE
Name: **Massimo Calafiore**
Title: **President and Chief Executive Officer, Director**

Dated: March 5, 2024

By: /s/ JULIE ANDREWS
Name: **Julie Andrews**
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/ MASSIMO CALAFIORE **Massimo Calafiore**	President and Chief Executive Officer, Director (Principal Executive Officer)	March 5, 2024
/s/ JULIE ANDREWS **Julie Andrews**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 5, 2024
/s/ CATHERINE BURZIK **Catherine Burzik**	Director, Chair of the Board	March 5, 2024
/s/ ALAN BAZAAR **Alan Bazaar**	Director	March 5, 2024
/s/ WAYNE BURRIS **Wayne Burris**	Director	March 5, 2024
/s/ STUART ESSIG **Stuart Essig**	Director	March 5, 2024
/s/ MICHAEL FINEGAN **Michael Finegan**	Director	March 5, 2024
/s/ JASON HANNON **Jason Hannon**	Director	March 5, 2024
/s/ JOHN HENNEMAN, III **John Henneman, III**	Director	March 5, 2024
/s/ JAMES HINRICHS **James Hinrichs**	Director	March 5, 2024
/s/ CHARLES KUMMETH **Charles Kummeth**	Director	March 5, 2024

/s/ SHWETA SINGH MANIAR	Director	March 5, 2024
Shweta Singh Maniar		
/s/ MIKE PAOLUCCI	Director	March 5, 2024
Mike Paolucci		

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

Massimo Calafiore
President and Chief Executive Officer, Director

Julie Andrews
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, 2023 and 2022, 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, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2023, 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, 2023, 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 March 5, 2024 expressed an adverse 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 the 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 a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Inventory Excess and Obsolescence Reserves

Description of the Matter

At December 31, 2023, the Company's inventory balance was $222.2 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 to determine the appropriate inventory reserves and to make corresponding adjustments to the carrying value of these inventories to reflect them at 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 estimated 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.

Accounting for business combination

Description of the Matter

As discussed in Note 4 to the consolidated financial statements, the Company completed a significant acquisition during 2023 for a total purchase price of $376.7 million. The transaction was accounted for as a business combination.

Auditing the Company's acquisition accounting was complex due to the significant size of the transaction and significant estimations used by management in determining the fair values of intangible assets, which utilized prospective financial information. The Company valued customer relationships using the multi-period excess earnings method and valued developed technologies using the relief from royalty method. The significant assumptions used in these models included weighted average cost of capital and certain assumptions that form the basis of the forecasted results (i.e. revenue growth rates, EBITDA margin and cost synergies). The significant assumptions used in the valuation of intangible assets are forward-looking and could be affected by future economic and market conditions.

How We Addressed the Matter in Our Audit

To test the estimated fair value of intangible assets, we performed audit procedures assisted by our valuation specialists that included, among others, evaluating the Company's selection of the valuation methodologies, evaluating the significant assumptions used in the Company's valuation calculations and evaluating the completeness and accuracy of the underlying data supporting the significant assumptions. For example, we performed sensitivity analyses and compared significant assumptions to historical results of the acquired business and to other guideline public companies within the same industry. We also evaluated the Company's

acquisition and related purchase accounting disclosures included in Note 4 to the consolidated financial statements.

/s/ Ernst & Young LLP

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

Dallas, Texas
March 5, 2024

ORTHOFIX MEDICAL INC.

Consolidated Balance Sheets as of December 31, 2023 and 2022

(U.S. Dollars, in thousands, except par value data)	2023	2022
Assets		
Current assets		
Cash and cash equivalents	$ 33,107	$ 50,700
Restricted cash	4,650	—
Accounts receivable, net of allowances of $7,130 and $6,419, respectively	128,098	82,857
Inventories	222,166	100,150
Prepaid expenses and other current assets	32,422	22,283
Total current assets	420,443	255,990
Property, plant and equipment, net	159,060	58,229
Intangible assets, net	117,490	47,388
Goodwill	194,934	71,317
Other long-term assets	33,388	25,705
Total assets	**$ 925,315**	**$ 458,629**
Liabilities and shareholders' equity		
Current liabilities		
Accounts payable	$ 58,357	$ 27,598
Current portion of long-term debt	1,250	—
Current portion of finance lease liability	708	652
Other current liabilities	104,908	55,374
Total current liabilities	165,223	83,624
Long-term debt	93,107	—
Long-term portion of finance lease liability	18,532	19,239
Other long-term liabilities	49,723	18,906
Total liabilities	326,585	121,769
Contingencies (Note 13)		
Shareholders' equity		
Common shares $0.10 par value; 100,000 shares authorized; 37,165 and 20,162 issued and outstanding as of December 31, 2023 and 2022, respectively	3,717	2,016
Additional paid-in capital	746,450	334,969
Retained earnings (accumulated deficit)	(150,144)	1,251
Accumulated other comprehensive loss	(1,293)	(1,376)
Total shareholders' equity	598,730	336,860
Total liabilities and shareholders' equity	**$ 925,315**	**$ 458,629**

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

ORTHOFIX MEDICAL INC.

Consolidated Statements of Operations and Comprehensive Loss
For the years ended December 31, 2023, 2022, and 2021

(U.S. Dollars, in thousands, except share and per share data)	2023	2022	2021
Net sales	$ 746,641	$ 460,713	$ 464,479
Cost of sales	260,368	123,544	114,914
Gross profit	486,273	337,169	349,565
Sales and marketing	385,736	228,810	221,318
General and administrative	144,659	79,966	69,353
Research and development	80,231	49,065	49,621
Acquisition-related amortization and remeasurement (Note 17)	14,757	(7,404)	17,588
Operating loss	(139,110)	(13,268)	(8,315)
Interest expense, net	(8,631)	(1,288)	(1,837)
Other expense, net	(938)	(3,150)	(3,343)
Loss before income taxes	(148,679)	(17,706)	(13,495)
Income tax expense	(2,716)	(2,043)	(24,884)
Net loss	**$ (151,395)**	**$ (19,749)**	**$ (38,379)**
Net loss per common share:			
Basic	$ (4.12)	$ (0.98)	$ (1.95)
Diluted	(4.12)	(0.98)	(1.95)
Weighted average number of common shares:			
Basic	36,729,258	20,053,548	19,690,593
Diluted	36,729,258	20,053,548	19,690,593
Other comprehensive income (loss), before tax			
Unrealized gain (loss) on debt securities	(1,334)	395	(942)
Currency translation adjustment	1,417	(1,771)	(2,544)
Other comprehensive income (loss), before tax	83	(1,376)	(3,486)
Income tax benefit (expense) related to items of other comprehensive income (loss)	—	—	234
Other comprehensive income (loss), net of tax	83	(1,376)	(3,252)
Comprehensive loss	$ (151,312)	$ (21,125)	$ (41,631)

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, 2023, 2022, and 2021

(U.S. Dollars, in thousands)	Number of Common Shares Outstanding	Common Shares	Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)	Total Shareholders' Equity
At December 31, 2020	19,424	$ 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	41	6,228	—	—	6,269
At December 31, 2021	**19,837**	**$ 1,983**	**$ 313,951**	**$ 21,000**	**$ —**	**$ 336,934**
Net loss	—	—	—	(19,749)	—	(19,749)
Other comprehensive loss, net of tax	—	—	—	—	(1,376)	(1,376)
Share-based compensation expense	—	—	18,443	—	—	18,443
Common shares issued, net	325	33	2,575	—	—	2,608
At December 31, 2022	**20,162**	**$ 2,016**	**$ 334,969**	**$ 1,251**	**$ (1,376)**	**$ 336,860**
Net loss	—	—	—	(151,395)	—	(151,395)
Other comprehensive income, net of tax	—	—	—	—	83	83
Share-based compensation expense	—	—	35,707	—	—	35,707
Common shares issued in connection with SeaSpine Merger	16,047	1,605	375,140	—	—	376,745
Common shares issued, net	956	96	634	—	—	730
At December 31, 2023	**37,165**	**$ 3,717**	**$ 746,450**	**$ (150,144)**	**$ (1,293)**	**$ 598,730**

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, 2023, 2022, and 2021

(U.S. Dollars, in thousands)	2023	2022	2021
Cash flows from operating activities			
Net loss	$ (151,395)	$ (19,749)	$ (38,379)
Adjustments to reconcile net loss to net cash from operating activities			
Depreciation and amortization	53,063	29,019	29,599
Inventory reserve expenses	27,576	14,907	10,826
Amortization of inventory fair value step up	36,044	—	—
Impairment of goodwill	—	—	11,756
Amortization of operating lease assets, debt costs, and other assets	7,498	3,056	3,496
Provision for expected credit losses	820	2,095	444
Deferred income taxes	579	314	24,482
Share-based compensation expense	35,707	18,443	15,432
Interest and (gain) loss on the valuation of investment securities	596	(308)	(1,146)
Change in fair value of contingent consideration	(2,700)	(17,200)	(3,575)
Other	423	2,027	1,064
Changes in operating assets and liabilities, net of effects of acquisitions			
Accounts receivable	(10,411)	(6,735)	(7,049)
Inventories	(58,051)	(33,040)	(10,207)
Prepaid expenses and other current assets	1,760	(874)	(2,834)
Accounts payable	8,642	2,282	4,253
Other current liabilities	4,069	627	1,013
Contract liability (Note 15)	—	(4,791)	(9,060)
Payment of contingent consideration	—	—	(6,595)
Other long-term assets and liabilities	27	(1,611)	(5,045)
Net cash from operating activities	**(45,753)**	**(11,538)**	**18,475**
Cash flows from investing activities			
Capital expenditures for property, plant and equipment	(60,256)	(21,364)	(17,785)
Capital expenditures for intangible assets	(1,794)	(1,796)	(1,807)
Contingent consideration payments related to asset acquisitions	—	(1,500)	—
Purchase of investment securities	—	—	(2,171)
Cash acquired in SeaSpine merger	29,419	—	—
Other investing activities	(500)	126	(1,250)
Net cash from investing activities	**(33,131)**	**(24,534)**	**(23,013)**
Cash flows from financing activities			
Proceeds from credit facilities	174,500	—	—
Repayment of borrowings from credit facilities	(79,000)	—	—
Payment of debt acquired from SeaSpine merger	(26,899)	—	—
Proceeds from issuance of common shares	5,127	4,337	8,824
Payments related to withholdings for share-based compensation	(4,397)	(1,729)	(2,555)
Payment of contingent consideration	(1,000)	—	(8,405)
Payments related to finance lease obligation	(652)	(2,594)	(537)
Payment of debt issuance costs and other financing activities	(2,357)	(92)	(948)
Net cash from financing activities	**65,322**	**(78)**	**(3,621)**
Effect of exchange rate changes on cash and restricted cash	619	(997)	(815)
Net change in cash, cash equivalents, and restricted cash	(12,943)	(37,147)	(8,974)
Cash, cash equivalents, and restricted cash at the beginning of the year	50,700	87,847	96,821
Cash, cash equivalents, and restricted cash at the end of the year	**$ 37,757**	**$ 50,700**	**$ 87,847**
Components of cash, cash equivalents, and restricted cash at the end of the year			
Cash and cash equivalents	$ 33,107	$ 50,700	$ 87,847
Restricted cash	4,650	—	—

Cash, cash equivalents, and restricted cash at the end of the year	**$ 37,757**	**$ 50,700**	**$ 87,847**

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

ORTHOFIX MEDICAL INC.

Notes to the Consolidated Financial Statements

1. Business and basis of presentation

Description of the Business

Orthofix Medical Inc. and its Subsidiaries (the “Company” or "Orthofix") merged with SeaSpine Holdings Corporation ("SeaSpine") in January 2023 to form a leading global spine and orthopedics company with a comprehensive portfolio of biologics, innovative spinal hardware, bone growth therapies, specialized orthopedic solutions, and a leading surgical navigation system. Its products are distributed in more than 60 countries worldwide.

The Company is headquartered in Lewisville, Texas, where it conducts general business, product development, medical education and manufacturing, and has primary offices in Carlsbad, CA, with a focus on spine and biologics product innovation and surgeon education, and Verona, Italy, with an emphasis on product innovation, production, and medical education for orthopedics. The combined company’s global research and development, commercial and manufacturing footprint also includes facilities and offices in Irvine, CA, Toronto, Canada, Sunnyvale, CA, Wayne, PA, Olive Branch, MS, Maidenhead, UK, Munich, Germany, Paris, France, and São Paulo, Brazil.

The merger with SeaSpine was completed on January 5, 2023, with SeaSpine continuing as a wholly-owned subsidiary of Orthofix following the transaction. For additional discussion of the merger with SeaSpine, see Note 4. The shares of common stock of Orthofix, as the corporate parent entity in the combined company structure, continue to trade on NASDAQ under the symbol "OFIX".

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.

Changes in Presentation of Consolidated Financial Statements

Certain prior year balances have been reclassified in the consolidated financial statements to conform to current period presentation.

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 (including fair value measurements associated with business combinations and/or asset acquisitions), 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 may 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 respective 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 exchange rates 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 income (expense), net and was a gain of $1.6 million, a loss of $3.3 million, and a loss of $4.0 million for the years ended December 31, 2023, 2022, and 2021, 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 November 2023, following the termination of the Second Amended and Restated Credit Agreement with JPMorgan Chase Bank, N.A., as Administrative Agent, and certain lender parties thereto, Bank of America required collateral of approximately $4.7 million of the Company's cash as a banking service obligation. This cash has been reclassified to restricted cash as of December 31, 2023.

Investing activities that did not result in cash receipts or cash payments during the years ended December 31, 2023, 2022, and 2021 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)	2023	2022	2021
Supplemental disclosure of cash flow information:			
Noncash investing activities:			
Intangible assets acquired in asset acquisitions	$ —	$ 2,000	$ —

Advertising costs

Advertising costs are expensed as incurred. Advertising costs are included within sales and marketing expense and totaled $0.5 million for each of the years ended December 31, 2023, 2022, and 2021, respectively.

Research and development costs, including collaborative arrangements

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, less than $0.1 million, and $0.8 million in research and development expense for the years ended December 31, 2023, 2022, and 2021, respectively.

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 totaled $0.1 million, $0.5 million, and $0.6 million for the years ended December 31, 2023, 2022, and 2021, respectively.

3. Recently adopted accounting standards and recently issued accounting pronouncements

Recently Adopted Accounting Standards

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 Coronavirus Aid, Relief, and Economic Security Act ("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 Accounting Standards Codification ("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 consolidated balance sheet, statements of operations, or cash flows.

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 the London Inter-Bank Offered Rate. 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 consolidated balance sheet, statements of operations, or cash flows.

Adoption of ASU 2021-08, Accounting for Contract Assets and Contract Liabilities with Contracts with Customers

In October 2021, the FASB issued ASU 2021-08, which aims to address diversity in practice and inconsistency related to the accounting for acquired revenue contracts with customers in a business combination. The amendments require that an entity recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with Topic 606, Revenue from Contracts with Customers. Adoption of this standard resulted in the recognition of $2.2 million in contract liabilities associated with acquired revenue contracts as a result of the Company's merger with SeaSpine, which closed on January 5, 2023.

Recently Issued Accounting Pronouncements

Topic	Description of Guidance	Effective Date	Status of Company's Evaluation
Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions (ASU 2022-03)	Clarifies the guidance in Topic 820, *Fair Value Measurement*, when measuring the fair value of an equity security subject to contractual restrictions that prohibit the sale of an equity security and introduces new disclosure requirements for equity securities subject to contractual sale restrictions. Certain of the provisions are to be applied retrospectively with other provisions applied prospectively.	January 1, 2024	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements, but does not expect this ASU to have a material impact on disclosures within the Company's consolidated financial statements.
Disclosure Improvements - Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative (ASU 2023-06)	Adds interim and annual disclosure requirements to a variety of subtopics in the Accounting Standards Codification, including those focusing on accounting changes, earnings per share, debt and repurchase agreements. The guidance will be applied prospectively. The effective date will be the date when the SEC's removal of the related disclosure requirement becomes effective, with early adoption prohibited.	Various	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.
Improvements to Reportable Segment Disclosures (ASU 2023-07)	Improve financial reporting by requiring disclosure of incremental segment information on an annual and interim basis for all public entities to enable investors to develop more decision-useful financial analyses. Provisions are to be applied retrospectively to all prior periods presented in financial statements.	January 1, 2024	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements; however, the Company expects to disclose additional information in regards to its reportable segments as a result of this ASU, including (i) significant segment expenses regularly provided to the Company's chief operating decision maker ("CODM"), (ii) disclosure of other segment items by reportable segment, and (iii) disclosure of the title and position of the Company's CODM, among other disclosure requirements.
Improvements to Income Tax Disclosures (ASU 2023-09)	Enhance the transparency and decision usefulness of income tax disclosures to better assess how an entity’s operations and related tax risks and tax planning and operational opportunities affect its tax rate and prospects for future cash flows. The amendments are to be applied prospectively, but retrospective application is permitted.	January 1, 2025	The Company is currently evaluating the impact this ASU may have on its consolidated financial statements.

4. Mergers and acquisitions

Merger with SeaSpine

On January 5, 2023, the Company and SeaSpine completed an all-stock merger of equals (the "Merger") to create a leading global spine and orthopedics company with highly complementary portfolios of biologics, innovative spinal hardware, bone growth therapies, specialized orthopedic solutions, and a leading surgical navigation system. As a result of the Merger, each share of SeaSpine common stock issued and outstanding immediately prior to the closing of the Merger was converted into the right to receive 0.4163 shares of Orthofix common stock.

The Merger is being accounted for as an acquisition of SeaSpine by Orthofix under the acquisition method of accounting for business combinations in accordance with U.S. GAAP. Therefore, Orthofix is treated as the acquirer for accounting purposes. In identifying the acquirer, Orthofix and SeaSpine considered the structure of the transaction and other actions contemplated by the merger agreement (the "Merger Agreement"), relative outstanding share ownership, market values, the composition of the combined company's Board of Directors, and the relative size of Orthofix and SeaSpine. Under the acquisition method of accounting, the assets and liabilities of SeaSpine and its subsidiaries have been recorded at their respective fair values as of the acquisition date.

The total estimated fair value of consideration associated with the Merger as of the acquisition date was comprised of:

(U.S. Dollars, in thousands, except shares and price per share)		
Share Consideration:		
Orthofix common shares to be issued in exchange for SeaSpine common shares		16,047,315
Orthofix closing price per share as of January 4, 2023	$	22.76
Estimated fair value of shares issued in exchange for SeaSpine common shares	$	365,237
Estimated fair value of Orthofix stock options and RSUs issued in exchange for outstanding SeaSpine equity awards		11,508
Total estimated fair value of consideration	$	376,745

The following table summarizes the estimated fair values of the assets acquired and liabilities assumed at the acquisition date. The Company finalized its valuation of assets acquired and liabilities assumed during the fourth quarter of 2023. Certain acquired assets and liabilities assumed were valued utilizing Level 3 inputs and assumptions.

(U.S. Dollars, in thousands)	Previously Reported	Adjustments	Final Acquisition Date Fair Value	Assigned Useful Life
Assets acquired:				
Current assets				
Cash and cash equivalents	$ 29,419	$ —	$ 29,419	
Accounts receivable, net	35,313	—	35,313	
Inventories	132,636	—	132,636	
Prepaid expenses and other current assets	4,590	—	4,590	
Total current assets	201,958	—	201,958	
Property, plant, and equipment, net	68,863	—	68,863	
Customer relationships	33,100	—	33,100	13 years
Developed technology	47,200	—	47,200	6 - 8 years
In-process research and development ("IPR&D")	5,750	—	5,750	Indefinite
Other long-term assets	20,501	—	20,501	
Total identifiable assets acquired	**$ 377,372**	$ —	**$ 377,372**	
Liabilities assumed:				
Current liabilities				
Accounts payable	$ 21,602	$ —	$ 21,602	
Other current liabilities	43,344	177	43,521	
Total current liabilities	64,946	177	65,123	
Long-term borrowings under SeaSpine credit facility	26,298	—	26,298	
Other long-term liabilities	32,833	(10)	32,823	
Total liabilities assumed	**124,077**	167	**124,244**	
Net identifiable assets acquired	**$ 253,295**	$ (167)	**$ 253,128**	
Total fair value of consideration transferred	376,745	—	376,745	
Residual goodwill	**$ 123,450**	$ 167	**$ 123,617**	

The purchase price exceeded the fair value of the net tangible and identifiable intangible assets acquired in the Merger. As of December 31, 2023, the Company recorded goodwill totaling $123.6 million, which was assigned to the Global Spine reporting segment. Specifically, the goodwill includes the assembled workforce and synergies associated with the combined entity. The

goodwill is not deductible for tax purposes.

The Company recognized $9.9 million in direct acquisition-related costs, which exclude integration-related activities, that were expensed during the year ended December 31, 2023. These costs are included in the consolidated statements of operations and comprehensive income (loss), primarily within general and administrative expenses. The Company's results of operations included $258.9 million of net sales from SeaSpine for the year ended December 31, 2023, and a net loss attributable to SeaSpine of $84.0 million for the year ended December 31, 2023.

Unaudited Pro Forma Financial Information

Due to the Merger closing on January 5, 2023, all SeaSpine financial results for fiscal year 2023, except for the first four days of January, are included in Orthofix's consolidated statement of operations and comprehensive loss. The following unaudited pro forma financial information for the year ended December 31, 2023, is based on the Company's historical consolidated financial statements adjusted to reflect as if the Merger closed as of January 1, 2022.

The unaudited pro-forma information makes certain adjustments to depreciation and amortization expense to reflect the fair value recognized in the purchase price allocation and to remove one-time transaction-related costs. The unaudited pro forma financial information is presented for informational purposes only and is not necessarily indicative of the results of operations that would have been achieved if the Merger closed as of January 1, 2022.

	For the Year Ended December 31,	
(U.S. Dollars, in millions)	**2023**	**2022**
Net sales	$ 746.6	$ 698.2
Net loss	$ (116.4)	$ (129.2)

Integration and Restructuring Activities

The Company has incurred significant integration and restructuring costs in connection with the Merger. The following table summarizes integration costs incurred for the year ended December 31, 2023, and 2022.

	For the Year Ended December 31,	
(U.S. Dollars, in millions)	**2023**	**2022**
Compensation-related integration costs	$ 17.7	$ —
International spine restructuring	1.3	—
Fee paid to financial advisor to the Merger	5.5	—
Professional fees / consulting fees	5.8	—
Product rationalization charges	6.0	—
Other costs to complete	1.4	—
Total	$ 37.7	$ —

In the first quarter of 2023, the Company approved and initiated certain restructuring activities to streamline costs and to better align talent with operational needs following the consummation of the Merger. This program was expanded in the third quarter of 2023 to include further restructuring activities related to the Company's international spine business. The Company expects to incur total pre-tax expenses of approximately $18.2 million associated with the restructuring activities, which will be recognized within operating expenses. The table below provides a summary of restructuring costs incurred during the period and the resulting liabilities as of December 31, 2023, which are recognized within other current liabilities.

(U.S. Dollars, in millions)	**Balance as of December 31, 2022**	**Charges Incurred**	**Payments Made / Currency Translation Adjustment**	**Balance as of December 31, 2023**
U.S. Severance costs	$ —	$ 11.2	$ (10.2)	$ 1.0
U.S. Retention costs	—	5.3	(0.3)	5.0
U.S. Payroll taxes	—	0.7	(0.4)	0.3
International spine restructuring severance	—	1.0	(0.3)	0.7
Total	$ —	$ 18.2	$ (11.2)	$ 7.0

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 the Company's 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 the Company's 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 by management, at least annually or more often, in the event circumstances indicate a change in cost has occurred.

Work-in-process and finished products include material, labor, and production overhead costs. Field and consignment inventory, which 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, is included within finished products.

	December 31,	
(U.S. Dollars, in thousands)	**2023**	**2022**
Raw materials	$ 28,390	$ 17,035
Work-in-process	53,510	19,243
Finished products	140,266	63,872
Inventories	$ 222,166	$ 100,150

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 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 or estimated fair value when acquired as part of a business combination, less accumulated depreciation. Costs include all expenditures necessary to place the asset in service, generally including freight and sales and use taxes. Property, plant, and equipment also 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 $34.2 million, $19.6 million, and $20.2 million for the years ended December 31, 2023, 2022, and 2021, respectively.

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

(U.S. Dollars, in thousands)	December 31, 2023	2022
Cost		
Buildings	$ 4,103	$ 3,867
Plant and equipment	70,252	48,358
Instrumentation	154,192	92,607
Computer software	43,040	40,685
Furniture and fixtures	11,010	7,917
Construction in progress	41,751	4,515
Finance lease assets	23,337	23,276
Property, plant, and equipment, gross	347,685	221,225
Accumulated depreciation	(188,625)	(162,996)
Property, plant, and equipment, net	$ 159,060	$ 58,229

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, which generally ranges from 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 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, less accumulated amortization. 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, 2023	2022
Cost			
Developed technology	7.9 years	$ 92,416	$ 43,699
Patents	10.0 years	43,262	40,108
IPR&D	Indefinite	4,674	300
Customer relationships	12.1 years	49,197	15,572
License and other	9.6 years	24,584	23,295
Trademarks—finite lived	10.0 years	1,797	1,875
	9.5 years	215,930	124,849
Accumulated amortization			
Developed technology		$ (28,898)	$ (17,830)
Patents		(40,494)	(37,506)
Customer relationships		(11,988)	(6,938)
License and other		(16,240)	(14,386)
Trademarks—finite lived		(820)	(801)
		(98,440)	(77,461)
Intangible assets, net		$ 117,490	$ 47,388

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 assets 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 reclassified to developed technology and are amortized over an assigned useful life that best reflects the economic benefits provided by these assets.

Amortization expense for intangible assets was $18.9 million, $9.4 million, and $9.4 million for the years ended December 31, 2023, December 31, 2022, and 2021, respectively. Future amortization expense for intangible assets is estimated as follows:

(U.S. Dollars, in thousands)	Amortization
2024	$ 20,948
2025	19,849
2026	18,810
2027	18,426
2028	14,890
Thereafter	19,893
Total finite-lived intangible assets, net	$ 112,816
Indefinite-lived intangible assets, net	4,674
Intangible assets, net	$ 117,490

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.

The following table presents the net carrying value of goodwill as of December 31, 2023, and 2022, and a rollforward of such balances from December 31, 2022, by reportable segment:

(U.S. Dollars, in thousands)	Balance as of December 31, 2022	Goodwill Acquired in the Merger with SeaSpine	Impairment	Currency translation adjustment	Balance as of December 31, 2023
Global Spine - Gross	$ 71,317	$ 123,617	$ —	$ —	$ 194,934
Global Spine - Accumulated Impairment Loss	—	—	—	—	$ —
Global Spine - Net	$ 71,317	$ 123,617	$ —	$ —	$ 194,934
Global Orthopedics - Gross	$ 11,130	$ —	$ —	$ 347	$ 11,477
Global Orthopedics - Accumulated Impairment Loss	(11,130)	—	—	(347)	$ (11,477)
Global Orthopedics - Net	$ —	$ —	$ —	$ —	$ —
Goodwill, net of accumulated impairment losses	$ 71,317	$ 123,617	$ —	$ —	$ 194,934

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 was reflected within Acquisition-related amortization and remeasurement. The assessment concluded there were no indicators of impairment for the Global Spine goodwill.

In the fourth quarter of 2022, the Company performed a qualitative assessment for its annual goodwill impairment analysis, which did not result in an impairment charge. This qualitative analysis considered all relevant factors specific to the reporting units, including macroeconomic conditions, industry and market considerations, overall financial performance, and relevant entity-specific events.

In the third quarter of 2023, the Company announced the termination of its former President and Chief Executive Officer, former Chief Financial Officer, and former Chief Legal Officer, from their respective roles. Immediately following the announcement, the Company’s market capitalization decreased by approximately 30%, indicating that an impairment may exist. As a result, the Company performed an interim quantitative assessment of its goodwill as of September 30, 2023. The Company estimated the fair value of each reporting unit using a weighted average of the fair value derived from both an income approach and a market approach (all Level 3 fair value measurements). Upon performing its assessment, the Company determined its Global Spine reporting unit's fair value exceed its carrying value of net assets as of September 30, 2023.

In the fourth quarter of 2023, the Company performed a qualitative assessment for its annual goodwill impairment analysis, which did not result in an 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.

9. Leases

The Company determines if a contractual arrangement qualifies as a lease at inception. The Company’s leases primarily relate to facilities, vehicles, equipment, and certain contract manufacturing agreements. Lease assets represent the Company’s right to use an underlying asset for the lease term, while 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 the impact of any lease incentives.

The Company does not recognize lease liabilities or lease assets on the balance sheet for short-term leases (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 the Company's short-term lease commitments.

For all classifications of leases, the Company combines lease and non-lease 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, 2023, and 2022, is presented in the table below:

(U.S. Dollars, in thousands, except lease term and discount rate)	Classification	December 31, 2023	December 31, 2022
Assets			
Operating leases	Other long-term assets	$ 19,869	$ 6,788
Finance leases	Property, plant and equipment, net	16,345	17,360
Total lease assets		$ 36,214	$ 24,148
Liabilities			
Current			
Operating leases	Other current liabilities	$ 3,477	$ 1,638
Finance leases	Current portion of finance lease liability	708	652
Long-term			
Operating leases	Other long-term liabilities	17,125	5,376
Finance leases	Long-term portion of finance lease liability	18,532	19,239
Total lease liabilities		$ 39,842	$ 26,905
Weighted Average Remaining Lease Term			
Operating leases		6.2 years	4.5 years
Finance leases		16.6 years	17.6 years
Weighted Average Discount Rate			
Operating leases		7.3%	4.0%
Finance leases		4.4%	4.4%

The components of lease costs were as follows:

(U.S. Dollars, in thousands)	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Finance lease costs:			
Amortization of right-of-use assets	$ 1,013	$ 1,238	$ 2,049
Interest on finance lease liabilities	857	890	933
Operating lease costs	5,015	2,126	2,234
Short-term lease costs	313	152	213
Variable lease costs	1,883	932	815
Total lease costs	$ 9,081	$ 5,338	$ 6,244

Supplemental cash flow information related to leases was as follows:

(U.S. Dollars, in thousands)	For the Year Ended December 31, 2023	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash flows from operating leases	$ 7,682	$ 3,805	$ 4,627
Operating cash flows from finance leases	857	885	907
Financing cash flows from finance leases	652	2,594	537
Right-of-use assets obtained in exchange for lease obligations			
Operating leases	16,688	5,603	589
Finance leases	—	—	149

A summary of the Company's remaining lease liabilities as of December 31, 2023, is included below:

(U.S. Dollars, in thousands)	Operating Leases	Finance Leases
2024	$ 4,861	$ 1,538
2025	4,788	1,543
2026	4,607	1,562
2027	3,441	1,593
2028	1,785	1,624
Thereafter	6,766	19,396
Total undiscounted value of lease liabilities	26,248	27,256
Less: Interest	(5,646)	(8,016)
Present value of lease liabilities	$ 20,602	$ 19,240
Current portion of lease liabilities	$ 3,477	$ 708
Long-term portion of lease liabilities	17,125	18,532
Total lease liabilities	$ 20,602	$ 19,240

10. Other current liabilities

	December 31,	
(U.S. Dollars, in thousands)	2023	2022
Accrued expenses	$ 12,189	$ 9,611
Salaries, bonuses, employee commissions, and related taxes payable	38,826	18,531
Accrued distributor commissions	22,602	10,483
Accrued litigation and investigation costs	12,077	3,891
Short-term operating lease liability	3,477	1,638
Non-income taxes payable	7,585	6,586
Other payables	8,152	4,634
Other current liabilities	$ 104,908	$ 55,374

11. Indebtedness

The carrying values of the Company's outstanding debt obligations as of December 31, 2023, and 2022, were as follows:

	December 31,	
(U.S. Dollars, in thousands)	2023	2022
Initial Term Loan		
Principal amount	$ 100,000	$ —
Unamortized original debt discount	(4,331)	—
Unamortized debt issuance costs and lenders fees	(1,312)	—
Total indebtedness from initial term loan	94,357	—
Revolving Credit Facilities		
Principal amount outstanding	—	—
Total indebtedness outstanding	$ 94,357	$ —
Current portion of long-term debt	$ 1,250	$ —
Long-term debt	93,107	—
Total indebtedness outstanding	$ 94,357	$ —

The Company paid cash related to interest of $5.8 million, $1.4 million, and $1.5 million for the years ended December 31,

2023, 2022, and 2021, respectively.

Financing Agreement

On November 6, 2023, the Company, as borrower, and certain subsidiaries of the Company as guarantors, entered into a Financing Agreement (the "Financing Agreement") with Blue Torch Finance LLC, as administrative agent and collateral agent (the "Agent"), and certain lenders party thereto. The Financing Agreement provides for a $100.0 million senior secured term loan (the "Initial Term Loan"), a $25.0 million senior secured delayed draw term loan facility (the "Delayed Draw Term Loan") which, subject to certain conditions specified in the Financing Agreement, may be drawn on or prior to March 30, 2024, and a $25.0 million senior secured revolving credit facility (the "Revolving Credit Facility," and together with the Initial Term Loan and the Delayed Draw Term Loan, the "Credit Facilities"), each of which mature on November 6, 2027. In connection with entering into the Financing Agreement, the Company repaid in full amounts outstanding and terminated all commitments under the Company's prior $175 million senior secured revolving credit facility evidenced by that certain Second Amended and Restated Credit Agreement, dated as of October 25, 2019, among the Company, certain subsidiaries of the Company as borrowers and guarantors, JPMorgan Chase Bank, N.A., as administrative agent, and the lenders party thereto (as amended, supplemented or otherwise modified, the "Prior Credit Agreement"). The Initial Term Loan was fully funded on the effective date of November 6, 2023. As of December 31, 2023, the Company had not made any borrowings under the Delayed Draw Term Loan or the Revolving Credit Facility. However, on January 10, 2024, the Company borrowed $15.0 million under the Revolving Credit Facility, which remains outstanding as of the date of this filing.

Borrowings under the Financing Agreement were and may be used for, among other things, the repayment in full of the Prior Credit Agreement, working capital and other general corporate purposes of the Company. Borrowings under the Credit Facilities bear interest at a floating rate, which will be, at the Company's option, either the three-month SOFR rate (subject to a floor of 3.00% and a credit spread adjustment of 0.26161%) (the "Adjusted Term SOFR Rate") plus an applicable margin of 7.25%, or a base rate plus an applicable margin of 6.25%. A revolving unused line fee of 2.00% is payable monthly in arrears based on the average amount of the undrawn portion of each lender's revolving credit commitments under the Revolving Credit Facility for the preceding month. A delayed draw unused fee equal to the Adjusted Term SOFR Rate plus a margin of 1.00% is payable monthly in arrears based on the average amount of the undrawn portion of each lender's delayed draw term loan commitments in respect of the Delayed Draw Term Loan for the preceding month.

Certain of the Company's existing and future material subsidiaries (collectively, the "Guarantors") are required to guarantee the repayment of the Company's obligations under the Financing Agreement. The obligations of the Company and each of the Guarantors with respect to the Financing Agreement are secured by a pledge of substantially all assets of the Company and each of the Guarantors, including, without limitation, accounts receivables, deposit accounts, intellectual property, investment property, inventory, equipment and equity interests in their respective subsidiaries.

The Financing 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 Financing Agreement contains financial covenants requiring the Company to maintain a minimum level of liquidity at all times, a maximum consolidated leverage ratio (measured on a quarterly basis), and a minimum asset coverage ratio (measured on a monthly basis). The Financing 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 Credit Facilities may be accelerated and/or the lenders' commitments terminated.

The Financing Agreement contains customary representations and warranties of the Company and the Guarantors. These representations and warranties have been made solely for the benefit of the Agent and the lenders party to the Financing Agreement and such representations and warranties should not be relied on by any other person, including investors. In addition, such representations and warranties (i) have been qualified by disclosures made to the Agent and the lenders in connection with the agreement, (ii) are subject to the materiality standards contained in the agreement which may differ from what may be viewed as material by investors and (iii) were made only as of the date of the agreement or such other date as is specified in the agreement.

In conjunction with obtaining the Financing Agreement, the Company paid $2.0 million in debt issuance costs and lenders fees. These costs have been allocated amongst each of the Initial Term Loan, Delayed Draw Term Loan, and Revolving Credit Facility and are being amortized over the life of the Financing Agreement. Capitalized debt issuance costs attributable to the Delayed Draw Term Loan and Revolving Credit Facility are included in other long-term assets, net of accumulated amortization, whereas capitalized debt issuance costs associated with the Initial Term Loan are recognized as a direct reduction of the outstanding indebtedness. As of December 31, 2023, and December 31, 2022, debt issuance costs associated with all credit facilities (whether the Financing Agreement or the Prior Credit Agreement), net of accumulated amortization, were $1.9 million and $0.7 million, respectively. Debt issuance costs amortized or expensed totaled $1.3 million, $0.4 million, and $0.4 million for each of the years ended December 31, 2023, 2022, and 2021, respectively.

Prior Credit Agreement

As disclosed above, 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 the Prior Credit Agreement with JPMorgan Chase Bank, N.A. (“JPMorgan”), as Administrative Agent, and certain lender parties thereto. The Prior Credit Agreement provided for a $300.0 million secured revolving credit facility, amending and restating the revolving credit facility that previously existed with such lenders. The Prior Credit Agreement had a maturity date of October 25, 2024. On March 1, 2023, the Amended Credit Agreement and the Facility were amended to replace London Inter-Bank Offered Rate ("LIBOR")-based pricing with Secured Overnight Financing Rate ("SOFR")-based pricing.

On June 13, 2023, the Company entered into a Limited Consent, Limited Waiver and Second Amendment to the Original Credit Agreement (the "Consent and Amendment"). Under the terms of the Consent and Amendment, the parties agreed to reduce the size of the secured revolving credit facility, off of which certain fees are based, from $300.0 million to $175.0 million, and to increase the applicable interest rate in certain circumstances.

On January 3, 2023, the Company borrowed $30.0 million for working capital purposes, including to fund certain Merger-related expenses, under the Prior Credit Agreement. Subsequently, the Company borrowed an additional $49.0 million to fund working capital needs whereby, as of the effective date of the Financing Agreement, the Company had $79.0 million in principal amount of borrowings outstanding under the Prior Credit Agreement. In connection with entering into the Financing Agreement, the Company repaid in full all amounts outstanding and terminated all commitments under the Prior Credit Agreement.

Italian Line of Credit

The Company has an unused available Italian line of credit of €5.5 million ($6.1 million and $5.9 million) at December 31, 2023, and 2022, 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.

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, 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, accounts receivable, and accounts payable approximate fair value due to the short-term maturities of these instruments. The Company’s secured term loan carries a floating rate of interest; 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)	Level 1	Level 2	Level 3	Balance December 31, 2023
Assets				
Neo Medical convertible loan agreement	$ —	$ —	$ 6,760	$ 6,760
Neo Medical preferred equity securities	—	4,951	—	4,951
Bone Biologics equity securities	—	—	—	—
Other investments	—	—	1,309	1,309
Total	$ —	$ 4,951	$ 8,069	$ 13,020
Liabilities				
Lattus contingent consideration	$ —	$ —	$ (8,500)	$ (8,500)
Spinal Kinetics contingent consideration	—	—	—	—
Deferred compensation plan	—	(1,674)	—	(1,674)
Total	$ —	$ (1,674)	$ —	$ (10,174)

(U.S. Dollars, in thousands)	Level 1	Level 2	Level 3	Balance December 31, 2022
Assets				
Neo Medical convertible loan agreements	$ —	$ —	$ 7,140	$ 7,140
Neo Medical preferred equity securities	—	6,084	—	6,084
Bone Biologics equity securities	—	—	—	—
Other Investments	—	—	1,726	1,726
Total	$ —	$ 6,084	$ 7,140	$ 14,950
Liabilities				
Spinal Kinetics contingent consideration	$ —	$ —	$ —	$ —
Deferred compensation plan	—	(1,515)	—	(1,515)
Total	$ —	$ (1,515)	$ —	$ (1,515)

The fair value of the Company's deferred compensation plan liabilities is 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 (the "Convertible Loan") pursuant to which Orthofix loaned Neo Medical CHF 4.6 million, or $5.0 million at the date of issuance. The Convertible 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.

In October 2021, the Company entered into an additional Convertible Loan Agreement (the "Additional Convertible Loan"), pursuant to which the Company loaned Neo Medical an additional CHF 0.6 million ($0.7 million as of the issuance date). In January 2022, the Company elected to convert the Additional Convertible Loan into shares of Neo Medical's preferred stock.

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.

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, 2023, and 2022:

(U.S. Dollars, in thousands)	2023	2022
Fair value of Neo Medical preferred equity securities at January 1	$ 6,084	$ 5,413
Conversion of loan into preferred equity securities	—	671
Foreign currency remeasurement recognized in other income, net	388	—
Unrealized loss recognized in other income (expense), net	(1,521)	—
Fair value of Neo Medical preferred equity securities at December 31	$ 4,951	$ 6,084
Cumulative unrealized gain (loss) on Neo Medical preferred equity securities	(720)	413

The Convertible Loan is recorded in other current assets as an available for sale debt security as of December 31, 2023, while as of December 31, 2022, this balance was classified within other long-term assets. The Convertible Loan is recorded at fair value, with applicable interest recorded in interest income. The fair value of the Convertible Loan 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 this asset as a Level 3 financial asset.

Some of the more significant unobservable inputs used in the fair value measurement of the Convertible Loan include applicable discount rates, implied volatility, the likelihood and projected timing of repayment or conversion, and projected cash flows in support of the estimated enterprise value of Neo Medical. Holding other inputs constant, changes in these assumptions could result in a significant change in the fair value of the Convertible Loan. If the amortized cost of the Convertible Loan exceeds its estimated fair value, the security is deemed to be impaired, and must be evaluated for the recognition of credit losses. Impairment resulting from credit losses is recognized within the statement of income, while impairment resulting from other factors is recognized within other comprehensive income (loss). As of December 31, 2023, the Company has recognized $0.3 million in credit losses related to the Convertible Loan.

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

(U.S. Dollars, in thousands)	2023	2022
Fair value of Neo Medical Convertible Loans at January 1	$ 7,140	$ 7,148
Additions	—	—
Interest recognized in interest income, net	496	436
Foreign currency remeasurement recognized in other income (expense), net	617	(67)
Unrealized gain (loss) recognized in other comprehensive income (loss)	(1,233)	294
Expected credit loss recognized in other income (expense), net	(260)	—
Conversion of Additional Convertible Loan into preferred equity securities	—	(671)
Fair value of Neo Medical Convertible Loans at December 31	$ 6,760	$ 7,140
Contractual value of Neo Medical Convertible Loans at December 31	$ 7,020	$ 5,907
Allowance for credit loss recognized in other income (expense), net	(260)	—
Amortized cost basis of Neo Medical Convertible Loans at December 31	$ 6,760	$ 5,907

The following table provides quantitative information related to certain key assumptions utilized within the valuation of the Convertible Loan as of December 31, 2023:

(U.S. Dollars, in thousands)	Fair Value as of December 31, 2023	Unobservable inputs	Estimate
Neo Medical Convertible Loan	$ 6,760	Cost of equity discount rate	19.3%
		Present value factor	15.3%
		Implied volatility	81.1%

Bone Biologics Equity Securities

Until August of 2022, the Company held 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 had very limited trading volumes. As such, the Company measured the investments at cost, less any impairments, plus or minus changes resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer.

In 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, Bone Biologics’ common stock became 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 subsequently had quoted prices in active markets for identical assets. As such, the Company recorded the investment at fair value, with changes in fair value recorded within other income (expense), net, subsequent to the public offering.

The following table presents the changes in fair value recognized for each of the years ended December 31, 2023, 2022, and 2021:

(U.S. Dollars, in thousands)	2023	2022	2021
Bone Biologics equity securities at January 1	$ —	$ 309	$ —
Fair value adjustments and impairments recognized in other income (expense), net	—	(183)	309
Proceeds from the disposition of equity securities	—	(126)	—
Bone Biologics equity securities at December 31	$ —	$ —	$ 309

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 is 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. This balance is classified within other current assets as of December 31, 2023, and was classified in other long-term assets as of December 31, 2022.

Spinal Kinetics Contingent Consideration

The Company recognized a contingent consideration obligation in connection with the acquisition of Spinal Kinetics in 2018. The fair value of the remaining Spinal Kinetics contingent consideration, attributable to a revenue-based milestone, was concluded to be zero as the Company did not achieve the milestone prior to April 30, 2023, the end of the measurement period for achieving such milestone.

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)	2023	2022
Spinal Kinetics contingent consideration at January 1	$ —	$ 17,200
Decrease in fair value recognized in acquisition-related amortization and remeasurement	—	(17,200)
Payment made	—	—
Spinal Kinetics contingent consideration at December 31	$ —	$ —

Lattus Contingent Consideration

In connection with the Merger, the Company assumed a contingent consideration obligation under a purchase agreement between SeaSpine and Lattus Spine LLC ("Lattus") executed in December 2022. Under the terms of the agreement, the Company may be required to make installment payments at certain dates based on future net sales of certain products (the "Lateral Products").

The estimated fair value of the Lattus contingent consideration is determined using a Monte Carlo simulation and a discounted cash flow model requiring significant inputs which are not observable in the market. The significant inputs include assumptions related to the timing and probability of certain product launch dates, estimated future sales of Lateral Products, revenue risk-adjusted discount rate, revenue volatility, and discount rates matched to the timing of payments. The following

table provides a reconciliation of the

beginning and ending balances for the Lattus contingent consideration measured at estimated fair value using significant unobservable inputs (Level 3):

(U.S. Dollars, in thousands)	2023	2022
Lattus contingent consideration estimated fair value at January 5	$ 11,200	$ —
Decrease in fair value recognized in acquisition-related amortization and remeasurement	(2,700)	—
Lattus contingent consideration estimated fair value at December 31	$ 8,500	$ —

The following table provides quantitative information related to certain key assumptions utilized within the valuation as of December 31, 2023:

(U.S. Dollars, in thousands)	Fair Value as of December 31, 2023	Unobservable inputs	Estimate
Lattus Contingent Consideration	$ 8,500	Counterparty discount rate	14.0%
		Revenue risk-adjusted discount rate	6.5%

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.

Arbitration claims with former executives

In September 2023, the Company's Board of Directors terminated the employment of Keith Valentine, John Bostjancic and Patrick Keran, who had served respectively as the Company's President and Chief Executive Officer, Chief Financial Officer and Chief Legal Officer. The Board's decision followed an investigation conducted by independent outside legal counsel and directed and overseen by the Company's independent directors. As a result of the investigation, the Board determined that each of these executives engaged in repeated inappropriate and offensive conduct that violated multiple code of conduct requirements and was inconsistent with the Company's values and culture. The Company notified each of Messrs. Valentine, Bostjancic and Keran that their respective terminations were being made for "Cause," as defined in applicable employment-related agreements (including each executive's respective Change in Control and Severance Agreement, dated June 19, 2023). The Company also notified each of Messrs. Valentine, Bostjancic and Keran that it did not believe it was required to make any further payments to them, other than payment of salary through September 12, 2023. The Board also requested that Mr. Valentine resign as a director, which he did in October 2023.

In January 2024, the Company received written notices of arbitration claims from counsel to Messrs. Valentine, Bostjancic and Keran. Each of the arbitration claims asserts that the respective former executive was wrongfully terminated for "Cause" because the former executive's conduct did not meet the contractually applicable definition of "Cause." The claims seek relief for, among other things, alleged breach of contract, defamation, false light invasion of privacy, deceit, as well as indemnification and advancement for attorneys' fees. The three former executives seek severance payments, as well as the value of forfeited equity grants, under applicable change in control and severance agreements and further damages as a result of purported defamatory statements. The Company disagrees with many of the assertions contained in the written notices of arbitration claims and intends to

vigorously defend the asserted claims. Due in part to the preliminary nature of this matter, the Company currently cannot reasonably estimate a possible loss, or range of loss, that may arise from the arbitration claims.

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.

In the third quarter of 2022, the Italian Ministry of Health provided guidelines to the Italian regions and provinces on seeking payback of expenditure overruns relating to the years ended December 31, 2015, through December 31, 2018. Since receiving the guidelines, several regions and provinces have requested payment from affected medical device companies, including the Company. The Company has taken legal action to dispute the legality of such measures.

The Company accounts for the estimated cost of the IMDP as sales and marketing expense and periodically reassesses the liability based upon current facts and circumstances. As a result, the Company recorded expense of $1.3 million for the year ended December 31, 2023, expense of $1.2 million for the year ended December 31, 2022, and a benefit of $1.2 million for the year ended December 31, 2021, as a result of certain temporary relief provided by the Italian National Healthcare System in response to the COVID-19 pandemic. As of December 31, 2023, the Company has accrued $7.6 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 all legal proceedings are resolved and upon further clarification of the IMDP by the Italian authorities for more recent fiscal years.

Commitments

The Company is party to certain agreements with distributor partners that provide the Company with an option to purchase, and/or an option for those partners to require the Company to purchase, the distribution business of those partners at specified future dates. At such time, the Company or distributor may (in certain cases, subject to satisfying certain conditions) submit written notice to the other of its intention to exercise its rights and initiate or require the purchase. Upon the receipt of the written notice, the Company and the distributor will work in good faith to consummate the purchase. Under certain of these agreements, the purchase price would be paid in shares of the Company's common stock whereas for others, the purchase price can be paid in cash or shares at the Company's option. Based on the closing price of the Company's common stock as of December 31, 2023, assuming all criteria are met and that the options under all the relevant agreements were exercised, the estimated total number of shares the Company would issue under these agreements was approximately 1.6 million shares for agreements that must be settled in shares of the Company's stock. The Company has received notification from one such distributor, who has notified the Company of its decision to exercise its buyout option. The Company is currently in negotiations with this distributor in regard to the consummation of the potential acquisition.

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 Financing 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	Neo Medical Convertible Loans	Other Investments	Accumulated Other Comprehensive Income (Loss)
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	$ —	$ —
Other comprehensive income (loss)	(1,771)	294	101	(1,376)
Income taxes	—	—	—	—
Balance at December 31, 2022	$ (2,482)	$ 1,005	$ 101	$ (1,376)
Other comprehensive income (loss)	1,417	(1,233)	(101)	83
Income taxes	—	—	—	—
Balance at December 31, 2023	$ (1,065)	$ (228)	$ —	$ (1,293)

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 to 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 mostly processed from within our Irvine facility. In addition, we have a long standing collaborative arrangement with MTF that provides exclusive global marketing rights to MTF's Trinity and FiberFuse product

families. 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 received marketing fees from MTF based on sales of products covered under the collaborative arrangement. MTF is considered the principal 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 for revenue recognition is estimated based upon the Company's historical collection experience with the stocking distributor.

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, 2023, 2022, and 2021.

	For the year ended December 31,		
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**
Product sales	$ 693,345	$ 405,437	$ 409,554
Marketing service fees	53,296	55,276	54,925
Net sales	$ 746,641	$ 460,713	$ 464,479

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, whereas product sales primarily consist of the sale of Bone Growth Therapies, Spinal Implants, non-MTF sourced Biologics, Enabling Technologies, and Global Orthopedics products. Marketing service fees received from MTF were $53.3 million, or approximately 32% of total Biologics revenues, for the year ended December 31, 2023. As MTF is the single supplier for certain 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 $9.5 million, $4.2 million, and $3.5 million for the years ended December 31, 2023, 2022, and 2021, 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.

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 certain 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, 2023, and 2022:

	For the year ended December 31,	
(U.S. Dollars, in thousands)	**2023**	**2022**
Allowance for expected credit losses beginning balance	$ 6,419	$ 4,944
Addition resulting from the Merger with SeaSpine	137	—
Current period provision for expected credit losses	820	2,095
Write-offs charged against the allowance and other	(381)	(450)
Effect of changes in foreign exchange rates	135	(170)
Allowance for expected credit losses ending balance	$ 7,130	$ 6,419

The Company will generally sell receivables from certain Italian public hospitals each year to accelerate cash collections. During 2023, 2022, and 2021, the Company sold €9.2 million, €9.2 million, and €8.4 million ($10.0 million, $9.6 million, and $9.9 million) of receivables, respectively. The related fees for 2023, 2022, and 2021, were $0.4 million, $0.3 million, and $0.2 million, respectively, which were recorded as interest expense. Accounts receivables sold without recourse are removed from the balance sheet at the time of sale.

Contract Liabilities

The Company's contract liabilities largely related to a prepayment of $13.9 million received in 2020 from the Centers for Medicare and Medicaid Services ("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. In April 2021, Medicare began to recoup 25% of Medicare payments otherwise owed to the provider or supplier for submitted claims. Recoupment then increased to 50% of Medicare payments in March 2022. Thus, during these time periods, rather than receiving the full amount of payment for newly submitted claims, the Company's outstanding balance under the Accelerated and Advance Payment Program was reduced by the recoupment amount until the full balance had been repaid.

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, 2023, and 2022:

	For the Year Ended December 31,	
(U.S. Dollars, in thousands)	**2023**	**2022**
Contract liability beginning balance	$ —	$ 4,791
Recoupment recognized in net sales	—	(4,791)
Contract liability ending balance	$ —	$ —

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 $0.3 million and $1.1 million as of December 31, 2023, and 2022, respectively.

Other Contract Assets are amortized on a straight-line basis over the term of the related contract. For the year ended December 31, 2023, the Company recorded $0.4 million in impairment charges related to the termination of certain distribution agreements. No impairments were incurred for other contract assets 2022. 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's operations are managed through two reporting segments: Global Spine and Global Orthopedics. These reporting segments represent the operating segments for which the Chief Executive Officer, who is also the CODM, reviews financial information and makes resource allocation decisions among businesses. The primary metric used by the CODM in managing the Company is adjusted earnings before interest, tax, depreciation, and amortization ("adjusted EBITDA", a non-GAAP financial measure). Adjusted EBITDA represents earnings before interest income (expense), income taxes, depreciation, and amortization, and excludes the impact of share-based compensation, gains and losses related to changes in foreign exchange rates, charges related to the SeaSpine merger and other strategic investments, acquisition-related fair value adjustments, gains and/or losses on investments, litigation and investigation charges, charges related to initial compliance with regulations set forth by the European Union Medical Device Regulation, gains and/or losses related to the realized effects the COVID-19 pandemic has had on the Company's business operations, and succession charges.

Corporate activities are comprised of operating expenses not directly identifiable within the two reporting segments, such as human resources, finance, legal, and information technology functions. The Company neither discretely allocates assets, other than goodwill, to its operating segments nor evaluates the operating segments using discrete asset information.

Global Spine

The Global Spine reporting segment offers two primary product categories: (i) Bone Growth Therapies and (ii) Spinal Implants, Biologics, and Enabling Technologies.

The Bone Growth Therapies product category manufactures, distributes, sells, and provides support services for market leading devices used adjunctively in high-risk spinal fusion procedures and to treat both nonunion and acute fractures in the orthopedic space. 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 acute and nonunion fractures. This product category uses distributors and a direct sales channel to sell its devices to hospitals, healthcare providers, and patients, in the U.S.

Spinal Implants, Biologics, and Enabling Technologies is comprised of (i) a broad portfolio of spine fixation and motion preservation implant products used in surgical procedures of the spine, (ii) one of the most comprehensive biologics portfolios in both the demineralized bone matrix and cellular allograft market segments, and (iii) image-guided surgical solutions to facilitate degenerative, minimally invasive, and complex surgical procedures. Spinal Implants, Biologics, and Enabling Technologies products are sold through a network of distributors and sales representatives to hospitals and healthcare providers on a global basis for Spinal Implants and Enabling Technologies, and primarily within the U.S. for Biologics.

Global Orthopedics

The Global Orthopedics reporting segment offers products and solutions for limb deformity correction and complex limb reconstruction with a focus on use in trauma, adult and pediatric limb reconstruction, and foot and ankle procedures. This reporting segment specializes in the design, development, and marketing of external and internal fixation orthopedic products that are coupled with enabling digital technologies to serve the complete patient treatment pathway. We sell these products through a global network of distributors and sales representatives to hospitals, healthcare organizations, 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:

	Year Ended December 31,					
	2023		2022		2021	
(U.S. Dollars, in thousands)	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales	Net Sales	Percent of Total Net Sales
Bone Growth Therapies	$212,530	28.5%	$187,247	40.7%	$187,448	40.4%
Spinal Implants, Biologics, and Enabling Technologies	418,789	56.1%	165,927	36.0%	171,515	36.9%
Global Spine	631,319	84.6%	353,174	76.7%	358,963	77.3%
Global Orthopedics	115,322	15.4%	107,539	23.3%	105,516	22.7%
Net sales	$746,641	100.0%	$460,713	100.0%	$464,479	100.0%

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

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**
Adjusted EBITDA by reporting segment			
Global Spine	$ 91,115	$ 62,692	$ 71,086
Global Orthopedics	442	5,267	9,260
Corporate	(45,272)	(19,406)	(19,084)
Consolidated adjusted EBITDA	$ 46,285	$ 48,553	$ 61,262
Reconciling items:			
Interest expense, net	$ 8,631	$ 1,288	$ 1,837
Depreciation and amortization	53,063	29,019	41,355
Share-based compensation expense	35,707	18,443	15,432
Foreign exchange impact	(1,581)	3,291	3,981
SeaSpine merger-related costs	36,623	12,010	—
Strategic investments	2,272	4,018	5,700
Acquisition-related fair value adjustments	33,393	(15,595)	(2,014)
(Gain) loss on investments	1,781	187	(644)
Litigation and investigation costs	14,453	803	33
Medical device regulation	9,446	10,261	8,018
Business interruption - COVID-19	—	2,387	320
Succession charges	1,176	147	739
Loss before income taxes	$ (148,679)	$ (17,706)	$ (13,495)

The following table presents depreciation and amortization by reporting segment:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**
Global Spine	$ 41,213	$ 18,213	$ 17,548
Global Orthopedics	7,158	6,696	8,233
Corporate	4,692	4,110	3,818
Total	$ 53,063	$ 29,019	$ 29,599

Geographical information

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)	**2023**	**2022**	**2021**
Global Spine			
U.S.	$ 591,937	$ 332,846	$ 337,455
International	39,382	20,328	21,508
Total Global Spine	631,319	353,174	358,963
Global Orthopedics			
U.S.	$ 28,892	25,997	24,490
International	86,430	81,542	81,026
Total Global Orthopedics	115,322	107,539	105,516
Consolidated			
U.S.	620,829	358,843	361,945
International	125,812	101,870	102,534

Net sales	$ 746,641	$ 460,713	$ 464,479

The following data includes net sales by geographic destination:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2023	2022	2021
U.S.	$ 620,829	$ 358,843	$ 361,945
Italy	20,060	19,098	20,187
Germany	11,467	11,569	13,716
United Kingdom	10,910	10,171	10,552
France	11,096	10,377	10,475
Brazil	6,452	5,668	5,108
Others	65,827	44,987	42,496
Net sales	$ 746,641	$ 460,713	$ 464,479

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

(U.S. Dollars, in thousands)	2023	2022
U.S.	$ 142,727	$ 44,802
Italy	10,187	8,535
Germany	3,030	3,115
Others	3,116	1,777
Total	$ 159,060	$ 58,229

17. Acquisition-related amortization and remeasurement

Acquisition-related amortization and remeasurement consists of (i) the remeasurement of any related contingent consideration arrangement, (ii) amortization related to intangible assets acquired through business combinations or asset acquisitions, (iii) recognized costs associated with acquired 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, 2023, 2022, and 2021, respectively, are as follows:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	2023	2022	2021
Changes in fair value of contingent consideration	$ (2,700)	$ (17,200)	$ (3,575)
Amortization of acquired intangibles	17,408	8,196	7,907
Acquired IPR&D	49	1,600	1,500
Impairment of Global Orthopedics goodwill	—	—	11,756
Total	$ 14,757	$ (7,404)	$ 17,588

Legion Innovations, LLC Asset Acquisition

On December 29, 2022, the Company entered into a technology assignment and royalty agreement with Legion Innovations, LLC, a U.S.-based medical device technology company, whereby the Company acquired intellectual property rights to certain assets. As consideration, the Company agreed to pay $0.2 million in January 2023, with additional payments contingent upon reaching future commercialization and revenue-based milestones. The Company accounted for this transaction as an asset acquisition. As the transaction was 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. The $0.2 million initial payment was accrued as of December 31, 2022, and was recognized as acquired IPR&D costs, which was then immediately expensed.

IGEA S.p.A Asset Acquisition

In April 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 Company accounted for this transaction as an asset acquisition. As the transaction was classified as an

asset acquisition, the value of the consideration associated with the contingent milestones are be recognized at the time that applicable contingencies are resolved and consideration is paid or becomes payable. The License Agreement also includes certain minimum purchase requirements.

In May 2022, the Company achieved FDA approval pertaining to the acquired technology, triggering a contingent consideration milestone obligation of $3.5 million. Of this amount, $1.5 million was paid in 2022 and $1.0 million was paid in 2023. The remaining $1.0 million is accrued within other current liabilities as of December 31, 2023.

18. Share-based compensation

At December 31, 2023, and 2022, the Company had stock option and award plans, and a stock purchase plan.

Merger with SeaSpine

Pursuant to the Merger Agreement, the equity awards of SeaSpine (including stock options and restricted stock units) outstanding as of immediately prior to the closing of the Merger were converted into equity awards denominated in shares of Orthofix common stock. The Company issued options to purchase 1.9 million shares of Orthofix common stock and 0.5 million shares of time-based vesting restricted stock in connection with the conversion of such awards. The estimated fair value of the portion of the SeaSpine equity awards for which the required service period had been completed at the time of the closing of the Merger was treated as purchase consideration. The remaining estimated fair value is recorded as compensation expense over the remainder of the service period associated with the awards.

In addition, as part of the Merger, the Board of Directors determined to treat the transaction as a “Change in Control” under applicable agreements and equity plans. Thus, in January 2023, all outstanding and previously granted performance-based and market-based restricted stock units were converted to time-based restricted stock units.

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, 2023, the Company reserves a total of 11.3 million shares of common stock for issuance pursuant to the 2012 LTIP, subject to certain adjustments set forth in the 2012 LTIP. At December 31, 2023, there were 1.6 million options outstanding under the 2012 LTIP, of which 0.7 million were exercisable. In addition, there were 1.6 million restricted stock units outstanding, some of which contain performance-based vesting conditions, under the 2012 LTIP as of December 31, 2023.

SeaSpine 2015 Plan

Pursuant to the Merger Agreement, the Company assumed awards outstanding under the SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan Award Plan (the “SeaSpine 2015 Plan”). The SeaSpine 2015 Plan 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 SeaSpine 2015 Plan. 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 SeaSpine 2015 Plan. At December 31, 2023, the Company reserves a total of 3.0 million shares of common stock for issuance pursuant to the SeaSpine 2015 Plan, subject to certain adjustments set forth in the SeaSpine 2015 Plan. At December 31, 2023, there were 1.0 million options outstanding under the SeaSpine 2015 Plan, of which 0.9 million were exercisable. In addition, there were 0.2 million restricted stock units outstanding, some of which contain performance-based vesting conditions, under the SeaSpine 2015 Plan as of December 31, 2023.

Inducement Plans

In August 2019, the Company appointed a new President of Global Spine, who was then subsequently promoted to President and Chief Executive Officer, a position held until the closing of the merger with SeaSpine on January 5, 2023. As an inducement to accept employment with the Company, the individual was awarded a grant of stock options to acquire up to less than 51 thousand shares

of common stock and an award of 15 thousand restricted stock units. As of December 31, 2023, there were 51 thousand options outstanding under this inducement, all of which were exercisable.

Pursuant to the Merger Agreement, the Company assumed awards outstanding under the SeaSpine 2018 Employment Inducement Incentive Award Plan and the SeaSpine 2020 Employment Inducement Incentive Award Plan. As of December 31, 2023, there were 0.3 million options outstanding under these inducements, 0.2 million of which were exercisable, and 17 thousand unvested restricted stock units outstanding.

In January 2023, the Company granted options to acquire up to 0.9 million shares of common stock and awarded 0.5 million restricted stock units to SeaSpine employees as an inducement to continue employment with the Company. As of December 31, 2023, there were 0.3 million options outstanding under this inducement, none of which were exercisable, and 0.2 million 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, 2023, the aggregate number of shares reserved for issuance under the Stock Purchase Plan is 3.6 million. As of December 31, 2023, a total of 2.8 million 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, 2023, 2022, and 2021:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**
Cost of sales	$ 1,901	$ 826	$ 779
Sales and marketing	8,174	3,865	3,385
General and administrative	21,743	12,917	10,289
Research and development	3,889	835	979
Total	$ 35,707	$ 18,443	$ 15,432

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**
Stock options	$ 6,130	$ 1,114	$ 1,893
Time-based restricted stock awards and stock units	27,290	9,452	7,437
Performance-based / Market-based restricted stock units	227	6,425	4,414
Stock purchase plan	2,060	1,452	1,688
Total	$ 35,707	$ 18,443	$ 15,432

The income tax benefit related to this expense was $5.8 million, $3.3 million, and $3.1 million for the years ended December 31, 2023, 2022, and 2021, 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 three to 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 each of the years ended December 31, 2023, 2022, and 2021, is shown in the following table. The Company did not grant any time-based stock options in 2022.

	Year Ended December 31,		
	2023	2022	2021
Assumptions:			
Expected term (in years)	6.0	—	6.0
Expected volatility	36.8% – 42.3%	—	34.4% – 34.8%
Risk free interest rate	3.38% – 4.61%	—	0.83% – 1.25%
Dividend yield	—	—	—
Weighted average grant date fair value	$ 8.43	$ —	$ 12.33

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, 2023, and 2022, and changes during the year ended December 31, 2023, are presented below:

(In thousands)	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)
Outstanding at December 31, 2022	1,299	$ 39.29	
Assumed SeaSpine awards	1,890	$ 36.05	
Granted	1,837	$ 19.92	
Exercised	-	$ -	
Forfeited or expired	(1,803)	$ 31.62	
Outstanding at December 31, 2023	3,223	$ 30.64	4.97
Vested and expected to vest at December 31, 2023	3,223	$ 30.64	4.97
Exercisable at December 31, 2023	1,828	$ 36.78	2.68

As of December 31, 2023, the unamortized compensation expense relating to options granted and expected to be recognized was $4.8 million. This amount is expected to be recognized through December 2027 over a weighted average period of approximately 1.2 years. The total intrinsic value of options exercised was $0.0 million, $0.0 million, and $0.6 million for the years ended December 31, 2023, 2022, and 2021, respectively. For the year ended December 31, 2023, we did not receive any cash from stock option exercises, and thus did not realize any tax benefit for the tax deductions from stock option exercises. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2023, 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 $13.48, the closing price of the Company's stock on December 31, 2023. The aggregate intrinsic value of options outstanding was $0.1 million as of December 31, 2023. The aggregate intrinsic value of options exercisable was $0.0 million as of that date.

Time-based Restricted Stock Awards and Stock Units

Compensation expense for time-based restricted stock awards and stock units, 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 three to four years, net of actual forfeitures.

The aggregate fair value of time-based restricted stock awards and stock units that vested during the years ended December 31, 2023, 2022, and 2021, was $17.2 million, $5.2 million, and $9.0 million, respectively. Unamortized compensation expense related to time-based restricted stock awards and stock units amounted to $22.6 million at December 31, 2023. This amount is

expected to be

recognized through December 2026 over a weighted average period of approximately 1.6 years. The aggregate intrinsic value of time-based restricted stock awards and stock units outstanding was $27.5 million as of December 31, 2023.

Performance-based and Market-based Restricted Stock Units

Certain of the Company's outstanding restricted stock units contain performance-based vested conditions or market-based vesting conditions. As previously discussed, all outstanding performance-based and market-based restricted stock units were converted to time-based restricted stock units in January 2023 upon completion of the Merger based on the Board of Directors' determination to treat the transaction as a "Change in Control" under applicable agreements and equity plans.

The fair value of performance-based restricted stock units is calculated based upon the closing stock price at the date of grant. Such value is recognized as expense over the 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 financial metrics or applicable milestones associated with the applicable grant.

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 fair value of performance-based and/or market-based restricted stock units that vested and settled during the years ended December 31, 2023, 2022, and 2021, totaled $0.0 million, $0.0 million, and $0.0 million, respectively. Unamortized compensation expense for performance-based and/or market-based restricted stock units totaled less than $0.1 million at December 31, 2023, and is expected to be recognized over a weighted average period of approximately 1.0 years. The aggregate intrinsic value of performance-based restricted stock units outstanding was $0.1 million as of December 31, 2023.

A summary of the status of our time-based and performance-based and/or market-based restricted stock units as of December 31, 2023, and 2022, and changes during the year ended December 31, 2023, are presented below:

	Time-based Restricted Stock Awards and Stock Units		Performance-based and/or Market-based Restricted Stock Units	
(In thousands)	Shares	Weighted Average Grant Date Fair Value	Shares	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2022	847	$ 34.18	516	$ 40.29
Assumed SeaSpine awards	490	$ 22.76	—	$ —
Conversion of performance-based and market-based stock units to time-based stock units	516	$ 40.29	(516)	$ 40.29
Granted	1,496	$ 18.51	13	$ 20.10
Vested and settled	(749)	$ 29.04	(4)	$ 22.76
Cancelled	(560)	$ 21.12	—	$ —
Outstanding at December 31, 2023	2,040	$ 26.96	9	$ 22.69

19. Defined contribution plans and deferred compensation

Defined Contribution Plans

Orthofix 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, 2023, 2022, and 2021, expenses incurred relating to the 401(k) Plan, including matching contributions, were approximately $4.6 million, $3.3 million, and $2.8 million, respectively.

The Company also operates defined contribution plans for its international employees meeting minimum service requirements. The Company’s expenses for such contributions during each of the years ended December 31, 2023, 2022, and 2021, were $1.1 million, $1.1 million, and $1.2 million, respectively.

Effective February 1, 2024, Orthofix amended the 401(k) Plan to allow participants to contribute up to 90% of their pre-tax compensation, subject to certain limitations, with the Company matching 100% of the first 4% of the employee's base compensation.

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 4% of total commissions earned from the Company. The Company's relations with its Italian employees, who represent 14% of total employees at December 31, 2023, 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, 2023, and 2022 was $1.7 million and $1.5 million, respectively, and represents the amount that 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)	**2023**	**2022**	**2021**
U.S.	$ (154,794)	$ (22,318)	$ (5,987)
Non-U.S.	6,115	4,612	(7,508)
Income (loss) before income taxes	$ (148,679)	$ (17,706)	$ (13,495)

The provision for income taxes consists of the following:

	Year Ended December 31,		
(U.S. Dollars, in thousands)	**2023**	**2022**	**2021**
U.S.			
Current	$ 17	$ 1,151	$ (607)
Deferred	1,160	67	24,292
	1,177	1,218	23,685
Non-U.S.			
Current	2,120	578	1,009
Deferred	(581)	247	190
	1,539	825	1,199
Income tax expense (benefit)	$ 2,716	$ 2,043	$ 24,884

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, 2023, 2022, and 2021, consist of the following:

	2023		2022		2021	
(U.S. Dollars, in thousands, except percentages)	**Amount**	**Percent**	**Amount**	**Percent**	**Amount**	**Percent**
Statutory U.S. federal income tax rate	$ (31,222)	21.0 %	$ (3,718)	21.0 %	$ (2,834)	21.0 %
State taxes, net of U.S. federal benefit	(3,452)	2.3	(1,312)	7.4	(24)	0.2
Foreign rate differential, including withholding taxes	(738)	0.5	475	(2.7)	480	(3.6)
Valuation allowances, net	28,322	(19.0)	7,638	(43.1)	27,819	(206.1)
Foreign income inclusions, net	2,333	(1.6)	1,018	(5.7)	—	—
Research credits	(1,219)	0.8	(750)	4.2	(537)	4.0
Unrecognized tax benefits, net of settlements	71	—	(599)	3.4	(1,363)	10.1
Equity compensation	4,210	(2.8)	1,441	(8.1)	1,091	(8.1)
Executive compensation	3,030	(2.0)	697	(3.9)	456	(3.4)
Contingent consideration	—	—	(3,316)	18.7	(640)	4.7
Other, net	1,381	(0.9)	469	(2.6)	436	(3.2)

Income tax expense (benefit) /effective rate	$ 2,716	(1.8)'	$ 2,043	(11.5)'	$ 24,884	(184.4)%

The Company paid (received or was refunded) cash relating to taxes totaling $0.9 million, ($0.9) million, and $4.8 million for the years ended December 31, 2023, 2022, and 2021, respectively.

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

	December 31,	
(U.S. Dollars, in thousands)	**2023**	**2022**
Intangible assets and goodwill	$ —	$ 5,807
Inventories and related reserves	33,122	17,819
Deferred revenue and cost of goods sold	4,409	3,642
Other accruals and reserves	5,382	2,756
Accrued compensation	14,861	8,795
Provision for expected credit losses	1,821	1,253
Accrued interest	1,227	—
Net operating loss and tax credit carryforwards	123,210	40,676
Research and development capitalization	15,174	4,353
Lease liabilities	9,632	6,440
Other, net	5,429	3,767
Total deferred tax assets	214,267	95,308
Valuation allowance	(200,192)	(83,797)
Deferred tax asset, net of valuation allowance	$ 14,075	$ 11,511
Intangible assets and goodwill	$ (1,662)	$ —
Withholding taxes	(10)	(10)
Property, plant, and equipment	(5,737)	(5,516)
Right-of-use lease assets	(8,755)	(5,771)
Deferred tax liability	$ (16,164)	$ (11,297)
Net deferred tax assets (liabilities)	$ (2,089)	$ 214
Reported as:		
Deferred income tax assets (classified within other long-term assets)	$ 2,081	$ 1,470
Deferred income tax liabilities (classified within other long-term liabilities)	(4,170)	(1,256)
Net deferred tax assets (liabilities)	$ (2,089)	$ 214

The Company historically presented deferred income tax assets as a separate and discrete line item on its consolidated balance sheet; however, as the significance of the asset has decreased as a result of the recognition of valuation allowances, the Company has reclassified this balance to be included within other long-term assets. Deferred income tax liabilities is included in Other Long Term Liabilities.

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 $116.4 million during the year principally relates to the existing valuation allowance against the SeaSpine deferred tax assets at the time of the merger. The remaining activity is related to recognizing a full valuation allowance against the net deferred tax asset within the Company's U.S. and Italy operations. 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 2024 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 $331.7 million and federal research and development credits of $4.7 million, including amounts from the acquisitions of SeaSpine and Spinal Kinetics. The increase in the current year is primarily related to U.S. Federal net operating loss carryforwards belonging to SeaSpine at the time of the Merger as well as research and development credit carryforwards. These federal carryforwards are subject to limitation under the provisions of Internal Revenue Code Section 382 and will begin to expire in 2026. The Company has state net operating loss carryforwards of approximately $221.4 million, principally related to California, Illinois, Michigan, and New York. Of this amount, $157.9 relates to SeaSpine and $20.6 million relates to Spinal Kinetics. The increase in state net operating loss carryforwards is primarily due to existing losses acquired from SeaSpine. The SeaSpine state losses begin to expire in 2024 and the Spinal Kinetics state losses begin to expire in 2027. These carryforwards are subject to limitation under various provisions implemented by each specific state jurisdiction. Additionally, the Company has net operating loss carryforwards in various foreign jurisdictions of approximately $129.0 million, which mainly relate to the Company's Netherlands, Brazil, and Canada operations. The majority of the foreign net operating losses do not expire. The Company also has research and development credits in Canada of $0.9 million which begin to expire in 2041.

Unremitted foreign earnings were $33.6 million as of December 31, 2023. 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. Quantification of the deferred tax liability, if any, associated with indefinitely reinvested earnings of foreign subsidiaries is not practicable.

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 $3.0 million and $1.7 million for the years ended December 31, 2023, and 2022, respectively. The Company recorded net interest and penalties expense (benefit) on unrecognized tax benefits of $0.2 million, $0.1 million, and $(0.4) million for the years ended December 31, 2023, 2022, and 2021, respectively, and had approximately $1.1 million and $0.9 million accrued for payment of interest and penalties as of December 31, 2023, and 2022, respectively. Approximately $0.4 million would unfavorably impact the Company's effective tax rate if recognized. The Company believes it is reasonably possible that, in the next 12 months, the amount of unrecognized tax benefits, exclusive of interest and penalties, related to the resolution of federal, state, and foreign matters could be reduced by $1.2 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, 2023, and 2022, is shown below:

(U.S. Dollars, in thousands)	2023	2022
Balance as of January 1,	$ 1,743	$ 3,462
Additions for current year tax positions	416	46
Increases for prior year tax positions	815	16
Settlements of prior year tax positions	—	(144)
Expiration of statutes	—	(1,637)
Balance as of December 31,	$ 2,974	$ 1,743

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 2019. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to 2018. 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)

For periods in which non-vested restricted stock awards with nonforfeitable rights to dividends or dividend equivalents (referred to as participating securities) were outstanding, the Company used the two-class method of computing basic and diluted EPS. In other periods, the Company used the treasury stock method of computing basic and diluted EPS.

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 (if other participating securities were outstanding). 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, 2023, 2022, and 2021, 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,		
(In thousands)	**2023**	**2022**	**2021**
Weighted average common shares-basic	36,729	20,054	19,691
Effect of diluted securities:			
Unexercised stock options and employee stock purchase plan	—	—	—
Unvested time-based restricted stock units	—	—	—
Weighted average common shares-diluted	36,729	20,054	19,691

There were 6.5 million, 2.3 million and 1.7 million weighted average outstanding options, time-based restricted stock awards and stock units, performance-based stock units, and market-based stock units not included in the diluted earnings per share computation for the years ended December 31, 2023, 2022, and 2021, respectively, because inclusion of these awards was anti-dilutive or, for performance-based stock units and market-based stock units, all necessary conditions had not been satisfied by the end of the respective period.