# 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, 2024**

**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: 000-19961**

## 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, 2024, as reported by the Nasdaq Global Select Market, was approximately $504.4 million.

As of February 21, 2025, 39,022,492 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. 2025 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, 2024**
**Table of Contents**


| | | | Page |
|---|---|---|---|
| PART I | | | |
| | Item 1. | Business | 6 |
| | Item 1A. | Risk Factors | 27 |
| | Item 1B. | Unresolved Staff Comments | 52 |
| | Item 1C. | Cybersecurity | 52 |
| | Item 2. | Properties | 54 |
| | Item 3. | Legal Proceedings | 54 |
| | Item 4. | Mine Safety Disclosure | 54 |
| PART II | | | |
| | Item 5. | Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities | 55 |
| | Item 6. | Reserved | 56 |
| | Item 7. | Management's Discussion and Analysis of Financial Condition and Results of Operations | 57 |
| | Item 7A. | Quantitative and Qualitative Disclosures About Market Risk | 69 |
| | Item 8. | Financial Statements and Supplementary Data | 70 |
| | Item 9. | Changes in and Disagreements with Accountants on Accounting and Financial Disclosure | 70 |
| | Item 9A. | Controls and Procedures | 70 |
| | Item 9B. | Other Information | 73 |
| | Item 9C. | Disclosure Regarding Foreign Jurisdictions that Prevent Inspections | 73 |
| PART III | | | |
| | Item 10. | Directors, Executive Officers, and Corporate Governance | 74 |
| | Item 11. | Executive Compensation | 74 |
| | Item 12. | Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters | 74 |
| | Item 13. | Certain Relationships, Related Transactions, and Director Independence | 74 |
| | Item 14. | Principal Accountant Fees and Services | 74 |
| PART IV | | | |
| | Item 15. | Exhibits and Financial Statement Schedules | 75 |
| | Item 16. | Form 10-K Summary | 82 |

**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 cross-selling opportunities 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 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.

**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 SeaSpine business is still ongoing. We may not be able to successfully complete remaining integration activities and/or realize all anticipated benefits of the merger.
- 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.
- Pandemics, wars and armed conflicts, terrorist attacks, and 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 group purchasing organization ("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 within 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, or that we will be able to maintain such clearances or approvals for current 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, misappropriation of PHI or personal identifiable information ("PII"), 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, including as the result of natural disasters and other catastrophic events outside our control.
- 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 party claims and litigation for infringement or misappropriation of their intellectual property, 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.
- Ongoing litigation and arbitration matters could negatively affect our business operations.
- Our efforts to identify, pursue, and implement new business opportunities (including acquisitions) may be unsuccessful.
- 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 $275.0 million credit 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.

**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 global medical technology company headquartered in Lewisville, Texas. By providing medical technologies that heal musculoskeletal pathologies, we deliver exceptional experiences and life-changing solutions to patients around the world. Orthofix offers a comprehensive portfolio of spinal hardware, bone growth therapies, specialized orthopedic solutions, biologics, and enabling technologies, including the 7D FLASH navigation system.

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.

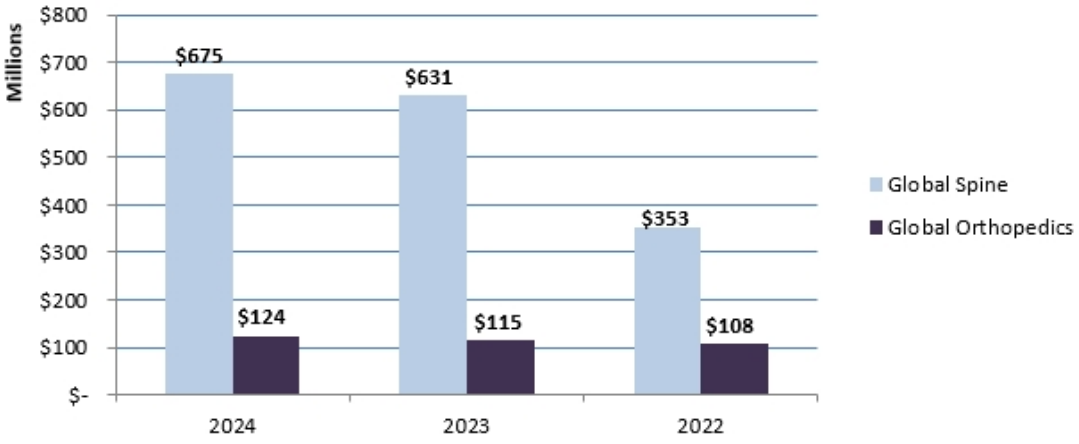
In January 2023 we completed a "merger of equals" transaction with SeaSpine whereby SeaSpine became a wholly owned subsidiary of the Company via an all-stock merger (the "Merger"). As a result of the Merger, each share of SeaSpine common stock issued and outstanding immediately prior to the closing of the Merger was converted into 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 following the Merger 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, 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 on our website or connected to our website is not incorporated by reference into this Annual Report. Our website is located at www.orthofix.com. Our SEC filings are also available on the SEC website at www.sec.gov.

### Business Segments

Orthofix manages the business by two reporting segments, Global Spine and Global Orthopedics, which accounted for 84% and 16% of our total net sales in 2024, 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, 2024, 2023, and 2022.



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;
- Investing in the further development of our pre-clinical and clinical programs designed to generate peer-reviewed scientific evidence in support of our products; and
- 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, treating both fresh fractures or 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 United States ("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 spine 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 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 Thoracolumbar Fixation Procedures | Pedicle screw systems for open and minimally invasive surgery ("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 thoracolumbar 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, hydroxyapatite ("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. In February 2025, the Company announced the discontinuation of the M6 line of products. |

| | |
|---|---|
| Artificial Lumbar Disc Replacement Procedures | Our next-generation artificial disc, M6-L artificial lumbar 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.) In February 2025, the Company announced the discontinuation of the M6 line of products. |
| 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 polyetheretherketone ("PEEK"), PEEK Titanium composite ("PTC"), and 3D printed Titanium. Some of our products 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. These products also 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 variations 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. These products include Northstar occipital cervical thoracic ("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. |
| 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, and in a number of material types, including 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. 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 our 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. |
| Sacroiliac ("SI") Joint 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 been, 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 (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 (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, maintains 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 (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. |
| FLASH External Ventricular Drain ("EVD") System (Cranial) | The FLASH EVD system leverages proprietary LiveTrack Machine Vision hardware and software to generate high-resolution three-dimensional images embedded with hundreds of thousands of virtual fiducials. This advanced navigation system enables a fully contactless workflow by seamlessly tracking disposable surgical instruments via integrated LiveTrack tile markers, ensuring precise surgical navigation for external ventricular drain bedside procedures. |

*Biologics Technologies*

| Product Categories | Products |
|---|---|
| Proprietary Technology | *Accell Bone Matrix ("ABM")*<br>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, including but not limited to, Strand Plus and Evo3. |
| Demineralized Bone Fibers ("DBF") | *Strand, Strand Plus, Fiberfuse*<br>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 ABM, and fibers mixed with cancellous bone. Provided in both putty and strip formulations. |
| Demineralized Bone Putty | *Evo3/Evo3c, Torrent/Torrent C, DynaGraft II, OrthoBlast II, Legacy Flowable* DBMs designed with putty-like handling characteristics to ease graft placement and conform to any bony anatomy to aid in bone fusion. Provided in multiple compositions of DBM particulate and carrier with and without Accell Bone Matrix or with and without cancellous bone. |
| Cellular Bone Matrixes ("CBM") | *Trinity Elite, Virtuos Lyograft*<br>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. |
| Synthetics | *Cove, Mozaik*<br>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.<br><br>*Ballast, Ballast MT*<br>Resorbable mesh filled with 100% DBM, or provided empty; aids in simplifying graft placement and prevents graft migration for posterolateral fusion.<br><br>*NorthStar Facet Fusion, Flash Facet Fusion*<br>Novel procedural solution for reproducible biologic placement within the facet joint for cervical and lumbar spine. Systems includes pre-shaped demineralized bone fibers with single-use instrumentation for facet prep and biologic delivery.<br><br>*RAPID, O-Genesis*<br>Reusable and sterile, single use options to aid in bone graft delivery to the surgical site. |
| Other | *Versashield*<br>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*

The M6-C cervical and M6-L lumbar artificial discs are used to treat patients suffering from degenerative disc disease of the spine. In February 2025, the Company announced that the M6 line of products is being discontinued.

*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, and plates. Our interbody spacer brands and materials include PTC, Waveform, Reef, and Nanovate 3D printed titanium surface technologies. Each comes 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 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 such products with Nanotechnology claims.

*Enabling Technologies*

Our machine vision 7D FLASH Navigation System is used in a variety of posterior spinal procedures, including degenerative, deformity, tumor, trauma, and revision surgery. The system 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 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. In 2024, we further enhanced the 7D FLASH Navigation System with the release of our 7D MRVision utilizing MRIguidance's BoneMRI software to generate a synthetic CT from an MRI scan that can be used for surgical planning and spinal navigation with the 7D FLASH Navigation System Spine Module. Traditional spine navigation requires a preoperative CT or intraoperative radiation for image acquisition and registration. 7D MRVision is the

first and only solution that eliminates radiation from the entire navigation workflow. Further enhancements and new features to the Spine Module and Percutaneous Module are in development and are expected to launch in 2025.

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 2025, we anticipate the commercial launch of FLASH EVD, a new mobile bed-side navigational system leveraging 7D FLASH Technology designed for fast and reliable EVD placement. Cadaveric testing has been completed and FLASH EVD achieved FDA 510K clearance in December 2024.

*Biologics — Regenerative Solutions*

Our biologics portfolio is focused on best-in-class bone grafting solutions from each of the major bone grafting categories - demineralized bone, cellular allografts, 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% DBM 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 recently released Virtuous Lyograft, both co-branded with MTF Biologics. Trinity Elite, an allograft with viable cells, has maintained position as a market leader with over a decade of clinical evidence and a series of peer-reviewed publications. 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, we have 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 Biologics for Virtuous, Trinity Elite, FiberFuse, and certain other tissues. MTF Biologics 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 new technology commercialization efforts. These new technologies apply to both the cervical and thoracolumbar spinal anatomy. We expect that the contribution of new, internally developed technologies and any future external acquisitions will be the primary driver of future growth.

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 the underserved limb reconstruction market that encompasses four pillars: deformity correction, limb lengthening, complex fracture management, and limb preservation. 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 has recently evolved to specifically focus on providing unrivaled limb reconstruction procedural solutions coupled with first-in-class service and support.

Our key strategies in this segment are:

- Expand our position as the worldwide leader in limb reconstruction, including both internal and external solutions, through a patient-centric approach and digital treatment journey;
- 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 the chosen surgical plan;
- Build on our historical position as a company at the forefront of innovation in the management of Charcot foot and ankle conditions by further investing into limb preservation technology advancements that address challenging conditions associated with diabetic foot;
- Promote and invest in our Fitbone intramedullary limb lengthening platform, including the newly released Transport and Lengthening System – the only all internal bone transport intramedullary nail available in the U.S.;
- Continue to be market leaders in deformity correction with our flagship TrueLok system, comprised of the most comprehensive external ring fixation solutions, and focusing on delivering enabling technology solutions to improve surgeons' ability to effectively treat their patients;
- Continue to focus on complex fracture management in select global markets, with the Galaxy Fixation System and by 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 digitally transformative technology, clinical evidence, and our industry-leading medical education program, Orthofix Academy;
- Continue the strong pace of new product launches; and
- 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 technologies that address the most complex patient conditions within deformity correction, limb lengthening, complex fracture management, and limb preservation. We provide innovative external and internal solutions to help surgeons improve the quality of life for patients of all ages.

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

| Products and Software | Primary Application |
|---|---|
| TrueLok | A surgeon-designed, lightweight external fixation system for complex fracture management, limb lengthening, limb preservation, 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 deformity correction with associated software newly integrated into the OrthoNext platform, 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 for complex fracture management, deformity correction, and limb preservation; it is the only circular fixation system to feature both radiolucent rings and struts that provides surgeons with clear radiographic visualization 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. |
| 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 correction, that uses callus distraction to lengthen bone in a variety of procedures, |

| | |
|---|---|
| | including bone transport, simultaneous compression and distraction at different sites, bifocal lengthening, and correction of deformities with shortening. |
| OrthoNext Digital Platform | A digital software platform developed specifically to enable surgeons to perform deformity analysis, plan out the correction, and template the appropriate implant to use. The platform includes modules for the JuniOrtho Plating System, Fitbone Intramedullary Limb Lengthening System, and more recently added TL-Hex system. |

*External Fixation*

External fixation devices are used to correct bone deformities, stabilize fractures, and offer an ideal treatment 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 fracture 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 and limb-salvaging procedures.

We offer most of our products in sterile packaged procedural kits, which fulfills the need of a streamlined and ready-to-use set of products, particularly in trauma applications or the military setting, 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. The portfolio was recently expanded with the release of the Fitbone Transport and Lengthening System specifically developed for bone defect management applications. We are continuing to invest in the Fitbone technology platform in order to offer surgeons more innovative solutions to meet both their needs to treat limb length discrepancies and complex deformities.

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

**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.

Like 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 orthopedic applications to treat patients of all ages.

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 2024, 2023, and 2022, we incurred research and development expenses of $73.6 million, $80.2 million, and $49.1 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, potential competitors, and other third parties. 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 or other third parties. 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 Compliance and Risk Officer, who reports directly to our Chief Executive Officer and the Compliance and Ethics 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, or approval of a premarket approval application ("PMA"). 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, an allogeneic bone matrix comprised of cancellous bone containing viable cells and a demineralized cortical bone component, as well as, demineralized cortical fibers, structural allografts, 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 demineralized bone putties, resorbable mesh with demineralized particulates, and synthetic putties and strips that are regulated by the FDA as medical devices. 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 or other regulatory agencies were to find that we or certain of our suppliers have failed to comply with applicable regulations, the agencies 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. In addition, during 2024 CMS considered establishing a pre-authorization requirement for bone growth therapy products and considered mandatory HCPCS code verifications for this class of durable medical equipment. Even though CMS did not implement any proposed revisions or new requirements in 2024, in the future we may be affected by these or other similar regulatory changes.

*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 OIG 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" ("PHI") 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 PHI 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, PHI, 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*

We manage our business by two reporting segments, Global Spine and Global Orthopedics, which account for 84% and 16%, respectively, of our total net sales in 2024.


*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, ASCs, 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"). Under the Orthofix Academy program, we organize regular multilingual teaching seminars in

multiple locations and 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 Highridge Medical, Enovis, Bioventus, Theragen, and Xstim. 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, Highridge Medical, Medtronic, Stryker, XTANT Medical, 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, OrthoNext preoperative planning, and our Orthofix Academy 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 "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 internally manufactured 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 synthetic offering 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 Lyograft, Trinity ELITE, FiberFuse and FiberFuse Strip, and certain other tissue forms.

**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 into our core values.

*Employees*

As of December 31, 2024, we had 1,616 employees worldwide. Of these, 1,256 were employed in the U.S. and 360 were employed at other non-U.S. locations. Our relations with our Italian employees, who numbered 229 at December 31, 2024, 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, a stock purchase plan, virtual physician consults, 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, flexible spending accounts, 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 an 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, engagement, and health and wellness, enabling them to do their best work as they grow their careers. All our employees are encouraged to work with their managers to create individual plans to guide their career progression to support their growth and continued success.

*Diversity and Inclusion*

We are committed to fostering, cultivating, and preserving a culture that promotes diversity and inclusion. We seek to demonstrate our commitment to providing equal and equitable opportunities to all employees. Throughout the year, we promote a variety of voices 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, Veterans' Day, Thanksgiving, Diwali, Ramadan, Kwanzaa, Christmas, Hannukah, Juneteenth, Memorial Day, and Hispanic and Native American Heritage Months among others. We seek to embrace and encourage our employees' differences and diverse backgrounds and know that our inclusive culture helps build a truly global, transformative business and will continue to be a source of our strength.

*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 2024, 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 2,517 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.

**Risks Related to our Merger with SeaSpine**

*Although we have made significant progress in integrating the SeaSpine business, the remainder of our integration activities may not be completed smoothly or successfully, and we may not achieve all of the anticipated benefits of the merger.*

While we have successfully completed many integration activities since the closing of merger, the remainder of our integration activities may not be completed smoothly or successfully. We may face challenges in completing remaining integration activities, which 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 resulting from the merger.*

As a result of the merger, the size of our business has become significantly larger. Our ability to successfully manage this expanded business depends, in part, upon our ability to design and implement strategic initiatives that address not only the integration of the SeaSpine business, 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 business 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 integration expenses.*

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. These activities remain ongoing for certain integration areas, and we expect to continue to incur significant expenses associated with these activities in the future. 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. 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. For example, during the financial close for the quarter ended December 31, 2023, we identified a material weakness in our internal controls over financial reporting (which we subsequently remediated), related to the operation of certain management review controls pertaining to business combinations and goodwill. 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 (including distribution and sales activities), and significant management distraction. Such consequences could have a material adverse effect on our business, results of operations, and financial condition.

*We are subject to various 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.

*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 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 regulations promulgated under 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, other such legislation, or the rules or regulations promulgated thereunder, 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 several countries. 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, state, federal and foreign prosecutorial scrutiny and governmental oversight 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. This 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.

*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. For example, in 2024 CMS considered establishing a pre-authorization requirement for bone growth therapy products and considered mandatory Healthcare Common Product Coding System ("HCPCS") code verifications for this class of durable medical equipment.

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 United Kingdom ("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 record keeping 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 or other domestic or foreign government authority or "Notified Body" were to investigate us, because of an allegation or otherwise, and if the FDA or such other authority or Notified Body 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, such agency or authority 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, any of which may result in unanticipated expenditures to address or defend such actions. The FDA and other regulatory bodies also have 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 or other body 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 ("MDD") 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 is considered a "Third Country" under the European MDD, which results in registration requirements in Switzerland being different than in other E.U countries. The company has, however, pursued registration of certain key products in Switzerland under their new laws. Similar activities have been pursued in the U.K. in relation to Brexit.

*Prohibitions on promotion of "off-label" uses of medical devices might affect the way we market our products and compete in the marketplace.*

The FDA, the OIG for the HHS, 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, cause 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.

*An 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 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 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. Future pandemics, wars and armed conflicts, terrorist attacks, and 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, 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 their 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), working efficiently (known as physician profiling), and developing 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 efforts 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 device 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 and orthopedic 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 and orthopedic markets 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 of 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, and suspension of studies, and 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 requirements related to 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.

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, may need to recall the modified product until we obtain clearance or approval, and 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 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 may 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. 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 competing 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 consistent with FDA and other applicable regulations developed both in the U.S. and other countries, if the FDA or another 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 competing 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. MDR, 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 Item 1A.

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 or carries previously undiscovered risks.

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' Agency for Healthcare Research and Quality ("AHRQ") 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, improves patient outcomes less than we initially expected, or carries previously undiscovered risks. 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 their reliability and integrity. 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 commensurately, with no assurance that the volume of business will increase. Any such upgrades to our information technology systems and infrastructure, 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 any businesses we acquire in the future will operate on different ERP systems and that we could face difficulties in integrating operational and accounting functions of such 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 to 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. 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 provide 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. We work with PII and PHI, and we may not be able to 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 and psychological 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 our 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, and duration of certain adverse weather conditions and natural disasters, such as hurricanes, tornadoes, earthquakes, wildfires, droughts, extreme temperatures, and 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 number of persons with medical conditions we treat, climate change could contribute to collateral effects such as increased transmission of viruses or airborne illnesses, which could lead to unpredictable events, such as additional stress on hospitals and other medical facilities and/or supply chains, which could in turn disrupt 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, such as the adoption of more stringent environmental laws and regulations or stricter enforcement of existing laws and regulations. These 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 including as the result of natural disasters and other catastrophic events outside our control.*

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, 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 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. Moreover, these types of events could negatively impact demand for our products in the impacted region(s), which could adversely impact our operating results.

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, which 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 account 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, and key stakeholders, including our independent sales agents and stocking distributors and physician customers, may 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 could 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 could 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 Biologics 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 International Organization of Standardization ("ISO") or other certification or as a result of any of the disruptions described above 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 including as the result of natural disasters and other catastrophic events outside our control." For example, a certain number of our products require titanium, which is sourced from third party suppliers. Although the titanium required for such products is not directly sourced from Russia, the current war between Russia and Ukraine and the resulting geopolitical events and consequences are negatively impacting the wider titanium supply chain. These geopolitical events and consequences, 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 an 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 government authorities require additional donor testing in the future, it could strain the supply of tissue. We cannot be certain that our supply of human tissue will be available from our suppliers 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 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 the disruption associated with restrictive covenants to which representatives or distributors may be subject and potential litigation and expenses 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 six to twelve 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 on 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, is 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 on 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, unexpected changes in regulatory requirements, and withdrawals of clearances or approvals;
- 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 or other parties. Furthermore, our patent rights may not prevent our competitors or other parties 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 or other parties.

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 or other third party, 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 to license proprietary rights from third parties, to satisfy judgments or to settle actual or threatened litigation.

Although patent and intellectual property disputes within the medical device 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 that 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 litigation and 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. Defending and litigating these claims 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 of litigation 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. We also maintain policies including directors' and officers' liability insurance, property insurance, cybersecurity insurance, general liability insurance, and workers' compensation insurance. However, we do not carry insurance for all categories of risk to which our business may be exposed, and there can be no assurance that product liability or other claims will not exceed our insurance coverage limits or be excluded from coverage under the terms of the applicable policy, nor that such insurance will continue to be available on reasonable, commercially acceptable terms, or at all. A successful claim not covered by our insurance could require us to pay substantial sums and could have a material adverse effect on our financial condition.

*Ongoing litigation and arbitration matters could negatively affect our business operations.*

In September 2023, following an investigation conducted by independent outside legal counsel, our 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 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).

Several litigation and arbitration matters against the Company (and in certain cases, current and former directors and officers) are pending in connection with these terminations. These matters include (i) arbitration claims by the three former executives against the Company for alleged breach of contract, defamation, false light invasion of privacy and deceit in connection with such terminations of employment, including payment of severance amounts and the value of forfeited equity grants, (ii) securities class action complaints alleging violations of the Securities Act of 1933 and the Securities Exchange Act of 1934 in connection with the Company's public disclosures during the periods preceding such terminations, and (iii) a derivative complaint alleging claims against certain of the Company's current and former officers and directors based on the same allegations made in the securities class action complaints. Additional lawsuits or proceedings against the Company and/or its current or former directors and officers in connection with these matters may be filed in the future.

In the event that any of these claims, or other future related or unrelated claims, are successful, they could result in costs to us that could negatively affect our near-term liquidity and financial condition. In addition, these matters may also divert management's attention and resources, which could adversely affect the operation of our business while such claims proceed.

**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 capitalize on 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 the ownership of 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 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 that 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 where the income-generating assets have been disposed of. These costs and expenses may be incurred at any time and may have a material impact on our results of operations.

**Risks Related to Our Financial Results and Financing Needs**

*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, including the factors described throughout this Item 1A.

*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 2024 had an unfavorable impact of $0.2 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.

*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.

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. 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.

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 reflected 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. Examples of such an event or change in circumstances 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 for the profitability of our business.

*We maintain a $275.0 million credit facility secured by a pledge of substantially all of our property.*

On November 7, 2024, the Company, as borrower, and its U.S. subsidiaries entered into a $275.0 million secured credit agreement (the "Credit Agreement") with Oxford Finance LLC, as administrative agent and as collateral agent ("Oxford") and certain lenders party thereto, including Oxford, K2 HealthVentures LLC, and HSBC Ventures USA Inc. Certain of the Company's foreign subsidiaries joined the Credit Agreement as guarantors shortly after the signing date. The Credit Agreement provides for a $160.0 million senior secured term loan (the "Initial Term Loan"), and a $65.0 million senior secured delayed draw term loan facility (the "Term B Loan"). Draws under the Term B Loan are at the Company's option from January 1, 2025 through June 30, 2026, subject to, among other conditions, the Company's continuing compliance with a pro-forma total debt-to-EBITDA leverage ratio of less than 4.0x. EBITDA is a non-GAAP financial measure which represents earnings before interest income (expense), income taxes, depreciation, amortization, and other negotiated addbacks and adjustments. In addition, at Oxford's discretion, an additional $50.0 million of draw capacity is available to the Company, through January 1, 2029 (the "Term C Loan" and, together with the Term B Loan, the "Delayed Draw Term Loans" and collectively with the Initial Term Loan, the "Credit Facilities"). The Initial Term Loan and Delayed Draw Term Loans, to the extent ultimately drawn, will each mature in November 2029, following an interest-only payment period ending December 2028, and monthly amortization of principal and accrued interest between January 2029 and November 2029.

The Credit Facilities are secured by a perfected first priority lien, or the equivalent security interest in each applicable jurisdiction, on substantially all of our assets and the applicable guarantors (subject to customary carveouts), including their respective U.S. intellectual property assets.

Borrowings under the Credit Facilities bear interest at a percentage rate equal to the greater of 8.75% or 5.75% plus the one-month term Secured Overnight Financing Rate ("SOFR") rate. A facility fee equal to 1.5% of each applicable funded loan tranche is due at the time of funding of such respective tranche, and a 0.5% unused line fee is payable annually on the Term B Loan.

The Credit 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 certain investments and acquisitions, merge or consolidate with others, dispose of certain assets, pay dividends and distributions, pay subordinated indebtedness, and enter into affiliate transactions, as well as financial covenants that we (i) maintain $15.0 million of unrestricted cash in U.S.-based accounts, and (ii) maintain a maximum total debt-to-EBITDA leverage ratio no greater than 4.0x during the term of the facility.

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 risks 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 typically 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 balances held in these accounts typically exceed the Federal Deposit Insurance Corporation ("FDIC") standard deposit insurance limit or similar applicable 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.

**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 for a company's securities. Such litigation, if instituted against us, could result in 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.

*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. In addition, various regulators around the world currently require, or may in the future require, increased reporting of company ESG metrics, which will raise our costs of ESG compliance. Our business could be negatively impacted by such requirements. Any such requirements or 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, 2024, 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 information technology ("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 26 years of experience in both military and corporate leadership roles, including 13 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 14 years in IT leadership roles and 6 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 and engineering team and is also responsible for the tactical execution of security operations. He has 25 years of experience in IT roles including 15 years of experience in security leadership. He also has the following certifications: ISC2 CISSP, EC-Council Certified Ethical Hacker ("CEH"), and numerous vendor specific certifications.

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 key performance indicator ("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 | 5,600 | Leased |
| Sales management, distribution and administrative facility for Brazil | São Paulo, Brazil | 26,300 | Leased |
| Sales management, distribution and administrative facility for France | Arcueil, France | 8,500 | Leased |
| Sales management, distribution and administrative facility for Germany | Munich, Germany | 2,300 | 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 Item 1, "Business", under the subheading "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 February 21, 2025, we had 428 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 February 21, 2025, was $17.95. 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 |
|---|---|---|
| **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 |
| **2024** | | |
| First Quarter | $ 14.90 | $ 12.38 |
| Second Quarter | 15.90 | 12.08 |
| Third Quarter | 17.67 | 12.72 |
| Fourth Quarter | 20.73 | 14.73 |

**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 Credit Agreement. We currently intend to retain all of our consolidated earnings to finance the continued growth of our business.

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

**Equity Compensation Plan Information**

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

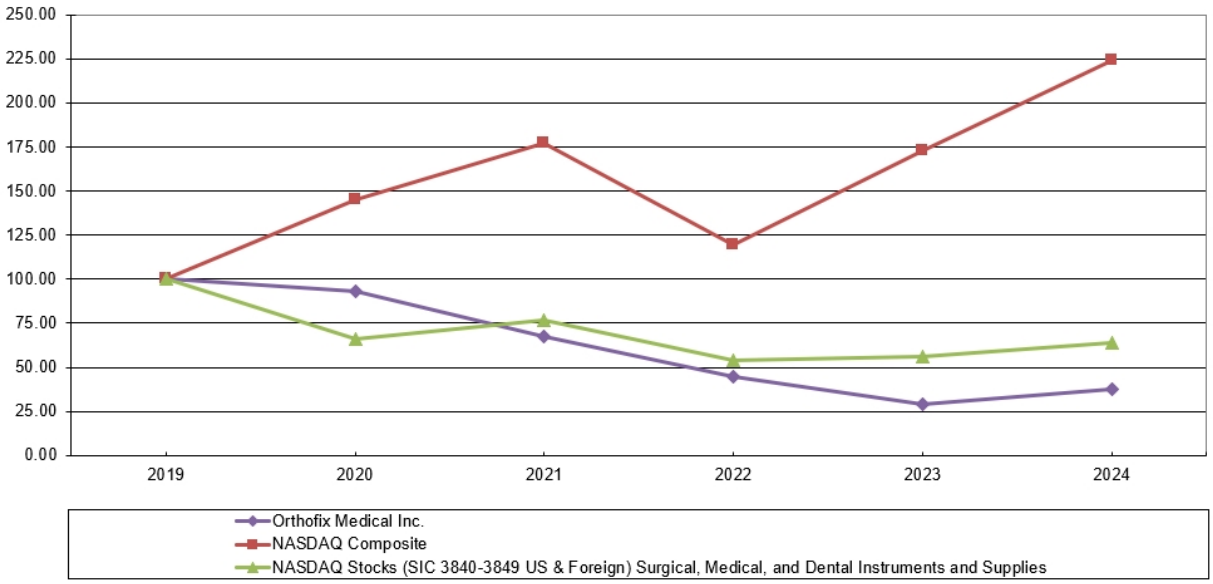
**Recent Sales of Unregistered Securities**

During the fourth quarter of 2024, 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 five years ended December 31, 2024, 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, 2019, 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 2024 and 2023 financial results, including comparisons of our year-over-year performance between these years. Discussion and analysis of our 2022 fiscal year specifically, as well as the year-over-year comparison of our 2023 financial performance to 2022, 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, 2023, filed with the SEC on March 5, 2024, which is available on our website at www.orthofix.com and the SEC's website at www.sec.gov.

### Executive Summary

Orthofix is a global medical technology company headquartered in Lewisville, Texas. By providing medical technologies that heal musculoskeletal pathologies, deliver exceptional experiences and life-changing solutions to patients around the world. Orthofix offers a comprehensive portfolio of spinal hardware, bone growth therapies, specialized orthopedic solutions, biologics, and enabling technologies, including the 7D FLASH navigation system.

In January 2023 we completed a "merger of equals" transaction with SeaSpine whereby SeaSpine became a wholly owned subsidiary of the Company via an all-stock merger (the "Merger"). 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 2024 include the following:

- Net sales were $799.5 million, an increase of 7.1% on both a reported and constant currency basis
- U.S. Spine Fixation net sales growth of 14.2% compared to prior year, driven by distribution expansion and further penetration in existing accounts
- Bone Growth Therapies growth of 9.8% and Bone Growth Therapies Fracture growth of 13.0% compared to prior year
- U.S. Spinal Implants, Biologics, and Enabling Technologies growth of 7.0% compared to prior year
- U.S. Orthopedics net sales growth of 16.4% compared to prior year
- Entered into record number of 7D FLASH Navigation System placements for full year 2024
- Entered into new $275.0 million credit facility that replaces existing financing and further optimized our capital structure to support long-term profitable growth

### 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, | | |
|---|---|---|---|
| | 2024 (%) | 2023 (%) | 2022 (%) |
| Net sales | 100.0 | 100.0 | 100.0 |
| Cost of sales | 31.7 | 34.9 | 26.8 |
| Gross profit | 68.3 | 65.1 | 73.2 |
| Sales, general, and administrative | 66.6 | 71.0 | 67.0 |
| Research and development | 9.2 | 10.7 | 10.7 |
| Acquisition-related amortization and remeasurement | 3.1 | 2.0 | (1.6) |
| Operating loss | (10.6) | (18.6) | (2.9) |
| Net loss | (15.8) | (20.3) | (4.3) |

***Net Sales by Reporting Segment***

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

| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 | Percentage Change 2024/2023 Reported | 2024/2023 Constant Currency | 2023/2022 Reported | 2023/2022 Constant Currency |
|---|---|---|---|---|---|---|---|
| Bone Growth Therapies | $ 233,405 | $ 212,530 | $ 187,247 | 9.8 % | 9.8 % | 13.5 % | 13.5 % |
| Spinal Implants, Biologics, and Enabling Technologies | 441,909 | 418,789 | 165,927 | 5.5 % | 5.5 % | 152.4 % | 152.4 % |
| Global Spine | 675,314 | 631,319 | 353,174 | 7.0 % | 7.0 % | 78.8 % | 78.7 % |
| Global Orthopedics | 124,177 | 115,322 | 107,539 | 7.7 % | 7.9 % | 7.2 % | 5.2 % |
| Net sales | $ 799,491 | $ 746,641 | $ 460,713 | 7.1 % | 7.1 % | 62.1 % | 61.6 % |

Global Spine

Global Spine offers the following products categories:

- Bone Growth Therapies, which manufactures, distributes, sells, and provides support services for market-leading devices 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.

*2024 Compared to 2023*

Net sales increased $44.0 million or 7.0%

- Bone Growth Therapies net sales increased $20.9 million, or 9.8%, driven by (i) an increase in gross order volumes from our continued investment in our direct sales channels for both the spine and fracture markets, (ii) capitalization of cross-selling opportunities, and (iii) continued growth and adoption of AccelStim
- Spinal Implants, Biologics, and Enabling Technologies net sales increased $23.1 million, or 5.5%, primarily due to increased sales growth from new and existing high-volume distribution partners, particularly within Spinal Implants and Biologics, which saw growth in each of our cervical, interbody, thoracolumbar, and demineralized bone matrices franchises; growth in these areas were partially offset by a decline in motion preservation net sales

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.

*2024 Compared to 2023*

Net sales increased $8.9 million, or 7.7% on a reported basis and 7.9% on a constant currency basis

- U.S. growth of $4.7 million, or 16.4%, largely due to investments made in recent product launches, commercial execution within our sales channel, and from growth within our OSCAR PRO product line
- International growth of $4.3 million, or 5.0% on a constant currency basis, driven by recent product launches in Europe and offset by the timing of certain tender offers and stocking distributor orders

- Decrease of $0.2 million due to movement in foreign current exchange rates, which had an unfavorable impact on net sales in 2024

***Gross Profit***

| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 | Percentage Change 2024/2023 | Percentage Change 2023/2022 |
|---|---|---|---|---|---|
| Net sales | $ 799,491 | $ 746,641 | $ 460,713 | 7.1% | 62.1% |
| Cost of sales | 253,606 | 260,368 | 123,544 | -2.6% | 110.7% |
| Gross profit | $ 545,885 | $ 486,273 | $ 337,169 | 12.3% | 44.2% |
| Gross margin | 68.3% | 65.1% | 73.2% | 3.2% | -8.1% |

*2024 Compared to 2023*

Gross profit increased $59.6 million, or 12.3%

- Increase in gross profit driven by net sales growth across all principal product categories
- Increase of $23.9 million driven by a reduction of amortization of the inventory fair value step-up recognized in the Merger, which is being amortized over the expected sales cycles of the acquired inventory

***Sales, General, and Administrative Expense***

| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 | Percentage Change 2024/2023 | Percentage Change 2023/2022 |
|---|---|---|---|---|---|
| Sales, general, and administrative | $ 532,525 | $ 530,395 | $ 308,776 | 0.4% | 71.8% |
| As a percentage of net sales | 66.6% | 71.0% | 67.0% | -4.4% | 4.0% |

*2024 Compared to 2023*

Sales, general, and administrative expense increased $2.1 million

- Increase of $16.0 million in variable compensation expenses, including commissions, largely resulting from changes in sales volume and sales mix
- Increase of $7.3 million in depreciation expense primarily related to an increase in deployed instrumentation to support increased sales demand
- Increase of $7.0 million in succession charges as a result of recent changes in executive leadership positions
- Partially offset by a decrease of integration-related expenses of $16.2 million primarily comprised of professional fees, advisor fees, and severance and retention costs
- Further offset by a decrease in sales, general, and administrative costs of over $10.0 million as a result of the realization of synergies, primarily related to compensation costs, professional fees, and share-based compensation expense

***Research and Development Expense***

| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 | Percentage Change 2024/2023 | Percentage Change 2023/2022 |
|---|---|---|---|---|---|
| Research and development | $ 73,643 | $ 80,231 | $ 49,065 | -8.2% | 63.5% |
| As a percentage of net sales | 9.2% | 10.7% | 10.7% | -1.5% | 0.0% |

*2024 Compared to 2023*

Research and development expense decreased $6.6 million

- Decrease of $7.0 million in costs to comply with the European Union Medical Device Regulations
- Decrease of $2.2 million related to merger and integration-related expenses, primarily related to severance and retention costs. In addition, research and development expenses were further reduced by the realization of Merger-related synergies
- Partially offset by an increase in certain product development and clinical expenses

***Acquisition-related Amortization and Remeasurement***

| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 | Percentage Change 2024/2023 | Percentage Change 2023/2022 |
|---|---|---|---|---|---|
| Acquisition-related amortization and remeasurement | $ 24,336 | $ 14,757 | $ (7,404) | 64.9% | -299.3% |
| As a percentage of net sales | 3.1% | 2.0% | -1.6% | 1.1% | 3.6% |

*2024 Compared to 2023*

Acquisition-related amortization and remeasurement increased $9.6 million

- Increase of $9.6 million associated with the remeasurement of a contingent consideration obligation with Lattus Spine LLC assumed in the Merger

***Non-operating Expense***

| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 | Percentage Change 2024/2023 | Percentage Change 2023/2022 |
|---|---|---|---|---|---|
| Interest expense, net | $ (29,631) | $ (8,631) | $ (1,288) | 243.3% | 570.1% |
| Other expense, net | (9,625) | (938) | (3,150) | 926.1% | -70.2% |

Non-operating expense largely consists of net 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.

*2024 Compared to 2023*

Interest expense, net, increased $21.0 million

- Unfavorable change of $13.3 million attributable to an increase in outstanding indebtedness compared to prior year
- Unfavorable change of $6.9 million attributable to the extinguishment of the Financing Agreement with Blue Torch Finance LLC
- Unfavorable change of $0.8 million as a result of the conversion of the convertible loan with Neo Medical into preferred equity securities in the second quarter of 2024 and subsequent sale of such securities in the fourth quarter of 2024

Other expense, net, increased $8.7 million

- Unfavorable change of $6.0 million associated with changes in foreign currency exchange rates, as we recorded a non-cash remeasurement loss of ($4.4 million) in 2024 compared to a gain of $1.6 million in 2023
- Unfavorable change of $2.5 million associated with gains and losses recognized on certain investments measured at fair value

***Income Tax Expense***

| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 | Percentage Change 2024/2023 | Percentage Change 2023/2022 |
|---|---|---|---|---|---|
| Income tax expense | $ 2,122 | $ 2,716 | $ 2,043 | -21.9% | 32.9% |
| Effective tax rate | -1.7% | -1.8% | -11.5% | 0.1% | 9.7% |

*2024 Compared to 2023*

Income tax expense decreased by $0.6 million

- Increase of $5.2 million associated with lower financial statement losses offset by valuation allowances
- Decrease of $2.0 million associated with foreign income inclusion
- Decrease of $1.5 million associated with statue expirations on uncertain tax positions
- Decrease of $2.4 million associated with financial statement expenses not deductible for tax, including executive and equity compensation

*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

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.

**Liquidity and Capital Resources**

Cash, cash equivalents, and restricted cash at December 31, 2024, was $85.7 million compared to $37.8 million at December 31, 2023.

| | Year Ended December, 31, | | |
|---|---|---|---|
| **(U.S. Dollars, in thousands)** | **2024** | **2023** | **Change** |
| Net cash provided by (used in) operating activities | $ 25,790 | $ (45,753) | $ 71,543 |
| Net cash used in investing activities | (27,580) | (33,131) | 5,551 |
| Net cash provided by (used in) financing activities | 50,709 | 65,322 | (14,613) |
| Effect of exchange rate changes on cash and restricted cash | (938) | 619 | (1,557) |
| Net change in cash, cash equivalents, and restricted cash | $ 47,981 | $ (12,943) | $ 60,924 |

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

| | Year Ended December, 31, | | |
|---|---|---|---|
| **(U.S. Dollars, in thousands)** | **2024** | **2023** | **Change** |
| Net cash provided by (used in) operating activities | $ 25,790 | $ (45,753) | $ 71,543 |
| Capital expenditures | (34,876) | (62,050) | 27,174 |
| Free cash flow | $ (9,086) | $ (107,803) | $ 98,717 |

***Operating Activities***

Cash flows from operating activities increased $71.5 million

- Favorable change in net loss of $25.4 million
- Favorable change of $11.4 million associated with non-cash gains and losses, such as amortization of the inventory fair value step-up recognized in the Merger, share-based compensation, inventory reserve expenses, depreciation and amortization, and gains and losses resulting from changes in fair value of certain assets and liabilities
- Favorable change of $34.7 million relating to changes in working capital accounts, primarily attributable to changes in inventories, prepaid expenses and other current assets, accounts payable, and other current liabilities

Two of our primary working capital accounts are accounts receivable and inventory. Day's sales in receivables were 57 days at December 31, 2024, compared to 59 days at December 31, 2023 (calculated using fourth quarter net sales and ending accounts receivable). Inventory turns improved to 1.3 times at December 31, 2024, compared to 1.2 times at December 31, 2023, respectively (calculated using trailing twelve month cost of goods sold and ending net inventories).

***Investing Activities***

Cash flows from investing activities increased $5.6 million

- Decrease in spend of $27.2 million in capital expenditures and $0.4 million in other investing activities

- Increase of $7.4 million relating to the sale of the Neo Medical preferred equity securities
- Partially offset by a decrease of $29.4 million attributable to cash acquired as a result of the Merger in 2023

***Financing Activities***

Cash flows from financing activities decreased $14.6 million

- Decrease of $13.5 million associated with net borrowing activities related to our credit facilities and assumption of SeaSpine's outstanding indebtedness at the time of the Merger
- Decrease of $1.3 million in debt issuance costs associated with the Credit Agreement with Oxford Finance LLC
- Partially offset by an increase of $0.2 million in net proceeds from the issuance of common shares

*Credit Facilities*

On November 7, 2024, the Company, as borrower, and its U.S. subsidiaries entered into a $275.0 million secured credit agreement (the "Credit Agreement") with Oxford Finance LLC, as administrative agent and as collateral agent ("Oxford") and certain lenders party thereto, including Oxford, K2 HealthVentures LLC, and HSBC Ventures USA Inc. Certain of the Company's foreign subsidiaries joined the Credit Agreement as guarantors shortly after the signing date. The Credit Agreement provides for a $160.0 million senior secured term loan (the "Initial Term Loan"), and a $65.0 million senior secured delayed draw term loan facility (the "Term B Loan"). Draws under the Term B Loan are at the Company's option from January 1, 2025 through June 30, 2026, subject to, among other conditions, the Company's continuing compliance with a pro-forma total debt-to-EBITDA leverage ratio of less than 4.0x. EBITDA is a non-GAAP financial measure which represents earnings before interest income (expense), income taxes, depreciation, amortization, and other negotiated addbacks and adjustments. In addition, at Oxford's discretion, an additional $50.0 million of draw capacity is available to the Company, through January 1, 2029 (the "Term C Loan" and, together with the Term B Loan, the "Delayed Draw Term Loans" and collectively with the Initial Term Loan, the "Credit Facilities"). The Initial Term Loan and Delayed Draw Term Loans, to the extent ultimately drawn, will each mature in November 2029, following an interest-only payment period ending December 2028, and monthly amortization of principal and accrued interest between January 2029 and November 2029.

Borrowings under the Credit Facilities bear interest at a percentage rate equal to the greater of 8.75% or 5.75% plus the one-month term SOFR rate. A facility fee equal to 1.5% of each applicable funded loan tranche is due at the time of funding of such respective tranche, and a 0.5% unused line fee is payable annually on the Term B Loan.

As of December 31, 2024, we had $160.0 million outstanding borrowings under the Credit Agreement related to the Initial Term Loan. As of December 31, 2024, we had not made any borrowings under the Delayed Draw Term Loans. 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 had no outstanding borrowings on our Italian line of credit of €5.5 million ($5.7 million) as of December 31, 2024. 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, 2024, was $15.4 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, 2024, we classified $7.1 million of the contingent consideration liability within other current liabilities and the remaining $8.3 million within other long-term liabilities. For additional discussion of this matter, see Note 12 of the Notes to the Consolidated Financial Statements in Item 8 of this Annual Report.

*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 received FDA approval for the acquired technology, which triggered 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 2023, and the remaining $1.0 million was paid in 2024.

***Unremitted Foreign Earnings***

Unremitted foreign earnings were $15.7 million as of December 31, 2024. 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, 2024, 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 and Finance 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 Biologics ("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, general, and administrative 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, 2024, would result in an increase or decrease to sales, general, and administrative 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, 2024, 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 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.

In the fourth quarter of 2024, we performed a quantitative assessment for our annual goodwill impairment analysis, which did not result in an impairment charge. Upon performing our assessment, we determined the Global Spine reporting unit's fair value exceeded its carrying value and concluded there were no indicators of impairment.

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, 2024, and 2023, 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, 2024, was $15.4 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. In April 2024, we converted the convertible loan into shares of Neo Medical preferred equity securities, which were recorded in other long-term assets and considered an investment that does not have a readily determinable fair value. The preferred equity securities were recorded at cost, less any impairment, plus or minus changes resulting from observable price changes in orderly transactions for identical or similar investments of the same issuer. In November 2024, we sold our shares of Neo Medical preferred equity for $7.4 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, 2024, the step-up in fair value on acquired inventory was fully amortized.

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, 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 our 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.

We recognize the tax impact of including certain foreign earnings in US taxable income as a period cost.

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, 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, 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 provided by or used in 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 Credit Agreement) plus an applicable borrowing margin. Therefore, interest rate changes generally do not affect the fair market value of the debt, but do impact future earnings and cash flows, assuming other factors are held constant.

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, 2024, we recorded a foreign currency loss of $4.4 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 unfavorably impacted during the year ended December 31, 2024, and favorably impacted during the year ended December 31, 2023, 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 $9.5 million and an increase in operating income of $0.3 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 $9.5 million and a decrease in operating income of $0.3 million.

## Item 8. Financial Statements and Supplementary Data

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

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

None.

## Item 9A. Controls and Procedures

**Evaluation of Disclosure Controls and Procedures**

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

**Management's Report on Internal Control over Financial Reporting**

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

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

In connection with the preparation and filing of this Annual Report, the Company's management, including our President and Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024, based on the framework set forth in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Based on its evaluation, the Company's management concluded that, as of December 31, 2024, the Company's internal control over financial reporting is effective based on the specified criteria.

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, 2024, which follows this report.

**Remediation of Material Weakness**

As disclosed in Part II, Item 9A of our 2023 Form 10-K, we identified a material weakness as of December 31, 2023, related to 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. During the year ended December 31, 2024, we

developed and implemented a remediation plan to address this material weakness, including enhancing existing controls. Based on management's assessment of the effectiveness of our internal control over financial reporting as of and for the year ending December 31, 2024, our President and Chief Executive Officer and Chief Financial Officer concluded that, as of the end of the period covered by this report, we had effectively remediated this past material weakness and that our controls and procedures were effective.

**Changes in Internal Control over Financial Reporting**

There have not been any changes in our internal control over financial reporting during the fourth quarter of 2024 that have materially affected or are reasonably likely to materially affect, our internal control over financial reporting.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

**Opinion on Internal Control Over Financial Reporting**

We have audited Orthofix Medical Inc.'s internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Orthofix Medical Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2024, and the related notes and our report dated February 25, 2025 expressed an unqualified opinion thereon.

**Basis for Opinion**

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

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

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

**Definition and Limitations of Internal Control Over Financial Reporting**

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

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

/s/ Ernst & Young LLP

Dallas, Texas
February 25, 2025

**Item 9B. Other Information**

During the fourth quarter of 2024, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) adopted, modified or terminated any contract, instruction, or written plan for the purchase or sale of our securities that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any "non-Rule 10b5-1 trading arrangement."

**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, 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 |
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| 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). |
| 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 | Loan and Security Agreement, dated as of November 7, 2024, among Orthofix Medical Inc., Orthofix US LLC, certain subsidiaries of Orthofix Medical Inc. from time to time party thereto as borrowers and/or guarantors, the lenders from time to time party thereto, and Oxford Finance LLC, as lender, administrative agent and collateral agent (filed as an exhibit to the Company's Current Report on Form 8-K dated November 7, 2024 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 Musculoskeletal 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). |

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| 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 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and incorporated herein by reference). |
| 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 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and incorporated herein by reference). |
| 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). |

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| 10.23 | 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). |
| 10.24 | 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). |
| 10.25 | 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). |
| 10.26 | 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). |
| 10.27 | 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). |
| 10.28 | Form of Non-Employee Director Restricted Stock Unit Agreement under the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 and incorporated herein by reference). |
| 10.29 | 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). |
| 10.30 | 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). |
| 10.31 | 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). |
| 10.32 | 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). |
| 10.33 | 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). |
| 10.34 | 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). |
| 10.35 | 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). |
| 10.36+ | 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). |
| 10.37+ | 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). |
| 10.38+ | 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). |
| 10.39+ | 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). |

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| 10.40+ | 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). |
| 10.41+ | 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). |
| 10.42+ | 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). |
| 10.43+ | 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). |
| 10.44+ | 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). |
| 10.45 | 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). |
| 10.46 | 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). |
| 10.47 | 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). |
| 10.48 | 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). |
| 10.49 | 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). |
| 10.50 | 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). |
| 10.51 | 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). |
| 10.52 | 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). |
| 10.53 | 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). |

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| 10.54 | 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). |
| 10.55+ | 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). |
| 10.56+ | 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) |
| 10.57+ | 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). |
| 10.58+ | 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). |
| 10.59+ | 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). |
| 10.60+ | 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). |
| 10.61+ | 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). |
| 10.62+ | 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). |
| 10.63+ | 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). |
| 10.64+ | 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). |
| 10.65+ | 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). |
| 10.66+ | 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). |
| 10.67+ | 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). |
| 10.68+ | Letter agreement, dated as of March 18, 2024, between Orthofix Medical Inc. and Andres Cedron (filed as an exhibit to the Company's Quarterly Report on Form 10-Q filed May 7, 2024, and incorporated herein by reference). |
| 10.69+ | Orthofix Medical Inc. 2024 CLO Inducement Plan (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration no. 333-278703) filed on April 16, 2024, and incorporated herein by reference). |
| 10.70+ | Orthofix Medical Inc. 2024 CLO Inducement Plan – Performance Stock Unit Grant Agreement (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration no. 333-278703) filed on April 16, 2024, and incorporated herein by reference). |

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| 10.71+ | Orthofix Medical Inc. 2024 CLO Inducement Plan – Time-Based Stock Unit Grant Agreement (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-8 (Registration no. 333-278703) filed on April 16, 2024, and incorporated herein by reference). |
| 10.72+ | Orthofix Medical Inc. 2024 CLO Inducement Plan – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-8 (Registration no. 333-278703) filed on April 16, 2024, and incorporated herein by reference). |
| 10.73+ | Change in Control and Severance Agreement, dated as of April 15, 2024, between Orthofix Medical Inc. and Andres Cedron (filed as Exhibit 10.18 to the Company's Quarterly Report on Form 10-Q filed May 7, 2024, and incorporated herein by reference). |
| 10.74+ | Letter agreement, dated as of February 2, 2024, between Orthofix Medical Inc. and Lucas Vitale (filed as Exhibit 10.19 to the Company's Quarterly Report on Form 10-Q filed May 7, 2024, and incorporated herein by reference). |
| 10.75+ | Orthofix Medical Inc. 2024 CP&BOO Inducement Plan (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration no. 333-278007) filed on March 15, 2024, and incorporated herein by reference). |
| 10.76+ | Orthofix Medical Inc. 2024 CP&BOO Inducement Plan – Performance Stock Unit Grant Agreement (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration no. 333-278007) filed on March 15, 2024, and incorporated herein by reference). |
| 10.77+ | Orthofix Medical Inc. 2024 CP&BOO Inducement Plan – Time-Based Annual Vesting Stock Unit Grant Agreement (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-8 (Registration no. 333-278007) filed on March 15, 2024, and incorporated herein by reference). |
| 10.78+ | Orthofix Medical Inc. 2024 CP&BOO Inducement Plan – Time-Based Cliff Vesting Stock Unit Grant Agreement (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-8 (Registration no. 333-278007) on March 15, 2024, and incorporated herein by reference). |
| 10.79+ | Orthofix Medical Inc. 2024 CP&BOO Inducement Plan – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.6 to the Company's Registration Statement on Form S-8 (Registration no. 333-278007) on March 15, 2024, and incorporated herein by reference). |
| 10.80+ | Change in Control and Severance Agreement, dated as of March 15, 2024, between Orthofix Medical Inc. and Lucas Vitale (filed as an exhibit to the Company's Quarterly Report on Form 10-Q filed May 7, 2024, and incorporated herein by reference). |
| 10.81+ | Orthofix Medical Inc. 2024 PGS Inducement Plan (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration no. 333-280101) filed on June 10, 2024, and incorporated herein by reference). |
| 10.82+ | Orthofix Medical Inc. 2024 PGS Inducement Plan – Performance Stock Unit Grant Agreement (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration no. 333-280101) filed on June 10, 2024, and incorporated herein by reference). |
| 10.83+ | Orthofix Medical Inc. 2024 PGS Inducement Plan – Time-Based Stock Unit Grant Agreement (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-8 (Registration no. 333-280101) filed on June 10, 2024, and incorporated herein by reference). |
| 10.84+ | Orthofix Medical Inc. 2024 PGS Inducement Plan – Nonqualified Cliff Vesting Stock Option Grant Agreement (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-8 (Registration no. 333-280101) filed on June 10, 2024, and incorporated herein by reference). |
| 10.85+ | Orthofix Medical Inc. 2024 PGS Inducement Plan – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.6 to the Company's Registration Statement on Form S-8 (Registration no. 333-280101) filed on June 10, 2024, and incorporated herein by reference). |
| 10.86+ | Orthofix Medical Inc. 2024 CIR&CO Inducement Plan (filed as Exhibit 4.7 to the Company's Registration Statement on Form S-8 (Registration no. 333-280101) filed on June 10, 2024, and incorporated herein by reference). |

| | |
|---|---|
| 10.87+ | Orthofix Medical Inc. 2024 CIR&CO Inducement Plan – Performance Stock Unit Grant Agreement (filed as Exhibit 4.8 to the Company's Registration Statement on Form S-8 (Registration no. 333-280101) filed on June 10, 2024, and incorporated herein by reference). |
| 10.88+ | Orthofix Medical Inc. 2024 CIR&CO Inducement Plan – Time-Based Stock Unit Grant Agreement (filed as Exhibit 4.9 to the Company's Registration Statement on Form S-8 (Registration no. 333-280101) filed on June 10, 2024, and incorporated herein by reference). |
| 10.89+ | Orthofix Medical Inc. 2024 CIR&CO Inducement Plan – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.10 to the Company's Registration Statement on Form S-8 (Registration no. 333-280101) filed on June 10, 2024, and incorporated herein by reference). |
| 10.90+ | Orthofix Medical Inc. 2024 PGO&Q Inducement Plan (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration no. 333-280277) filed on June 17, 2024, and incorporated herein by reference). |
| 10.91+ | Orthofix Medical Inc. 2024 PGO&Q Inducement Plan – Performance Stock Unit Grant Agreement (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration no. 333-280277) filed on June 17, 2024, and incorporated herein by reference). |
| 10.92+ | Orthofix Medical Inc. 2024 PGO&Q Inducement Plan – Time-Based Stock Unit Grant Agreement (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-8 (Registration no. 333-280277) filed on June 17, 2024, and incorporated herein by reference). |
| 10.93+ | Orthofix Medical Inc. 2024 PGO&Q Inducement Plan – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-8 (Registration no. 333-280277) filed on June 17, 2024, and incorporated herein by reference). |
| 10.94 | First Amendment to Financing Agreement, dated as of March 15, 2024, 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 10.26 to the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, and incorporated herein by reference). |
| 10.95 | Amendment No. 5 to the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan (filed as Exhibit 10.1 to the Company's Current Report on Form 8-K dated June 20, 2024, and incorporated herein by reference). |
| 10.96 | Amendment No. 4 to the Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan (filed as Exhibit 10.2 to the Company's Current Report on Form 8-K dated June 20, 2024, and incorporated herein by reference). |
| 10.97+ | Orthofix Medical Inc. 2024 CHRO Inducement Plan (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration no. 333-280820) filed on July 15, 2024, and incorporated herein by reference). |
| 10.98+ | Orthofix Medical Inc. 2024 CHRO Inducement Plan – Time-Based Stock Unit Grant Agreement (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration no. 333-280820) filed on July 15, 2024, and incorporated herein by reference). |
| 10.99+ | Orthofix Medical Inc. 2024 CHRO Inducement Plan – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-8 (Registration no. 333-280820) filed on July 15, 2024, and incorporated herein by reference). |
| 10.100+ | Orthofix Medical Inc. 2024 PGO Inducement Plan (filed as Exhibit 4.2 to the Company's Registration Statement on Form S-8 (Registration no. 333-281580) filed on August 15, 2024, and incorporated herein by reference). |
| 10.101+ | Orthofix Medical Inc. 2024 PGO Inducement Plan – Performance Stock Unit Grant Agreement (filed as Exhibit 4.3 to the Company's Registration Statement on Form S-8 (Registration no. 333-281580) filed on August 15, 2024, and incorporated herein by reference). |
| 10.102+ | Orthofix Medical Inc. 2024 PGO Inducement Plan – Time-Based Stock Unit Grant Agreement (filed as Exhibit 4.4 to the Company's Registration Statement on Form S-8 (Registration no. 333-281580) filed on August 15, 2024, and incorporated herein by reference). |

| | |
|---|---|
| 10.103+ | Orthofix Medical Inc. 2024 PGO Inducement Plan – Nonqualified Stock Option Grant Agreement (filed as Exhibit 4.5 to the Company's Registration Statement on Form S-8 (Registration no. 333-281580) filed on August 15, 2024, and incorporated herein by reference). |
| 10.104+ | Change in Control and Severance Agreement, dated as of June 10, 2024, between Orthofix Medical Inc. and Max Reinhardt (filed as exhibit 10.8 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, and incorporated herein by reference). |
| 10.105+ | Change in Control and Severance Agreement, dated as of August 15, 2024, between Orthofix Medical Inc. and Patrick Fisher (filed as exhibit 10.9 to the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, and incorporated herein by reference). |
| 19.1* | Insider Trading Policy |
| 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 (filed as an exhibit to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and incorporated herein by reference). |
| 101.INS | Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document. |
| 101.SCH* | Inline XBRL Taxonomy Extension Schema with Embedded Linkbase Documents. |
| 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 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.
+ Management contracts and compensation plans and arrangements.

**Item 16. Form 10-K Summary**

None

**SIGNATURES**

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

ORTHOFIX MEDICAL INC.

Dated: February 25, 2025

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

Dated: February 25, 2025

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<br>**Massimo Calafiore** | President and Chief Executive Officer, Director<br>(Principal Executive Officer) | February 25, 2025 |
| /s/ JULIE ANDREWS<br>**Julie Andrews** | Chief Financial Officer<br>(Principal Financial and Accounting Officer) | February 25, 2025 |
| /s/ MICHAEL FINEGAN<br>**Michael Finegan** | Director, Chair of the Board | February 25, 2025 |
| /s/ ALAN BAZAAR<br>**Alan Bazaar** | Director | February 25, 2025 |
| /s/ WAYNE BURRIS<br>**Wayne Burris** | Director | February 25, 2025 |
| /s/ JASON HANNON<br>**Jason Hannon** | Director | February 25, 2025 |
| /s/ JOHN HENNEMAN, III<br>**John Henneman, III** | Director | February 25, 2025 |
| /s/ CHARLES KUMMETH<br>**Charles Kummeth** | Director | February 25, 2025 |
| /s/ SHWETA SINGH MANIAR<br>**Shweta Singh Maniar** | Director | February 25, 2025 |
| /s/ MICHAEL PAOLUCCI<br>**Michael Paolucci** | Director | February 25, 2025 |

**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 and Finance 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 and Finance Committee.

**Wayne Burris**
Chairman of the Audit and Finance Committee

**Massimo Calafiore**
President and Chief Executive Officer, Director

**Julie Andrews**
Chief Financial Officer

**ORTHOFIX MEDICAL INC.**

**Index to Consolidated Financial Statements**


| | Page |
|---|---|
| Index to Consolidated Financial Statements | F-1 |
| Report of Independent Registered Public Accounting Firm (PCAOB ID: 42) | F-2 |
| Consolidated Balance Sheets as of December 31, 2024 and 2023 | F-4 |
| Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2024, 2023, and 2022 | F-5 |
| Consolidated Statements of Changes in Shareholders' Equity for the years ended December 31, 2024, 2023, and 2022 | F-6 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2024, 2023, and 2022 | F-7 |
| Notes to the Consolidated Financial Statements | F-8 |

## 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, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity and cash flows for each of the three years in the period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, 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, 2024, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 25, 2025 expressed an unqualified opinion thereon.

**Basis for Opinion**

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

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

**Critical Audit Matters**

The critical audit matter communicated below is a matter 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) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

***Inventory Excess and Obsolescence Reserves***

| | |
|---|---|
| *Description of the Matter* | At December 31, 2024, the Company's inventory balance was $189.5 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.<br><br>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.<br><br>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. |

/s/ Ernst & Young LLP

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

Dallas, Texas
February 25, 2025

**ORTHOFIX MEDICAL INC.**

**Consolidated Balance Sheets as of December 31, 2024 and 2023**

| (U.S. Dollars, in thousands, except par value data) | 2024 | 2023 |
|---|---|---|
| **Assets** | | |
| Current assets | | |
| Cash and cash equivalents | $ 83,238 | $ 33,107 |
| Restricted cash | 2,500 | 4,650 |
| Accounts receivable, net of allowances of $7,418 and $7,130, respectively | 134,713 | 128,098 |
| Inventories | 189,452 | 222,166 |
| Prepaid expenses and other current assets | 23,382 | 32,422 |
| Total current assets | 433,285 | 420,443 |
| Property, plant and equipment, net | 139,804 | 159,060 |
| Intangible assets, net | 98,803 | 117,490 |
| Goodwill | 194,934 | 194,934 |
| Other long-term assets | 26,468 | 33,388 |
| **Total assets** | **$ 893,294** | **$ 925,315** |
| **Liabilities and shareholders' equity** | | |
| Current liabilities | | |
| Accounts payable | $ 48,803 | $ 58,357 |
| Current portion of long-term debt | — | 1,250 |
| Current portion of finance lease liability | 755 | 708 |
| Other current liabilities | 119,070 | 104,908 |
| Total current liabilities | 168,628 | 165,223 |
| Long-term debt | 157,015 | 93,107 |
| Long-term portion of finance lease liability | 17,835 | 18,532 |
| Other long-term liabilities | 46,692 | 49,723 |
| Total liabilities | 390,170 | 326,585 |
| Contingencies (Note 13) | | |
| Shareholders' equity | | |
| Common shares $0.10 par value; 100,000 shares authorized; 38,486 and 37,165 issued and outstanding as of December 31, 2024 and 2023, respectively | 3,849 | 3,717 |
| Additional paid-in capital | 779,718 | 746,450 |
| Accumulated deficit | (276,141) | (150,144) |
| Accumulated other comprehensive loss | (4,302) | (1,293) |
| Total shareholders' equity | 503,124 | 598,730 |
| **Total liabilities and shareholders' equity** | **$ 893,294** | **$ 925,315** |

*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, 2024, 2023, and 2022**

| (U.S. Dollars, in thousands, except share and per share data) | 2024 | 2023 | 2022 |
|---|---|---|---|
| Net sales | $ 799,491 | $ 746,641 | $ 460,713 |
| Cost of sales | 253,606 | 260,368 | 123,544 |
| Gross profit | 545,885 | 486,273 | 337,169 |
| Sales, general, and administrative | 532,525 | 530,395 | 308,776 |
| Research and development | 73,643 | 80,231 | 49,065 |
| Acquisition-related amortization and remeasurement (Note 17) | 24,336 | 14,757 | (7,404) |
| Operating loss | (84,619) | (139,110) | (13,268) |
| Interest expense, net | (29,631) | (8,631) | (1,288) |
| Other expense, net | (9,625) | (938) | (3,150) |
| Loss before income taxes | (123,875) | (148,679) | (17,706) |
| Income tax expense | (2,122) | (2,716) | (2,043) |
| **Net loss** | **$ (125,997)** | **$ (151,395)** | **$ (19,749)** |
| | | | |
| Net loss per common share: | | | |
| Basic | $ (3.30) | $ (4.12) | $ (0.98) |
| Diluted | (3.30) | (4.12) | (0.98) |
| Weighted average number of common shares: | | | |
| Basic | 38,133,684 | 36,729,258 | 20,053,548 |
| Diluted | 38,133,684 | 36,729,258 | 20,053,548 |
| | | | |
| Other comprehensive income (loss), before tax | | | |
| Unrealized gain (loss) on debt securities | — | (1,334) | 395 |
| Currency translation adjustment | (3,009) | 1,417 | (1,771) |
| Other comprehensive income (loss), before tax | (3,009) | 83 | (1,376) |
| Income tax benefit (expense) related to items of other comprehensive income (loss) | — | — | — |
| Other comprehensive income (loss), net of tax | (3,009) | 83 | (1,376) |
| Comprehensive loss | $ (129,006) | $ (151,312) | $ (21,125) |

*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, 2024, 2023, and 2022**

| (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, 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** |
| Net loss | — | — | — | (125,997) | — | (125,997) |
| Other comprehensive loss, net of tax | — | — | — | — | (3,009) | (3,009) |
| Share-based compensation expense | — | — | 32,455 | — | — | 32,455 |
| Common shares issued, net | 1,321 | 132 | 813 | — | — | 945 |
| **At December 31, 2024** | **38,486** | **$ 3,849** | **$ 779,718** | **$ (276,141)** | **$ (4,302)** | **$ 503,124** |

*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, 2024, 2023, and 2022**

| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 |
|---|---|---|---|
| Cash flows from operating activities | | | |
| Net loss | $ (125,997) | $ (151,395) | $ (19,749) |
| Adjustments to reconcile net loss to net cash from operating activities | | | |
| Depreciation and amortization | 60,061 | 53,063 | 29,019 |
| Inventory reserve expenses | 26,254 | 27,576 | 14,907 |
| Amortization of inventory fair value step up | 12,188 | 36,044 | — |
| Amortization of operating lease assets, debt costs, and other assets | 15,901 | 7,498 | 3,056 |
| Provision for expected credit losses | 1,999 | 820 | 2,095 |
| Deferred income taxes | 1,883 | 579 | 314 |
| Share-based compensation expense | 32,455 | 35,707 | 18,443 |
| Loss on disposal of fixed assets | 2,025 | 2,300 | 2,072 |
| Interest and (gain) loss on the valuation of investment securities | 7,528 | 596 | (308) |
| Change in fair value of contingent consideration | 6,900 | (2,700) | (17,200) |
| Other | 3,844 | (1,877) | (45) |
| Changes in operating assets and liabilities, net of effects of acquisitions | | | |
| Accounts receivable | (9,526) | (10,411) | (6,735) |
| Inventories | (5,546) | (58,051) | (33,040) |
| Prepaid expenses and other current assets | 593 | 1,760 | (874) |
| Accounts payable | (5,571) | 8,642 | 2,282 |
| Other current liabilities | 9,527 | 4,069 | 627 |
| Contract liability | — | — | (4,791) |
| Other long-term assets and liabilities | (8,728) | 27 | (1,611) |
| **Net cash provided by (used in) operating activities** | **25,790** | **(45,753)** | **(11,538)** |
| Cash flows from investing activities | | | |
| Capital expenditures | (34,876) | (62,050) | (23,160) |
| Contingent consideration payments related to asset acquisitions | — | — | (1,500) |
| Cash acquired in SeaSpine merger | — | 29,419 | — |
| Sale of investment securities | 7,396 | — | 126 |
| Other investing activities | (100) | (500) | — |
| **Net cash used in investing activities** | **(27,580)** | **(33,131)** | **(24,534)** |
| Cash flows from financing activities | | | |
| Proceeds from credit facilities | 197,600 | 174,500 | — |
| Repayment of borrowings from credit facilities | (142,500) | (79,000) | — |
| Payment of debt acquired from SeaSpine merger | — | (26,899) | — |
| Proceeds from issuance of common shares | 6,257 | 5,127 | 4,337 |
| Payments related to withholdings for share-based compensation | (5,312) | (4,397) | (1,729) |
| Payment of contingent consideration | (1,000) | (1,000) | — |
| Payments related to finance lease obligation | (706) | (652) | (2,594) |
| Payment of debt issuance costs and other financing activities | (3,630) | (2,357) | (92) |
| **Net cash provided by (used in) financing activities** | **50,709** | **65,322** | **(78)** |
| Effect of exchange rate changes on cash and restricted cash | (938) | 619 | (997) |
| Net change in cash, cash equivalents, and restricted cash | 47,981 | (12,943) | (37,147) |
| Cash, cash equivalents, and restricted cash at the beginning of the year | 37,757 | 50,700 | 87,847 |
| **Cash, cash equivalents, and restricted cash at the end of the year** | **$ 85,738** | **$ 37,757** | **$ 50,700** |
| **Components of cash, cash equivalents, and restricted cash at the end of the year** | | | |
| Cash and cash equivalents | $ 83,238 | $ 33,107 | $ 50,700 |
| Restricted cash | 2,500 | 4,650 | — |
| **Cash, cash equivalents, and restricted cash at the end of the year** | **$ 85,738** | **$ 37,757** | **$ 50,700** |

*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. (the "Company" or "Orthofix") is a global medical technology company headquartered in Lewisville, Texas. By providing medical technologies that heal musculoskeletal pathologies, the Company delivers exceptional experiences and life-changing solutions to patients around the world. Orthofix offers a comprehensive portfolio of spinal hardware, bone growth therapies, specialized orthopedic solutions, biologics, and enabling technologies, including the 7D FLASH navigation system.

*Basis of Presentation*

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions are eliminated in consolidation. Information on our accounting policies and methods used in the preparation of our consolidated financial statements are included, where applicable, in the respective footnotes that follow.

| Footnote | Footnote Reference |
|---|---|
| Business and basis of presentation | 1 |
| Significant accounting policies | 2 |
| Recently adopted accounting standards and recently issued accounting pronouncements | 3 |
| Mergers and acquisitions | 4 |
| Inventories | 5 |
| Property, plant, and equipment | 6 |
| Intangible assets | 7 |
| Goodwill | 8 |
| Leases | 9 |
| Other current liabilities | 10 |
| Indebtedness | 11 |
| Fair value measurements and investments | 12 |
| Commitments and contingencies | 13 |
| Shareholders' equity | 14 |
| Revenue recognition and accounts receivable | 15 |
| Business segment information | 16 |
| Acquisition-related amortization and remeasurement | 17 |
| Share-based compensation | 18 |
| Defined contribution plans and deferred compensation | 19 |
| Income taxes | 20 |
| Earnings per share | 21 |
| Subsequent events | 22 |

*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 as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates 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. Estimates are based 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 the 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 each subsidiary's 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 loss of $4.4 million, a gain of $1.6 million, and a loss of $3.3 million for the years ended December 31, 2024, 2023, and 2022, 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. 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, which was classified as restricted cash as of December 31, 2023. In March 2024, the Company entered into a Security Agreement with Bank of America to reduce the required collateral to $2.5 million.

Investing activities that did not result in cash receipts or cash payments during the years ended December 31, 2024, 2023, and 2022 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) | 2024 | 2023 | 2022 |
|---|---|---|---|
| **Supplemental disclosure of cash flow information:** | | | |
| Noncash investing activities: | | | |
| Changes in accrued purchases of property, plant, and equipment | $ (3,040) | $ — | $ — |
| Intangible assets acquired in asset acquisitions | — | — | 2,000 |

*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 $0.3 million, $0.8 million, and less than $0.1 million in research and development expense for the years ended December 31, 2024, 2023, and 2022, respectively, related to this arrangement.

**3. Recently adopted accounting standards and recently issued accounting pronouncements**

***Recently Adopted Accounting Standards***

*Adoption of Accounting Standards Update ("ASU") 2021-08, Accounting for Contract Assets and Contract Liabilities with Contracts with Customers*

In October 2021, the Financial Accounting Standards Board ("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.

*Adoption of ASU 2022-03 - Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*

In June 2022, the FASB issued ASU 2022-03, which 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 and to introduce new disclosure requirements. The Company adopted this standard effective January 1, 2024, on a prospective basis. Adoption of this standard did not have a material impact to the Company's consolidated balance sheet, statements of operations, or cash flows, but did modify the Company's disclosures related to certain investments. Refer to Note 12 for the Company's updated disclosures on investments in equity securities subject to capital sale restrictions.

*Adoption of ASU 2023-07 - Improvements to Reportable Segment Disclosures*

In November 2023, the FASB issued ASU 2023-07, which enhances and improves disclosures about operating segment revenues, measures of profit/loss, and expenses to enable investors to better understand an entity's overall performance and assess potential future cash flows. The amendment requires that an entity disclose (i) significant expenses that are regularly provided to the Chief Operating Decision Maker ("CODM"), (ii) other segment items by reportable segment including a description of its composition, (iii) all annual disclosures required by Topic 280, *Reporting Measures of Segment Profit or Loss,* in interim periods, (iv) additional measures of a segment's profit or loss used by the CODM in assessing segment performance and allocation of resources, and (v) the title and position of the CODM and an explanation of how the CODM uses the reported measure(s) of segment profit or loss. The Company adopted this standard effective January 1, 2024, on a prospective basis. Refer to Note 16 for the Company's updated business segment disclosures.

***Recently Issued Accounting Pronouncements***

| Topic | Description of Guidance | Effective Date | Status of Company's Evaluation |
|---|---|---|---|
| *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 Income Tax Disclosures (ASU 2023-09)* | Enhances the transparency and decision-making 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. |
| *Disaggregation of Income Statement Expenses (ASU 2024-03)* | Improve financial reporting by requiring that public business entities disclose additional information about specific expense categories in the note to the financial statements at interim and annual reporting periods. The amendments are to be applied prospectively to financial statements issued and retrospectively to all prior periods presented in the financial statements. | January 1, 2027 | The Company is currently evaluating the impact this ASU may have on its consolidated financial statements. |

Other recently issued ASUs, excluding those ASUs which have already been disclosed as adopted or described above, were assessed and determined not applicable, or are expected to have minimal impact on the Company's 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 global medical technology company that provides medical technologies that heal musculoskeletal pathologies, and delivers exceptional experiences and life-changing solutions to patients around the world. 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 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) | | Final Acquisition Date Fair Value | Assigned Useful Life |
|---|---|---|---|
| **Assets acquired:** | | | |
| Current assets | | | |
| Cash and cash equivalents | $ | 29,419 | |
| Accounts receivable, net | | 35,313 | |
| Inventories | | 132,636 | |
| Prepaid expenses and other current assets | | 4,590 | |
| Total current assets | | 201,958 | |
| Property, plant, and equipment, net | | 68,863 | |
| Customer relationships | | 33,100 | 13 years |
| Developed technology | | 47,200 | 6 - 8 years |
| In-process research and development ("IPR&D") | | 5,750 | Indefinite |
| Other long-term assets | | 20,501 | |
| **Total identifiable assets acquired** | **$** | **377,372** | |
| | | | |
| **Liabilities assumed**: | | | |
| Current liabilities | | | |
| Accounts payable | $ | 21,602 | |
| Other current liabilities | | 43,521 | |
| Total current liabilities | | 65,123 | |
| Long-term borrowings under SeaSpine credit facility | | 26,298 | |
| Other long-term liabilities | | 32,823 | |
| **Total liabilities assumed** | | **124,244** | |
| **Net identifiable assets acquired** | **$** | **253,128** | |
| Total fair value of consideration transferred | | 376,745 | |
| **Residual goodwill** | **$** | **123,617** | |

The Company did not recognize any direct acquisition-related costs, which exclude integration-related activities, during the year ended December 31, 2024, however, the Company recognized $9.9 million in such costs that were expensed during the year ended December 31, 2023. These costs are included in the consolidated statements of operations and comprehensive loss, primarily within general and administrative expenses. The Company's results of operations included $294.0 million of net sales from SeaSpine for the year ended December 31, 2024, and a net loss attributable to SeaSpine of $63.4 million for the year ended December 31, 2024. 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.

Due to the consummation of the Merger occurring on January 5, 2023, all SeaSpine financial results for fiscal year 2023, except for the first four days of January, were included in the Company's condensed consolidated statement of operations and comprehensive loss. Therefore, the Company did not prepare unaudited pro forma financial information for the year ended December 31, 2023 or 2024, on the basis that the Merger was completed on January 1, 2023.

*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, 2024, and 2023.

| | For the Year Ended December 31, | |
|---|---|---|
| (U.S. Dollars, in millions) | 2024 | 2023 |
| Compensation-related integration costs | $ 4.0 | $ 17.7 |
| International spine restructuring | 0.5 | 1.3 |
| Fee paid to financial advisor to the Merger | — | 5.5 |
| Professional fees / consulting fees | 2.1 | 5.8 |
| Product rationalization charges | 9.7 | 6.0 |
| Other costs | 1.5 | 1.4 |
| Total | $ 17.8 | $ 37.7 |

After the consummation of the Merger, the Company approved and initiated certain restructuring activities to streamline costs and to better align talent with operational needs, including review of the Company's international spine business. As reported in the prior year, the Company expected to incur total pre-tax expenses of approximately $18.2 million associated with restructuring activities, which were recognized in operating expenses and resulted in accrued liabilities of $7.0 million as of December 31, 2023. The Company paid all remaining liabilities related to these activities in 2024, which primarily related to severance and retention payments.

**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. With respect to the Company’s manufacturing facilities in Texas and California, for inventory procured or produced internally or through contract manufacturing arrangements, standard cost, which approximates actual cost on the first-in, first-out ("FIFO") method, is used to value inventory. With respect to the Company’s manufacturing facilities in Italy, for inventory procured or produced internally or through contract manufacturing arrangements, weighted-average, which approximates actual cost on the first-in, first-out ("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 hospitals, is included within finished products.

| | December 31, | |
|---|---|---|
| (U.S. Dollars, in thousands) | 2024 | 2023 |
| Raw materials | $ 27,180 | $ 28,390 |
| Work-in-process | 56,920 | 53,510 |
| Finished products | 105,352 | 140,266 |
| Inventories | $ 189,452 | $ 222,166 |

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. 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, 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 $41.1 million, $34.2 million, and $19.6 million for the years ended December 31, 2024, 2023, and 2022, respectively.

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

| | December 31, | |
|---|---|---|
| (U.S. Dollars, in thousands) | 2024 | 2023 |
| **Cost** | | |
| Buildings | $ 3,874 | $ 4,103 |
| Plant and equipment | 76,481 | 70,252 |
| Instrumentation | 176,387 | 154,192 |
| Computer software | 41,396 | 43,040 |
| Furniture and fixtures | 9,832 | 11,010 |
| Construction in progress | 22,693 | 41,751 |
| Finance lease assets | 21,383 | 23,337 |
| Property, plant, and equipment, gross | 352,046 | 347,685 |
| Accumulated depreciation | (212,242) | (188,625) |
| **Property, plant, and equipment, net** | $ 139,804 | $ 159,060 |

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 consistent with the pattern of economic benefit provided by the assets.

| | | December 31, | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | Weighted Average Amortization Period | 2024 | 2023 |
| **Cost** | | | |
| Developed technology | 7.9 years | $ 92,686 | $ 92,416 |
| Patents | 10.0 years | 38,329 | 43,262 |
| IPR&D | Indefinite | 4,116 | 4,674 |
| Customer relationships | 12.5 years | 49,145 | 49,197 |
| License and other | 9.7 years | 18,359 | 24,584 |
| Trademarks—finite lived | 10.0 years | 1,735 | 1,797 |
| | 9.7 years | 204,370 | 215,930 |
| **Accumulated amortization** | | | |
| Developed technology | | $ (40,813) | $ (28,898) |
| Patents | | (35,918) | (40,494) |
| Customer relationships | | (17,044) | (11,988) |
| License and other | | (10,892) | (16,240) |
| Trademarks—finite lived | | (900) | (820) |
| | | (105,567) | (98,440) |
| **Intangible assets, net** | | $ 98,803 | $ 117,490 |

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 $19.0 million, $18.9 million, and $9.4 million for the years ended December 31, 2024, December 31, 2023, and 2022, respectively. Future amortization expense for intangible assets is estimated as follows:

| (U.S. Dollars, in thousands) | Amortization |
|---|---|
| 2025 | $ 19,859 |
| 2026 | 18,780 |
| 2027 | 18,418 |
| 2028 | 15,043 |
| 2029 | 7,139 |
| Thereafter | 15,448 |
| Total finite-lived intangible assets, net | $ 94,687 |
| Indefinite-lived intangible assets | 4,116 |
| Intangible assets, net | $ 98,803 |

## 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, 2024, and 2023, and a rollforward of such balances from December 31, 2023, by reportable unit:

| (U.S. Dollars, in thousands) | Balance as of December 31, 2023 | Impairment | Currency translation adjustment | Balance as of December 31, 2024 |
|---|---|---|---|---|
| Global Spine - Gross | $ 194,934 | $ — | $ — | $ 194,934 |
| Global Spine - Accumulated Impairment Loss | — | — | — | $ — |
| Global Spine - Net | $ 194,934 | $ — | $ — | $ 194,934 |
| | | | | |
| Global Orthopedics - Gross | $ 11,477 | $ — | $ (712) | $ 10,765 |
| Global Orthopedics - Accumulated Impairment Loss | (11,477) | — | 712 | $ (10,765) |
| Global Orthopedics - Net | $ — | $ — | $ — | $ — |
| | | | | |
| Goodwill, net of accumulated impairment losses | $ 194,934 | $ — | $ — | $ 194,934 |

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.

In the fourth quarter of 2024, the Company performed a quantitative assessment for its annual goodwill impairment analysis, which did not result in an impairment charge. Upon performing the assessment, the Company determined the Global Spine reporting unit's fair value exceeded its carrying value and concluded there were no indicators of impairment.

**9. Leases**

The Company determines if a contractual arrangement qualifies as a lease at inception. The Company's leases primarily relate to facilities, vehicles, and equipment. Lease assets represent the Company's right to use an underlying asset for the lease term, 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, 2024, and 2023, is presented in the table below:

| (U.S. Dollars, in thousands, except lease term and discount rate) | Classification | December 31, 2024 | December 31, 2023 |
|---|---|---|---|
| **Assets** | | | |
| Operating leases | Other long-term assets | $ 17,238 | $ 19,869 |
| Finance leases | Property, plant and equipment, net | 15,386 | 16,345 |
| Total lease assets | | $ 32,624 | $ 36,214 |
| **Liabilities** | | | |
| Current | | | |
| Operating leases | Other current liabilities | $ 4,023 | $ 3,477 |
| Finance leases | Current portion of finance lease liability | 755 | 708 |
| Long-term | | | |
| Operating leases | Other long-term liabilities | 14,084 | 17,125 |
| Finance leases | Long-term portion of finance lease liability | 17,835 | 18,532 |
| Total lease liabilities | | $ 36,697 | $ 39,842 |
| | | | |
| **Weighted Average Remaining Lease Term** | | | |
| Operating leases | | 5.4 years | 6.2 years |
| Finance leases | | 15.6 years | 16.6 years |
| | | | |
| **Weighted Average Discount Rate** | | | |
| Operating leases | | 7.6% | 7.3% |
| 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, 2024 | For the Year Ended December 31, 2023 | For the Year Ended December 31, 2022 |
|---|---|---|---|
| Finance lease costs: | | | |
| Amortization of right-of-use assets | $ 1,014 | $ 1,013 | $ 1,238 |
| Interest on finance lease liabilities | 832 | 857 | 890 |
| Operating lease costs | 5,257 | 5,015 | 2,126 |
| Short-term lease costs | 249 | 313 | 152 |
| Variable lease costs | 1,796 | 1,883 | 932 |
| Total lease costs | $ 9,148 | $ 9,081 | $ 5,338 |

Supplemental cash flow information related to leases was as follows:

| (U.S. Dollars, in thousands) | For the Year Ended December 31, 2024 | For the Year Ended December 31, 2023 | For the Year Ended December 31, 2022 |
|---|---|---|---|
| Cash paid for amounts included in the measurement of lease liabilities | | | |
| Operating cash flows from operating leases | $ 8,917 | $ 7,682 | $ 3,805 |
| Operating cash flows from finance leases | 831 | 857 | 885 |
| Financing cash flows from finance leases | 706 | 652 | 2,594 |
| Right-of-use assets obtained in exchange for lease obligations | | | |
| Operating leases | 1,449 | 16,688 | 5,603 |
| Finance leases | 55 | — | — |

A summary of the Company's remaining lease liabilities as of December 31, 2024, is included below:

| (U.S. Dollars, in thousands) | Operating Leases | Finance Leases |
|---|---|---|
| 2025 | $ 5,185 | $ 1,553 |
| 2026 | 5,006 | 1,581 |
| 2027 | 3,651 | 1,612 |
| 2028 | 1,841 | 1,643 |
| 2029 | 1,636 | 1,662 |
| Thereafter | 5,116 | 17,740 |
| Total undiscounted value of lease liabilities | 22,435 | 25,791 |
| Less: Interest | (4,328) | (7,201) |
| Present value of lease liabilities | $ 18,107 | $ 18,590 |
| | | |
| Current portion of lease liabilities | $ 4,023 | $ 755 |
| Long-term portion of lease liabilities | 14,084 | 17,835 |
| Total lease liabilities | $ 18,107 | $ 18,590 |

## 10. Other current liabilities

| (U.S. Dollars, in thousands) | December 31, 2024 | 2023 |
|---|---|---|
| Accrued expenses | $ 11,391 | $ 12,189 |
| Salaries, bonuses, employee commissions, and related taxes payable | 43,899 | 38,826 |
| Accrued distributor commissions | 23,064 | 22,602 |
| Accrued litigation and investigation costs | 11,891 | 12,077 |
| Short-term operating lease liability | 4,023 | 3,477 |
| Non-income taxes payable | 8,414 | 7,585 |
| Contingent consideration short-term | 7,100 | 1,000 |
| Other payables | 9,288 | 7,152 |
| Other current liabilities | $ 119,070 | $ 104,908 |

## 11. Indebtedness

The carrying values of the Company's outstanding debt obligations as of December 31, 2024, and 2023, were as follows:

| (U.S. Dollars, in thousands) | December 31, 2024 | 2023 |
|---|---|---|
| *Outstanding Term Loans* | | |
| Principal amount | $ 160,000 | $ 100,000 |
| Unamortized original debt discount | (2,327) | (4,331) |
| Unamortized debt issuance costs and lenders fees | (658) | (1,312) |
| Total indebtedness from outstanding term loans | 157,015 | 94,357 |
| | | |
| *Revolving Credit Facilities* | | |
| Principal amount outstanding | — | — |
| **Total indebtedness outstanding** | $ 157,015 | $ 94,357 |
| | | |
| Current portion of long-term debt | $ — | $ 1,250 |
| Long-term debt | 157,015 | 93,107 |
| **Total indebtedness outstanding** | $ 157,015 | $ 94,357 |

The Company paid cash related to interest of $16.9 million, $5.8 million, and $1.4 million for the years ended December 31, 2024, 2023, and 2022, respectively.

*Credit Agreement*

On November 7, 2024, the Company, as borrower, and its U.S. subsidiaries entered into a $275.0 million secured credit agreement (the "Credit Agreement") with Oxford Finance LLC, as administrative agent and as collateral agent ("Oxford") and certain lenders party thereto, including Oxford, K2 HealthVentures LLC, and HSBC Ventures USA Inc. Certain of the Company's foreign subsidiaries joined the Credit Agreement as guarantors shortly after the signing date. The Credit Agreement provides for a $160.0 million senior secured term loan (the "Initial Term Loan"), and a $65.0 million senior secured delayed draw term loan facility (the "Term B Loan"). Draws under the Term B Loan are at the Company's option from January 1, 2025 through June 30, 2026, subject to, among other conditions, the Company's continuing compliance with a pro-forma total debt-to-EBITDA leverage ratio of less than 4.0x. EBITDA is a non-GAAP financial measure which represents earnings before interest income (expense), income taxes, depreciation, amortization, and other negotiated addbacks and adjustments. In addition, at Oxford's discretion, an additional $50.0 million of draw capacity is available to the Company, through January 1, 2029 (the "Term C Loan" and, together with the Term B Loan, the "Delayed Draw Term Loans" and collectively with the Initial Term Loan, the "Credit Facilities"). The Initial Term Loan and Delayed Draw Term Loans, to the extent ultimately drawn, will each mature in November 2029, following an interest-only payment period ending December 2028, and monthly amortization of principal and accrued interest between January 2029 and November 2029.

The Credit Facilities are secured by a perfected first priority lien, or the equivalent security interest in each applicable jurisdiction, on substantially all of the assets of the Company and the applicable guarantors (subject to customary carveouts), including their respective U.S. intellectual property assets.

Borrowings under the Credit Facilities bear interest at a percentage rate equal to the greater of 8.75% or 5.75% plus the one-month term SOFR rate. A facility fee equal to 1.5% of each applicable funded loan tranche is due at the time of funding of such respective tranche, and a 0.5% unused line fee is payable annually on the Term B Loan.

The Credit Agreement contains customary affirmative and negative covenants, including limitations on the Company's and its subsidiaries' ability to incur additional debt, grant or permit additional liens, make certain investments and acquisitions, merge or consolidate with others, dispose of certain assets, pay dividends and distributions, pay subordinated indebtedness, and enter into affiliate transactions, as well as financial covenants that the Company (i) possess at least $45.0 million of unrestricted cash at the time the Initial Term Loan is funded and thereafter maintain $15.0 million of unrestricted cash in U.S.-based accounts, and (ii) maintain a maximum total debt-to-EBITDA leverage ratio no greater than 4.0x during the term of the facility.

In conjunction with obtaining the Credit Agreement, the Company paid $1.2 million in debt issuance costs. These costs have been allocated amongst each of the Initial Term Loan, Term B Loan, and Term C Loan and are being amortized over the term of the Credit Agreement. Capitalized debt issuance costs attributable to the Term B Loan and Term C Loan 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, 2024, and December 31, 2023, debt issuance costs associated with all credit facilities, net of accumulated amortization, were $1.1 million and $1.9 million, respectively. Debt issuance costs amortized or expensed totaled $4.4 million, $1.3 million, and $0.4 million for each of the years ended December 31, 2024, 2023, and 2022, respectively.

As of the effective date of the Credit Agreement, the Company had $125.0 million in principal amount of borrowings outstanding under the Company's prior financing agreement with Blue Torch Finance LLC. In connection with entering into the Credit Agreement, the Company repaid in full all amounts outstanding and terminated all commitments under such prior financing agreement.

*Prior 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 provided for a $100.0 million senior secured term loan (the "Blue Torch 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, was available to 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 Blue Torch Initial Term Loan and the Delayed Draw Term Loan, the "Blue Torch Credit Facilities"), each of which were scheduled to 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 "JPMorgan Credit Agreement"). The Blue Torch 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 was fully repaid as of the effective date of the Credit Agreement.

Borrowings under the Financing Agreement were used for, among other things, the repayment in full of the JPMorgan Credit Agreement, working capital and other general corporate purposes of the Company. Borrowings under the Blue Torch Credit Facilities bore interest at a floating rate, which was, 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% was 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% was 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") were 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 were 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.

*JPMorgan 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 JPMorgan Credit Agreement. The JPMorgan 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 JPMorgan Credit Agreement had a maturity date of October 25, 2024. On March 1, 2023, the JPMorgan Credit Agreement was 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 were 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 JPMorgan 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 JPMorgan Credit Agreement. In connection with entering into the Financing Agreement, the Company repaid in full all amounts outstanding and terminated all commitments under the JPMorgan Credit Agreement.

*Italian Line of Credit*

The Company has an unused available Italian line of credit of €5.5 million ($5.7 million and $6.1 million) at December 31, 2024, and 2023, 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, or in some cases, were 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, 2024 |
|---|---|---|---|---|
| Assets | | | | |
| Neo Medical convertible loan agreement | $ — | $ — | $ — | $ — |
| Neo Medical preferred equity securities | — | — | — | — |
| Other investments | — | — | — | — |
| Total | $ — | $ — | $ — | $ — |
| Liabilities | | | | |
| Lattus contingent consideration | $ — | $ — | $ (15,400) | $ (15,400) |
| Deferred compensation plan | — | (1,703) | — | (1,703) |
| Total | $ — | $ (1,703) | $ (15,400) | $ (17,103) |

| (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) |
| Deferred compensation plan | — | (1,674) | — | (1,674) |
| Total | $ — | $ (1,674) | $ (8,500) | $ (10,174) |

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.

In April 2024, the Company converted the Convertible Loan into shares of Neo Medical preferred equity securities. The preferred equity securities were recorded in other long-term assets and were considered an investment that did not have a readily determinable fair value. As such, the Company measured 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.

On November 14, 2024, the Company sold and transferred all shares of Neo Medical's preferred equity securities for CHF 6.6 million, or $7.4 million. The Company recorded a realized loss of $5.8 million as a result of the sale, recognized within other expense, net.

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, 2024, and 2023:

| (U.S. Dollars, in thousands) | 2024 | 2023 |
|---|---|---|
| Fair value of Neo Medical preferred equity securities at January 1 | $ 4,951 | $ 6,084 |
| Conversion of loan into preferred equity securities | 8,224 | — |
| Foreign currency remeasurement recognized in other income, net | — | 388 |
| Unrealized loss recognized in other expense, net | — | (1,521) |
| Sale of preferred equity securities | (7,396) | — |
| Realized loss recognized in other expense, net | (5,779) | — |
| Fair value of Neo Medical preferred equity securities at December 31 | $ — | $ 4,951 |
| Cumulative unrealized gain (loss) on Neo Medical preferred equity securities | $ — | $ (720) |

Prior to conversion, the Convertible Loan was recorded at fair value, with applicable interest recorded in interest income. The fair value of the Convertible Loan was 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 had 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 included 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 have resulted 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).

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

| (U.S. Dollars, in thousands) | 2024 | 2023 |
|---|---|---|
| Fair value of Neo Medical Convertible Loans at January 1 | $ 6,760 | $ 7,140 |
| Gains (losses) recognized in other comprehensive income (loss) | 1,671 | (1,233) |
| Interest recognized in interest income, net | 162 | 496 |
| Foreign currency remeasurement recognized in other income (expense), net | (629) | 617 |
| Expected credit loss recognized in other income (expense), net | 260 | (260) |
| Conversion into preferred equity securities | (8,224) | — |
| Fair value of Neo Medical Convertible Loans at December 31 | $ — | $ 6,760 |
| | | |
| Contractual value of Neo Medical Convertible Loans at December 31 | $ — | $ 7,020 |
| Allowance for credit loss recognized in other expense, net | — | (260) |
| Amortized cost basis of Neo Medical Convertible Loans at December 31 | $ — | $ 6,760 |

*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. Bone Biologics' common stock is 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, 2024, 2023, and 2022:

| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 |
|---|---|---|---|
| Bone Biologics equity securities at January 1 | $ — | $ — | $ 309 |
| Fair value adjustments and impairments recognized in other expense, net | — | — | (183) |
| Proceeds from the disposition of equity securities | — | — | (126) |
| Bone Biologics equity securities at December 31 | $ — | $ — | $ — |

*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, 2024, and was fully impaired as of such date, and was classified in other long-term assets as of December 31, 2023.

*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) | 2024 | 2023 |
|---|---|---|
| Lattus contingent consideration estimated fair value at January 1 | $ 8,500 | $ 11,200 |
| Change in fair value recognized in acquisition-related amortization and remeasurement | 6,900 | (2,700) |
| Lattus contingent consideration estimated fair value at December 31 | $ 15,400 | $ 8,500 |

The following table provides quantitative information related to certain key assumptions utilized within the valuation as of December 31, 2024:

| (U.S. Dollars, in thousands) | Fair Value as of December 31, 2024 | Unobservable inputs | Estimate |
|---|---|---|---|
| Lattus Contingent Consideration | $ 15,400 | Counterparty discount rate | 10.9% |
| | | Revenue risk-adjusted discount rate | 7.6% - 7.8% |

## 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 (the "Board") 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. In addition, in September 2024, Messrs. Valentine, Bostjancic and Keran filed an action in California State Court against former director and interim CEO Catherine Burzik and current director Wayne Burris, seeking relief for, among other things, alleged defamation, false light invasion of privacy, intentional misrepresentation, false promise, and tortious interference with contract.

The Company disagrees with the allegations contained in the arbitration demands and in the action against Ms. Burzik and Mr. Burris, 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 these claims.

*Securities class action complaints*

On August 21, 2024, a securities class action complaint captioned Bernal v. Orthofix Medical Inc., et al., Case No. 24-cv-00690, was filed in the United States District Court for the Eastern District of Texas (the "Bernal Complaint"). The plaintiff, a purported Company shareholder, alleges through the complaint violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, and SEC Rule 10b-5 promulgated thereunder, and names as defendants the Company and the following former Company directors and officers: Jon Serbousek (former director and former President and Chief Executive Officer), Keith Valentine (former director and former President and Chief Executive Officer), John Bostjancic (former Chief Financial Officer), and Patrick Keran (former Chief Legal Officer). The complaint alleges that the Company made, and the named former directors and officers caused the Company to make, materially false and misleading statements between October 11, 2022 and September 12, 2023 that, according to the complaint, falsely assured the market regarding Messrs. Valentine, Bostjancic and Keran's respective commitments to, among other things, ethical and legal standards and corporate responsibility.

On September 6, 2024, a securities class action complaint captioned O'Hara v. Orthofix Medical Inc., et al., Case No. 24-cv-01593, was filed in the United States District Court for the Southern District of California (the "O'Hara Complaint"). The plaintiff, a purported former shareholder of SeaSpine at the time of the Merger, alleges through the complaint violations of Sections 11, 12 and 15 of the Securities Act of 1933, and names most of the same defendants as the Bernal Complaint, as well as certain additional current and/or former Company directors and officers. The complaint makes similar assertions to the Bernal complaint, and alleges that the Company's registration statement on Form S-4 filed in 2022 in connection with the Merger, as well as related written and oral offering materials, contained untrue statements of material fact and material omissions, including, among other things, with respect to the effectiveness of the Company's internal controls. On November 26, 2024, the O'Hara Complaint was transferred to the Eastern District of Texas, and on December 11, 2024, the O'Hara Complaint was consolidated with the Bernal Complaint.

On October 28, 2024, a derivative shareholder complaint was filed against certain of the Company's current and former officers and directors alleging derivative liability for the allegations made in the two complaints noted above. On December 18, 2024, a second

derivative shareholder complaint was filed with the same allegations made in the first derivative shareholder complaint. A motion to consolidate the two derivative shareholder complaints is pending.

The Company disagrees with the legal claims asserted in these complaints and intends to defend them vigorously. Due in part to the preliminary nature of these three matters, the Company currently cannot reasonably estimate a possible loss, or range of loss, that may arise from the respective complaints.

*Commitments*

As a result of the Merger, the Company became party to agreements with certain distributor partners that provide the Company with an option to purchase, and 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 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, 2024, assuming the options under all the relevant agreements were exercised, the estimated total number of shares the Company would issue under these agreements was approximately 0.2 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.

*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 2015 through 2018 calendar years. 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. In July 2024, the Italian Constitutional Court issued two judgments following public hearings on the matter held in May 2024. These judgments (i) declared the payback system itself as constitutionally legitimate and (ii) extended previously communicated reductions in the payback liability for certain fiscal years to all medical device companies, regardless of whether or not they had waived their legal claims on the matter.

The Company accounts for the estimated cost of the IMDP as sales, general, and administrative expense and periodically reassesses the liability based upon current facts and circumstances. As a result, the Company recorded expenses of $1.4 million, $1.3 million, and $1.2 million for the years ended December 31, 2024, 2023, and 2022, respectively, 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, 2024, the Company has accrued $8.2 million related to the IMDP, which it has classified within other long-term liabilities; however, the actual liability could be higher or lower than the amount accrued once all legal proceedings are resolved and upon further clarification of the IMDP by the Italian authorities for more recent fiscal years.

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

*Accumulated Other Comprehensive Income (Loss)*

Accumulated other comprehensive income (loss) is comprised of foreign currency translation adjustments and unrealized gains (losses) on available for sale debt securities. The Company's policy is to release income tax effects related to items recognized within accumulated other comprehensive income (loss) using a portfolio approach. The components of and changes in accumulated other comprehensive income (loss) are as follows:

| (U.S. Dollars, in thousands) | Currency Translation Adjustments | Neo Medical Convertible Loans | Other Investments | Accumulated Other Comprehensive Income (Loss) |
|---|---|---|---|---|
| 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) |
| Other comprehensive income (loss) | (3,009) | 1,671 | — | (1,338) |
| Income taxes | — | — | — | — |
| Reclassification adjustment to: | | | | |
| Other expense, net | — | (1,671) | — | (1,671) |
| Balance at December 31, 2024 | $ (4,074) | $ (228) | $ — | $ (4,302) |

**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 the Company's Irvine facility. In addition, the Company has 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 receives 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, 2024, 2023, and 2022.

| | For the year ended December 31, | | |
|---|---|---|---|
| **(U.S. Dollars, in thousands)** | **2024** | **2023** | **2022** |
| Product sales | $ 747,783 | $ 693,345 | $ 405,437 |
| Marketing service fees | 51,708 | 53,296 | 55,276 |
| Net sales | $ 799,491 | $ 746,641 | $ 460,713 |

Marketing service fees are received from MTF based on total sales of biologics tissues and relate 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 $51.7 million, or approximately 31% of total Biologics revenues, for the year ended December 31, 2024. 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 $9.9 million, $9.5 million, and $4.2 million for the years ended December 31, 2024, 2023, and 2022, 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 generally 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, general, and administrative expenses. Revisions to contractual allowances are recorded as an adjustment to net sales. These estimates are periodically tested against actual collection or adjustment 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 the detail of changes in the Company's allowance for expected credit losses for the years ended December 31, 2024, and 2023:

| | For the year ended December 31, | |
|---|---|---|
| (U.S. Dollars, in thousands) | 2024 | 2023 |
| Allowance for expected credit losses beginning balance | $ 7,130 | $ 6,419 |
| Addition resulting from the Merger with SeaSpine | — | 137 |
| Current period provision for expected credit losses | 1,999 | 820 |
| Write-offs charged against the allowance and other | (1,451) | (381) |
| Effect of changes in foreign exchange rates | (260) | 135 |
| Allowance for expected credit losses ending balance | $ 7,418 | $ 7,130 |

The Company will generally sell receivables from certain Italian public hospitals each year to accelerate cash collections. During 2024, 2023, and 2022, the Company sold €7.9 million, €9.2 million, and €9.2 million ($8.5 million, $10.0 million, and $9.6 million) of receivables, respectively. The related fees for 2024, 2023, and 2022, were $0.3 million, $0.4 million, and $0.3 million, respectively, which were recorded as interest expense. Accounts receivables sold without recourse are removed from the balance sheet at the time of sale.

**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 President and 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, 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 comprises (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.

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

| | Year Ended December 31, | | | | | |
|---|---|---|---|---|---|---|
| | 2024 | | 2023 | | 2022 | |
| (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 | $ 233,405 | 29.2 % | $ 212,530 | 28.5 % | $ 187,247 | 40.7 % |
| Spinal Implants, Biologics, and Enabling Technologies | 441,909 | 55.3 % | 418,789 | 56.1 % | 165,927 | 36.0 % |
| Global Spine | 675,314 | 84.5 % | 631,319 | 84.6 % | 353,174 | 76.7 % |
| Global Orthopedics | 124,177 | 15.5 % | 115,322 | 15.4 % | 107,539 | 23.3 % |
| Net sales | $ 799,491 | 100.0 % | $ 746,641 | 100.0 % | $ 460,713 | 100.0 % |

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

| | Year Ended December 31, 2024 | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | Global Spine | Global Orthopedics | Total |
| Segment revenues | $ 675,314 | $ 124,177 | $ 799,491 |
| Less: | | | |
| Non-GAAP Cost of sales | 183,064 | 48,638 | 231,702 |
| Non-GAAP Sales, general, and administrative | 368,817 | 70,185 | 439,002 |
| Non-GAAP Research and development | 58,262 | 13,154 | 71,416 |
| Other segment benefits | (22) | (54) | (76) |
| Add: | | | |
| Non-GAAP Depreciation, amortization, and share-based compensation expense | 42,193 | 12,367 | 54,560 |
| **Segment Adjusted EBITDA** | $ 107,386 | $ 4,621 | $ 112,007 |
| | | | |
| *Reconciling items:* | | | |
| Corporate operating expenses | | | $ 44,591 |
| Interest expense, net | | | 29,631 |
| Depreciation and amortization | | | 60,061 |
| Share-based compensation expense | | | 32,455 |
| Foreign exchange impact | | | 4,395 |
| SeaSpine merger-related costs | | | 14,485 |
| Strategic investments | | | 910 |
| Acquisition-related fair value adjustments | | | 19,088 |
| Interest and loss on investments | | | 5,120 |
| Litigation and investigation costs | | | 15,770 |
| Succession charges | | | 9,376 |
| Medical device regulation | | | — |
| Business interruption - COVID-19 | | | — |
| **Loss before income taxes** | | | $ (123,875) |

| | Year Ended December 31, 2023 | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | Global Spine | Global Orthopedics | Total |
| Segment Revenues | $ 631,319 | $ 115,322 | $ 746,641 |
| Less: | | | |
| Non-GAAP Cost of sales | 166,885 | 47,928 | 214,813 |
| Non-GAAP Sales, general, and administrative | 355,827 | 67,815 | 423,642 |
| Non-GAAP Research and development | 56,512 | 10,726 | 67,238 |
| Other segment expenses (benefits) | 45 | (82) | (37) |
| Add: | | | |
| Non-GAAP Depreciation, amortization, and share-based compensation expense | 39,065 | 11,507 | 50,572 |
| **Segment Adjusted EBITDA** | $ 91,115 | $ 442 | $ 91,557 |
| | | | |
| *Reconciling items:* | | | |
| Corporate operating expenses | | | $ 45,272 |
| Interest expense, net | | | 8,631 |
| Depreciation and amortization | | | 53,063 |
| Share-based compensation expense | | | 35,707 |
| Foreign exchange impact | | | (1,581) |
| SeaSpine merger-related costs | | | 36,577 |
| Strategic investments | | | 2,272 |
| Acquisition-related fair value adjustments | | | 33,393 |
| Interest and loss on investments | | | 1,781 |
| Litigation and investigation costs | | | 14,453 |
| Succession charges | | | 1,176 |
| Medical device regulation | | | 9,492 |
| Business interruption - COVID-19 | | | — |
| **Loss before income taxes** | | | $ (148,679) |

| | Year Ended December 31, 2022 | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | Global Spine | Global Orthopedics | Total |
| Segment Revenues | $ 353,174 | $ 107,539 | $ 460,713 |
| Less: | | | |
| Non-GAAP Cost of sales | 74,573 | 44,784 | 119,357 |
| Non-GAAP Sales, general, and administrative | 204,840 | 56,760 | 261,600 |
| Non-GAAP Research and development | 29,220 | 8,364 | 37,584 |
| Other segment benefits | (183) | (49) | (232) |
| Add: | | | |
| Non-GAAP Depreciation, amortization, and share-based compensation expense | 17,969 | 7,587 | 25,556 |
| **Segment Adjusted EBITDA** | $ 62,693 | $ 5,267 | $ 67,960 |
| | | | |
| *Reconciling items:* | | | |
| Corporate operating expenses | | | $ 19,406 |
| Interest expense, net | | | 1,288 |
| Depreciation and amortization | | | 29,019 |
| Share-based compensation expense | | | 18,443 |
| Foreign exchange impact | | | 3,291 |
| SeaSpine merger-related costs | | | 11,902 |
| Strategic investments | | | 4,018 |
| Acquisition-related fair value adjustments | | | (15,595) |
| Interest and loss on investments | | | 187 |
| Litigation and investigation costs | | | 803 |
| Succession charges | | | 147 |
| Medical device regulation | | | 10,370 |
| Business interruption - COVID-19 | | | 2,387 |
| **Loss before income taxes** | | | $ (17,706) |

The following table presents depreciation and amortization by reporting segment:

| | Year Ended December 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 |
| Global Spine | $ 49,507 | $ 41,213 | $ 18,213 |
| Global Orthopedics | 7,748 | 7,158 | 6,696 |
| Corporate | 2,806 | 4,692 | 4,110 |
| Total | $ 60,061 | $ 53,063 | $ 29,019 |

*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)** | **2024** | **2023** | **2022** |
| *Global Spine* | | | |
| U.S. | $ 639,196 | $ 591,937 | $ 332,846 |
| International | 36,118 | 39,382 | 20,328 |
| Total Global Spine | 675,314 | 631,319 | 353,174 |
| | | | |
| *Global Orthopedics* | | | |
| U.S. | $ 33,620 | $ 28,892 | $ 25,997 |
| International | 90,557 | 86,430 | 81,542 |
| Total Global Orthopedics | 124,177 | 115,322 | 107,539 |
| | | | |
| *Consolidated* | | | |
| U.S. | $ 672,816 | $ 620,829 | $ 358,843 |
| International | 126,675 | 125,812 | 101,870 |
| Net sales | $ 799,491 | $ 746,641 | $ 460,713 |

The following data includes net sales by geographic destination:

| | Year Ended December 31, | | |
|---|---|---|---|
| **(U.S. Dollars, in thousands)** | **2024** | **2023** | **2022** |
| U.S. | $ 672,816 | $ 620,829 | $ 358,843 |
| Italy | 21,001 | 20,060 | 19,098 |
| Germany | 9,004 | 11,467 | 11,569 |
| United Kingdom | 11,183 | 10,910 | 10,171 |
| France | 13,385 | 11,096 | 10,377 |
| Brazil | 5,707 | 6,452 | 5,668 |
| Others | 66,395 | 65,827 | 44,987 |
| Net sales | $ 799,491 | $ 746,641 | $ 460,713 |

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

| **(U.S. Dollars, in thousands)** | **2024** | **2023** |
|---|---|---|
| U.S. | $ 125,541 | $ 142,727 |
| Italy | 9,472 | 10,187 |
| Germany | 1,904 | 3,030 |
| Others | 2,887 | 3,116 |
| Total | $ 139,804 | $ 159,060 |

**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, and (iii) recognized costs associated with acquired IPR&D assets, which are recognized immediately upon acquisition. Components of

acquisition-related amortization and remeasurement for the years ended December 31, 2024, 2023, and 2022, respectively, are as follows:

| | Year Ended December 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 |
| Changes in fair value of contingent consideration | $ 6,900 | $ (2,700) | $ (17,200) |
| Amortization of acquired intangibles | 17,436 | 17,408 | 8,196 |
| Acquired IPR&D | — | 49 | 1,600 |
| Total | $ 24,336 | $ 14,757 | $ (7,404) |

*Lattus Contingent Consideration*

In connection with the Merger, the Company assumed a contingent consideration obligation under a purchase agreement between SeaSpine and 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 Lateral Products. For additional information regarding this contingent consideration liability, see Note 12.

*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 last contingent milestone payment, 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, which resulted in a decrease in fair value recognized within acquisition-related amortization and remeasurement of $17.2 million for the year ended December 31, 2022.

*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 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, $1.0 million was paid in 2023, and $1.0 million was paid in 2024.

**18. Share-based compensation**

At December 31, 2024, and 2023, 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 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 became time-based restricted stock units with the performance goals deemed achieved at the target level of 100%.

*2012 Long Term Incentive Plan*

The Board 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, 2024, the Company reserves a total of 16.3 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, 2024, there were 1.7 million options outstanding under the 2012 LTIP, of which 1.2 million were exercisable. In addition, there were 1.4 million restricted stock units outstanding, some of which contain performance-based vesting conditions, under the 2012 LTIP as of December 31, 2024.

*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, 2024, 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, 2024, there were 0.7 million options outstanding under the SeaSpine 2015 Plan, of which 0.5 million were exercisable. In addition, there were 0.4 million restricted stock units outstanding, some of which contain performance-based vesting conditions, under the SeaSpine 2015 Plan as of December 31, 2024.

*Inducement Plans*

As an inducement to accept employment, the Company has periodically granted inducement awards to new employees and has also assumed inducement awards that were granted by SeaSpine prior to the Merger. During 2024, new employees were granted options to acquire up to 0.9 million shares of common stock and awarded 1.1 million restricted stock units, some of which contain performance-based vesting conditions. Under all inducement plans, as of December 31, 2024, there were 1.6 million options outstanding, of which 0.5 million were exercisable, and 1.2 million unvested restricted stock units outstanding, some of which contain performance-based vesting conditions.

*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, 2024, the aggregate number of shares reserved for issuance under the Stock Purchase Plan is 4.9 million. As of December 31, 2024, a total of 3.4 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, 2024, 2023, and 2022:

| | Year Ended December 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 |
| Cost of sales | $ 2,053 | $ 1,901 | $ 826 |
| Sales, general, and administrative | 27,123 | 29,917 | 16,782 |
| Research and development | 3,279 | 3,889 | 835 |
| Total | $ 32,455 | $ 35,707 | $ 18,443 |

| | Year Ended December 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 |
| Stock options | $ 4,331 | $ 6,130 | $ 1,114 |
| Market-based stock options | 2,118 | — | — |
| Time-based restricted stock awards and stock units | 18,818 | 27,290 | 9,452 |
| Performance-based / Market-based restricted stock units | 4,941 | 227 | 6,425 |
| Stock purchase plan | 2,247 | 2,060 | 1,452 |
| Total | $ 32,455 | $ 35,707 | $ 18,443 |

The income tax benefit related to this expense was $5.8 million, $5.8 million, and $3.3 million for the years ended December 31, 2024, 2023, and 2022, 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, 2024, 2023, and 2022, is shown in the following table. The Company did not grant any time-based stock options in 2022.

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2024 | 2023 | 2022 |
| Assumptions: | | | |
| Expected term (in years) | 4.5 | 6 | — |
| Expected volatility | 45.7% – 47.6% | 36.8% – 42.3% | — |
| Risk free interest rate | 3.47% – 4.65% | 3.38% – 4.61% | — |
| Dividend yield | — | — | — |
| Weighted average grant date fair value | $ 5.90 | $ 8.43 | $ — |

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.

Certain of the Company's outstanding stock options contain market-based vesting conditions. The fair value of market-based stock options is determined at the date of the grant using the Monte Carlo valuation methodology. The Monte Carlo methodology incorporates into the valuation the possibility that the market condition may not be satisfied. Such value is recognized over the three-year service period, net of actual forfeitures.

A summary of the status of the Company's time-based stock option plans as of December 31, 2024, and 2023, and changes during the year ended December 31, 2024, is presented below:

| (In thousands) | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) |
|---|---|---|---|
| Outstanding at December 31, 2023 | 3,223 | $ 30.64 | |
| Granted | 773 | $ 13.54 | |
| Exercised | (12) | $ 14.69 | |
| Forfeited or expired | (787) | $ 32.31 | |
| Outstanding at December 31, 2024 | 3,197 | $ 26.15 | 4.52 |
| Vested and expected to vest at December 31, 2024 | 3,197 | $ 26.15 | 4.52 |
| Exercisable at December 31, 2024 | 2,119 | $ 30.84 | 3.32 |

A summary of the status of the Company's market-based stock option plans as of December 31, 2024, and 2023, and changes during the year ended December 31, 2024, is presented below:

| (In thousands) | Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term (Years) |
|---|---|---|---|
| Outstanding at December 31, 2023 | — | — | |
| Granted | 754 | $ 13.39 | |
| Exercised | — | — | |
| Forfeited or expired | — | — | |
| Outstanding at December 31, 2024 | 754 | $ 13.39 | 6.19 |
| Vested and expected to vest at December 31, 2024 | 754 | $ 13.39 | 6.19 |
| Exercisable at December 31, 2024 | — | — | — |

As of December 31, 2024, the unamortized compensation expense relating to options granted and expected to be recognized was $5.3 million. This amount is expected to be recognized through December 2027 over a weighted average period of approximately 1.1 years. The total intrinsic value of options exercised was less than $0.1 million, $0.0 million, and $0.0 million for the years ended December 31, 2024, 2023, and 2022, respectively. For the year ended December 31, 2024, the Company received $0.2 million cash from stock option exercises, and realized $0.1 million in tax benefit for the tax deductions from stock option exercises. The aggregate intrinsic value of options outstanding and options exercisable as of December 31, 2024, 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 $17.46, the closing price of the Company's stock on December 31, 2024. The aggregate intrinsic value of options outstanding was $6.9 million as of December 31, 2024. The aggregate intrinsic value of options exercisable was $0.7 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, 2024, 2023, and 2022, was $13.3 million, $17.2 million, and $5.2 million, respectively. Unamortized compensation expense related to time-based restricted stock awards and stock units amounted to $15.7 million at December 31, 2024. This amount is expected to

be recognized through December 2027 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 $35.2 million as of December 31, 2024.

*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, in January 2023 all then outstanding performance-based and market-based restricted stock units became time-based restricted stock units with the performance goals deemed achieved at the target level of 100% 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 each of the years ended December 31, 2024, 2023, and 2022, totaled less than $0.1 million, respectively. Unamortized compensation expense for performance-based and/or market-based restricted stock units totaled $11.1 million at December 31, 2024, and is expected to be recognized over a weighted average period of approximately 2.0 years. The aggregate intrinsic value of performance-based restricted stock units outstanding was $16.8 million as of December 31, 2024.

A summary of the status of our time-based and performance-based and/or market-based restricted stock units as of December 31, 2024, and 2023, and changes during the year ended December 31, 2024, is 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, 2023 | 2,040 | $ 26.96 | 9 | $ 22.69 |
| Granted | 1,264 | $ 13.48 | 1,062 | $ 16.73 |
| Vested and settled | (1,089) | $ 28.41 | (6) | $ 16.78 |
| Cancelled | (200) | $ 16.77 | (105) | $ 16.60 |
| Outstanding at December 31, 2024 | 2,015 | $ 18.73 | 960 | $ 16.81 |

**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 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. During the years ended December 31, 2024, 2023, and 2022, incurred expenses relating to the 401(k) Plan, including matching contributions, were approximately $5.9 million, $4.6 million, and $3.3 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, 2024, 2023, and 2022, were $1.2 million, $1.1 million, and $1.1 million, respectively.

*Deferred Compensation Plans*

Under Italian Law, our Italian subsidiary accrues deferred compensation on behalf of its employees, which is paid on termination of employment. The accrual for deferred compensation is based on a percentage of the employee's current annual remuneration plus an annual charge. Deferred compensation is also accrued for the leaving indemnity payable to agents in case of dismissal, which is regulated by a national contract and is equal to approximately 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, 2024, 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 liability is recorded within other long-term liabilities as of December 31, 2024, and 2023, and totaled $1.7 million and $1.7 million, respectively. This 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) | 2024 | 2023 | 2022 |
| U.S. | $ (113,197) | $ (154,794) | $ (22,318) |
| Non-U.S. | (10,678) | 6,115 | 4,612 |
| Loss before income taxes | $ (123,875) | $ (148,679) | $ (17,706) |

The provision for income taxes consists of the following:

| | Year Ended December 31, | | |
|---|---|---|---|
| (U.S. Dollars, in thousands) | 2024 | 2023 | 2022 |
| U.S. | | | |
| Current | $ (590) | $ 17 | $ 1,151 |
| Deferred | 1,572 | 1,160 | 67 |
| | 982 | 1,177 | 1,218 |
| Non-U.S. | | | |
| Current | 829 | 2,120 | 578 |
| Deferred | 311 | (581) | 247 |
| | 1,140 | 1,539 | 825 |
| Income tax expense | $ 2,122 | $ 2,716 | $ 2,043 |

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, 2024, 2023, and 2022, consist of the following:

| | 2024 | | 2023 | | 2022 | |
|---|---|---|---|---|---|---|
| (U.S. Dollars, in thousands, except percentages) | Amount | Percent | Amount | Percent | Amount | Percent |
| Statutory U.S. federal income tax rate | $ (26,013) | 21.0% | $ (31,222) | 21.0% | $ (3,718) | 21.0% |
| State taxes, net of U.S. federal benefit | (3,753) | 3.0 | (3,452) | 2.3 | (1,312) | 7.4 |
| Foreign rate differential, including withholding taxes | (1,304) | 1.1 | (738) | 0.5 | 475 | (2.7) |
| Valuation allowances, net | 30,491 | (24.6) | 28,322 | (19.0) | 7,638 | (43.1) |
| Foreign income inclusions, net | 320 | (0.3) | 2,333 | (1.6) | 1,018 | (5.7) |
| Research credits | (1,262) | 1.0 | (1,219) | 0.8 | (750) | 4.2 |
| Unrecognized tax benefits, net of settlements | (1,393) | 1.1 | 71 | — | (599) | 3.4 |
| Equity compensation | 2,781 | (2.2) | 4,210 | (2.8) | 1,441 | (8.1) |
| Executive compensation | 2,001 | (1.6) | 3,030 | (2.0) | 697 | (3.9) |
| Contingent consideration | — | — | — | — | (3,316) | 18.7 |
| Other, net | 254 | (0.2) | 1,381 | (0.9) | 469 | (2.6) |
| Income tax expense/effective rate | $ 2,122 | (1.7)% | $ 2,716 | (1.8)% | $ 2,043 | (11.5)% |

The Company paid (received or was refunded) cash relating to taxes totaling $1.3 million, $0.9 million, and ($0.9) million for the years ended December 31, 2024, 2023, and 2022, respectively.

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

| | December 31, | |
|---|---|---|
| (U.S. Dollars, in thousands) | 2024 | 2023 |
| Intangible assets and goodwill | $ — | $ — |
| Inventories and related reserves | 34,745 | 33,122 |
| Deferred revenue and cost of goods sold | 5,775 | 4,409 |
| Other accruals and reserves | 5,738 | 5,382 |
| Accrued compensation | 17,216 | 15,434 |
| Provision for expected credit losses | 1,797 | 1,821 |
| Accrued interest | 6,336 | 1,227 |
| Net operating loss and tax credit carryforwards | 132,524 | 123,210 |
| Research and development capitalization | 18,016 | 15,174 |
| Lease liabilities | 8,856 | 9,632 |
| Other, net | 8,456 | 4,856 |
| Total deferred tax assets | 239,459 | 214,267 |
| Valuation allowance | (228,724) | (200,192) |
| Deferred tax asset, net of valuation allowance | $ 10,735 | $ 14,075 |
| Intangible assets and goodwill | $ (3,557) | $ (1,662) |
| Withholding taxes | (10) | (10) |
| Property, plant, and equipment | (3,390) | (5,737) |
| Right-of-use lease assets | (7,875) | (8,755) |
| Deferred tax liability | $ (14,832) | $ (16,164) |
| Net deferred tax assets (liabilities) | $ (4,097) | $ (2,089) |
| | | |
| **Reported as:** | | |
| Deferred income tax assets (classified within other long-term assets) | $ 1,542 | $ 2,081 |
| Deferred income tax liabilities (classified within other long-term liabilities) | (5,639) | (4,170) |
| Net deferred tax assets (liabilities) | $ (4,097) | $ (2,089) |

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 are 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. We recognize the tax impact of including certain foreign earnings in US taxable income as a period cost.

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 $28.5 million during the year principally relates 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 2025 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 $351.4 million and federal research and development credits of $5.9 million. These federal carryforwards are subject to limitation under the provisions of Internal Revenue Code Section 382 and will

begin to expire in 2025. The Company has state net operating loss carryforwards of approximately $252.1 million, principally related to California, Colorado, Michigan, and New York. 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 $137.8 million, which mainly relate to the Company's Netherlands, Brazil, Italy, 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 $1.3 million which begin to expire in 2041.

Unremitted foreign earnings were $15.7 million as of December 31, 2024. 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 $1.7 million and $3.0 million for the years ended December 31, 2024, and 2023, respectively. The Company recorded net interest and penalties expense (benefit) on unrecognized tax benefits of $0.2 million, $0.2 million, and $0.1 million for the years ended December 31, 2024, 2023, and 2022, respectively, and had approximately $1.0 million and $1.1 million accrued for payment of interest and penalties as of December 31, 2024, and 2023, respectively. The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company's effective tax rate if recognized. The Company believes it is reasonably possible that, in the next 12 months, no unrecognized tax benefits, exclusive of interest and penalties, will be resolved.

A reconciliation of the gross unrecognized tax benefits (excluding interest and penalties) for the years ended December 31, 2024, and 2023, is shown below:

| (U.S. Dollars, in thousands) | 2024 | 2023 |
|---|---|---|
| Balance as of January 1, | $ 2,974 | $ 1,743 |
| Additions for current year tax positions | 40 | 416 |
| Increases for prior year tax positions | 42 | 815 |
| Settlements of prior year tax positions | — | — |
| Expiration of statutes | (1,333) | — |
| Balance as of December 31, | $ 1,723 | $ 2,974 |

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 2021. The statute of limitations with respect to the major foreign tax filing jurisdictions is closed for years prior to 2020. In October 2024, the Company was notified of an examination of its Italian subsidiary for 2020 and in December 2024, the examination was concluded with no change. The Company cannot reasonably determine if any state and local or foreign examinations will have a material impact on its financial statements and cannot predict the timing regarding the resolution of these tax examinations.

## 21. Earnings per share (EPS)

The Company 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, 2024, 2023, and 2022, 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) | 2024 | 2023 | 2022 |
| Weighted average common shares-basic | 38,134 | 36,729 | 20,054 |
| Effect of diluted securities: | | | |
| Unexercised stock options and employee stock purchase plan | — | — | — |
| Unvested time-based restricted stock units | — | — | — |
| Weighted average common shares-diluted | 38,134 | 36,729 | 20,054 |

There were 7.2 million, 6.5 million, and 2.3 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, 2024, 2023, and 2022, 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.

## 22. Subsequent events

Consistent with Orthofix's strategic focus on spinal fixation and deformity correction, the Company made an assessment and decided in January 2025 to discontinue its M6-C artificial cervical disc and M6-L artificial lumbar disc product lines (together, the "M6 artificial discs" or "M6 devices") and will allocate associated resources and investment to more profitable growth opportunities in those focus areas on a prospective basis. Global net sales for the M6-C artificial cervical and M6-L artificial lumbar discs were $23.4 million in 2024. Manufacturing activities related to the M6 artificial discs are expected to cease before March 31, 2025. Orthofix intends to fulfill all requirements related to post-market surveillance activities and meet our obligations with respect to premarket approval ("PMA") of M6 devices, including completion of the investigational device exemption ("IDE") study in the United States.

Management has evaluated this decision within the context of ASC 855, Subsequent Events, and has determined this to be a nonrecognized subsequent event. Accordingly, the Company has not incorporated the financial impact of this decision within its consolidated balance sheet, statements of operations, or cash flows as of and for the period ending December 31, 2024. The related financial impact of this decision is currently being evaluated and cannot be reasonably estimated as of the date of these financial statements. However, this information will be reflected within the Company's consolidated financial statements for the quarter ended March 31, 2025.

| ORTHOFIX | GLOBAL POLICY | Policy Number LE2 |
|---|---|---|
| Topic: INSIDER TRADING AND RELATED MATTERS | | Version: 4 |
| Owner: Legal | Effective Date: December 10, 2024 | |

## I. POLICY STATEMENT

Orthofix Medical Inc. (together with its direct and indirect subsidiaries, "**Orthofix**" or the "**Company**") is committed to complying with the federal securities laws of the United States and to helping prevent insider trading by assisting its directors, officers, managers, and other employees (collectively, "**Employees**") meet their legal obligations.

## II. SCOPE

This Insider Trading and Related Matters Policy ("**Policy**") applies to Orthofix and all of its Employees.

## III. PURPOSE

This Policy sets forth steps to help prevent insider trading and to assist Employees in complying with their obligations under the federal securities laws of the United States.

## IV. DEFINITIONS

The term "***Insider Trading Compliance Officers***" or "***Compliance Officers***" means Orthofix's Chief Legal Officer and Chief Financial Officer or, in the absence or unavailability of both of them, Orthofix's Deputy General Counsel and/or Chief Accounting Officer.

The term "***material***" refers to information about which there is a substantial likelihood that a reasonable stockholder or investor would consider it important in making an investment or voting decision, or if the disclosure of the information would be expected to significantly alter the total mix of the information in the marketplace about such company. In simple terms, material information is any type of information which could reasonably be expected to affect the price of a company's securities. While it is not possible to identify all information that would be deemed "material," the following types of information ordinarily would be considered material:

(a) financial performance, especially quarterly and year-end revenues and earnings, and significant changes in financial performance or liquidity;

(b) potential mergers and acquisitions involving the Company or the sale of Company assets or subsidiaries;

(c) new major contracts, or changes in major contract terms;

(d) stock splits, public or private securities/debt offerings or sales;

(e) a change in control or significant changes in Company management;

(f) actual or threatened major litigation, or the resolution of such litigation; and

(g) the establishment of a program to repurchase securities of the Company.

The term "***non-public***" refers to information that has not been widely disseminated to the public through major newswire services, national news services or financial news services, or via filings with the Securities and Exchange Commission ("**SEC**"). For the purposes of this Policy, information will be considered public (i.e., no longer "non-public") after the close of trading on the first full trading day following a company's widespread public release of the information. Insider trading is not made permissible because material information is reflected in rumors or other unofficial statements in the press or marketplace. When employees become aware of rumors or other unofficial statements concerning the Company, the Compliance Officers should be notified immediately so that a determination can be made as to whether or not arrangements should be made for adequate, broad public release of any information that is material.

The term "***Trading Window***" means the period beginning at the close of trading on the second full trading day following the Company's widespread, public release of quarterly or year-end earnings for the immediately preceding quarter or year, and ending fifteen (15) days prior to the close of the current fiscal quarter.

## V. STANDARDS

### 1. CERTAIN FEDERAL SECURITIES LAWS AND REGULATIONS APPLICABLE TO THIS POLICY

This Policy is adopted in response to several provisions of the federal securities laws:

**A.** ***Rule 10b-5 of the Exchange Act.*** Rule 10b-5, adopted pursuant to Section 10(b) of the Securities Exchange Act of 1934 (the "**Exchange Act**"), prohibits, among other things, the directors, officers, and employees of a publicly traded company, and their family members, from trading in any company's (including the Company's) securities while possessing material, non-public information about such company. In addition, Rule 10b-5 prohibits any of these persons from "tipping" material, non-public information about their company to outsiders, whether or not they derive any benefit from the actions of the outsider.

**B.** ***Section 16(a) of the Exchange Act.*** Section 16(a) of the Exchange Act provides that directors, officers and beneficial owners of more than ten percent (10%) of any class of the Company's equity securities registered pursuant to the Exchange Act (collectively referred to as "**Section 16 Persons**") must file with the SEC reports disclosing their holdings of and transactions in the Company's equity securities. Reports required by Section 16(a) must be filed electronically with the SEC and posted by the Company on its website by the next business day after the filing. An initial report on Form 3 must be filed by every Section 16 Person within ten (10) calendar

days after they become a Section 16 Person. Unless exempt from reporting or eligible for deferred reporting, any subsequent change in beneficial ownership by the insider must be reported on a Form 4 filed within two (2) business days after the change occurs. Form 5, a "clean up" report due within forty-five (45) days after the close of the issuer's fiscal year, must be filed to disclose transactions and holdings exempt from prior reporting (primarily gifts), as well as transactions and holdings that should have been reported previously but were not.

**C.** ***Section 16(b) of the Exchange Act.*** Section 16(b) of the Exchange Act provides that any profit realized by a Section 16 Person on a "short-swing" transaction (i.e., a non-exempt purchase and sale, or non-exempt sale and purchase, of the Company's equity securities within a period of less than six (6) months) must be disgorged to the Company upon demand by the Company or a stockholder acting on the Company's behalf. By law, the Company cannot waive or release any claim it may have under Section 16(b) or enter into an enforceable agreement to provide indemnification for amounts recovered under Section 16(b).

**D.** ***Rule 144 of the Securities Act.*** The Securities Act of 1933 (the "**Securities Act**") requires every person who offers or sells securities to register such securities with the SEC unless an exemption from registration is available. An exemption frequently relied upon by insiders for public sales of their securities is provided by Rule 144 under the Securities Act. The rule is available for public sales by any person of "restricted securities" (i.e., securities acquired in a private offering or certain other types of exempt offerings) and for sales by "affiliates" of any securities, whether restricted or unrestricted ("control securities"). As defined in Rule 144, an "affiliate" is a person that, directly or indirectly, through the use of one or more intermediaries, controls, or is controlled by, or is under common control with, the Company. Generally, directors, executive officers, and stockholders holding more than 10% of the Company's voting securities are presumed to be affiliates of the Company. Securities held by directors and executive officers of the Company, whether or not acquired in an unregistered transaction, are presumed to be "control securities" for purposes of Rule 144, absent countervailing facts.

## 2. PERSONS AND TRANSACTIONS SUBJECT TO THE POLICY

**A.** ***Applicability.*** This Policy applies to any and all transactions in the Company's securities, including its common stock and any other type of securities that the Company may issue, such as preferred stock, convertible debentures, warrants and exchange-traded options or other derivative securities and securities of other companies under certain circumstances described below. A copy of this Policy will be delivered to the following persons:

- directors;
- executive officers; and

- certain other designated employees ("**Non-Executive Insiders**").

All of the foregoing persons are collectively referred to as "**Insiders**."

**B.** ***List of Company Insiders.*** A list of the Company's Insiders shall be maintained by the Compliance Officers (the "**Orthofix Insider List**"). The Compliance Officers will update the Orthofix Insider List periodically and will notify affected individuals when they have been added to the list. The latest versions of such list will be made available upon request, available via the Company's intranet, and provided to Insiders.

**C.** ***Effective Date.*** This Policy applies to all Insiders upon its adoption by the Company, and will apply to new Insiders at the start of their employment or relationship with the Company. Upon first receiving a copy of this Policy, each person must sign an acknowledgment that he or she has received a copy and agrees to comply with the Policy's terms.

## 3. HOW THE POLICY APPLIES TO DIFFERENT GROUPS OF INSIDERS

**A.** ***Section 16 Persons.*** The persons identified as "Section 16 Persons" on the Orthofix Insider List are subject to the reporting provisions and trading restrictions of Section 16 of the Exchange Act, and the underlying rules and regulations promulgated by the SEC. Section 16 Persons must comply with this Policy, including the Trading Window and blackout period rules set forth in Section V.5.B of this Policy and must obtain prior approval of all transactions in Company securities from a Compliance Officer in accordance with the procedures set forth in Section V.5.C of this Policy.

**B.** ***Non-Executive Insiders***. The persons identified as "Non-Executive Insiders" on the Orthofix Insider List must comply with this Policy, including the Trading Window and blackout period rules set forth in Section V.5.B of this Policy.

**C.** ***Other Employees.*** Employees who are neither Section 16 Persons nor Non-Executive Insiders are nevertheless subject to the Company's code of conduct, which prohibits insider trading, and the federal securities laws that prohibit insider trading. All Employees should review and be familiar with this Policy and the insider trading section of the Company's code of conduct.

**D.** ***Family Members.*** The same rules and restrictions that apply to a Section 16 Person or a Non-Executive Insider apply to that person's family members and others living in his or her household. Each Insider is expected to be responsible for such persons' compliance as well as his or her own.

## 4. INSIDER TRADING COMPLIANCE OFFICERS

**A.** ***Insider Trading Compliance Officers.*** One of the Compliance Officers will review and either approve or prohibit all proposed transactions by Section 16 Persons in accordance with the procedures set forth in Section V.5.C of this Policy.

**B.** ***Duties of Compliance Officers.*** In addition to the trading approval duties

described in Section V.5.C of this Policy, the duties of the Compliance Officers will include the following:

i. administering this Policy and enforcing compliance with the Policy;

ii. responding to all inquiries relating to this Policy and its procedures;

iii. designating special trading blackout periods during which no Insiders may trade in Company securities;

iv. providing copies of this Policy and other appropriate materials to all current and new Section 16 Persons and Non-Executive Insiders; and

v. revising this Policy, as necessary, to reflect changes in certain federal and state insider trading laws and regulations.

**C.** ***Designated Authority.*** The Compliance Officers may designate one or more individuals who may perform the Compliance Officers' duties in the event that any of them is unable or unavailable to perform such duties. As noted above, the Chief Legal Officer and the Chief Financial Officer will have principal responsibility over the administration of this Policy, and should be the initial contact persons for any inquiry or request for approval hereunder.

## 5. STATEMENT OF COMPANY POLICY AND PROCEDURES

### A. *Prohibited Activities*

i. ***No Transactions While Possessing Material, Non-public Information.*** No Insider may enter into transactions involving Company securities while possessing material, non-public information concerning the Company or its subsidiaries. This prohibition extends not only to transactions involving the Company's securities but also to transactions involving securities of other entities with which the Company has a relationship.

ii. ***No Transactions Outside Trading Windows or During Blackout Periods.*** No Insider may enter into transactions involving Company securities (a) outside of the applicable "Trading Windows" described in Section V.5.B of this Policy, or (b) during any special trading blackout period designated by the Compliance Officers.

iii. ***No Insider Tipping.*** No Insider may "tip" or disclose material, non-public information concerning the Company to any outside person (including family members, analysts, individual investors, and members of the investment community and news media). In order to avoid "tipping" inside information to others in violation of the law, you should exercise care both when speaking with other Company personnel who do not have a "need to know," and when communicating with family, friends and other persons not associated with the Company. To avoid even the appearance of impropriety, you should refrain from making recommendations about buying or selling the securities of the Company or other entities with which the Company has a relationship. Because any statement you make in an

Internet chat room or message board regarding the Company may be seen as a recommendation to buy or sell the Company's securities, the Company's policy is that no director, officers, or other employee of the Company should participate in Internet chat rooms or message boards regarding the Company or any of its subsidiaries.

iv. ***No Transactions without Prior Approval.*** No Section 16 Person may enter into a transaction involving Company securities unless such transaction has been approved by a Compliance Officer in accordance with the applicable procedures set forth in Section V.5.C of this Policy. No Compliance Officer may enter into a transaction involving Company securities unless the transaction has been approved by another Compliance Officer in accordance with the procedures set forth in Section V.5.C of this policy.

v. ***No Insider Trading Advice to Third Parties.*** No Insider may give trading advice of any kind about the Company to anyone while possessing material, non-public information about the Company except that Insiders should advise others not to trade if doing so might violate the law or this Policy. The Company strongly discourages all Insiders from giving trading advice concerning the Company to third parties even when the Insiders do not possess material, non-public information about the Company.

vi. ***No Insider Put, Call, Short Sale or other Hedging Transaction; No Pledging.*** No Insider may trade in any interest or position relating to the future price of Company securities, such as a put, call, short sale or other hedging transaction. Similarly, no Insider may hold Company securities in a margin account or otherwise pledge Company shares as collateral for a loan or any other indebtedness. For purposes of this policy, "hedging" means purchasing any financial instrument or otherwise engaging in any transaction or series of related transactions designed to or having the effect of hedging or mitigating the risk of, or offsetting, any decrease in the market value of a Company equity security, including, but not by way of limitation, selling, purchasing, entering into or otherwise engaging in any prepaid variable forward contract, equity swap, collar, short sale or security future of, with respect to, or based on, or acquiring any interest in any exchange fund relating to, such equity security or its market value.

vii. ***Insider Prohibited Activities.*** No Insider may (a) enter into a transaction involving securities of any other public company while possessing material, non-public information concerning such company; (b) "tip" or disclose material, non-public information concerning any other public company to anyone; or (c) give trading advice of any kind to anyone concerning any other public company while possessing material, non-public information about that company.

viii. ***No Resale without SEC Registration Statement.*** Section 16 Persons, generally, may not resell Company shares on the open market unless pursuant to an effective SEC registration statement or pursuant to SEC Rule 144.

ix. ***Exception for Vesting of Restricted Stock Units.*** The Compensation and Talent Development Committee of the Board of Directors administers certain equity incentive plans pursuant to which the Company has issued, and will in the future issue, restricted stock units that settle into shares of the Company's common stock following the vesting thereof. In its capacity as plan administrator, such committee has determined and directed that tax withholding obligations triggered by the vesting and/or settlement of such restricted stock units will be satisfied on a mandatory and automatic basis by the Company entering into a sell-to-cover transaction whereby a portion of the settled shares of common stock are sold to fund the applicable tax withholding amount. The award recipient will have no discretion with respect to such sell-to-cover transactions, and such transactions will not be subject to the prohibitions in Sections V.5.A.i., V.5.A.ii, V.5.B.i., V.5.B.ii. and V.5.B.iii.

**B.** ***Trading Windows and Blackout Periods***

i. ***Trading Window for All Insiders / No Trading During Blackout Periods***. Insiders may not enter into a transaction involving Company securities except during a Trading Window. In addition, the Compliance Officers may close a Trading Window (sometimes referred to as a "special blackout period") if they determine that there are pending developments that would make it inappropriate for Insiders to trade in the Company's securities. Insiders may not enter into a transaction involving Company securities during any period where the Trading Window is closed. No Insiders may disclose to any outsider that a special blackout period has been designated.

Section 16 Persons also will be required to obtain trading approval from a Compliance Officer in accordance with the procedures set forth in Section V.5.C of this Policy, even though the proposed transaction would occur during a Trading Window.

ii. ***No Transactions during Trading Windows while in Possession of Material, Non-Public Information.*** No Insiders possessing material, non-public information concerning the Company may enter into a transaction involving Company securities even during applicable Trading Windows. Persons possessing such information may enter into a transaction during a Trading Window only after the close of trading on the second full trading day following the Company's widespread, public release of the information.

iii. ***No Trading During 401(k) Retirement Plan Blackout Periods***. Section 16 Persons may not directly or indirectly purchase, sell, or otherwise acquire or transfer any Company security acquired by the director or such officer in connection with his or her service or employment with the Company during any blackout periods applicable to the Company's 401(k) Plan, except for blackout periods that are regularly scheduled suspensions of trading that are incorporated into the plan document and

are timely disclosed to plan participants or any suspension of trading periods that are imposed on an individual who becomes a participant or a beneficiary in such plans following a merger, acquisition, or similar event.

iv. ***Exceptions for Hardship Cases***. A Compliance Officer may, on a case-by-case basis, authorize trading in Company securities outside of a Trading Window (but not during a special blackout period) after (i) consultation with and approval by the chairperson of the Nominating, Governance and Sustainability Committee or the Chairperson of the Board of Directors, (ii) the Company has determined that the individual is not in possession of material, non-public information relating to the Company, and (iii) a Compliance Officer approves the amount, nature, and timing of the proposed transaction.

v. ***Rule 10b5-1 Plan.*** Notwithstanding the restrictions and limitations on trading in the securities of the Company set forth in this Policy, an individual may trade in the securities of the Company to the extent permitted by the "safe harbor" provisions of Rule 10b5-1; *provided*, *however*, any Rule 10b5-1 plan must be reviewed and approved by a Compliance Officer in advance of implementation. A standard "limit" trading order to a broker will not meet the requirements of a Rule 10b5-1 plan. Therefore, individuals will need to contact their financial advisor, attorney, or broker to prepare a contract or plan meeting the requirements of Rule 10b5-1. A person may not enter into a Rule 10b5-1 plan at a time when such person is in possession of material, non-public information.

**C.** ***Procedures for Approving Transactions by Section 16 Persons***.

i. ***Section 16 Persons***. In addition to the restrictions set forth elsewhere in this Policy, no Section 16 Person may engage in a transaction involving Company securities until:

a. the person trading has notified a Compliance Officer in writing of the amount and nature of the proposed transaction(s) at least one business day before the proposed transaction;

b. the person trading has certified to the Compliance Officer in writing prior to the proposed transaction(s) that (i) he or she is not in possession of material, non- public information concerning the Company and (ii) the proposed transaction(s) do not violate the trading restrictions of Section 16 or Rule 144; and

c. the Compliance Officer has approved the transaction(s) in writing.

(The applicable Application and Approval Form for Trading is attached hereto as Exhibit A.)

ii. ***Duration of Approval***. Approval by a Compliance Officer will remain effective only until earlier to occur of (i) the end of the Trading Window for which the approval was given, and (ii) five (5) business days. If the transaction is not executed by the end of this timeframe, the approval will

lapse. (For example, a limit order that is approved by a Compliance Officer must be withdrawn if it is not executed by the end of the timeframe.) In addition, a Compliance Officer may withdraw approval if there is a change in circumstances.

iii. ***Power of Attorney.*** Attached as Exhibit B is a model power of attorney that would give the Compliance Officers the authority to sign Forms 3, 4, and 5 on behalf of Section 16 Persons. Section 16 Persons must complete this power of attorney if they agree to have the Company file Forms 3, 4 and 5 on their behalf.

**D.** ***Employee Benefit Plans***.

i. ***Employee Stock Purchase Plans***. The trading prohibitions and restrictions set forth in this Policy do not apply to periodic contributions by the Company or employees to employee benefit plans (e.g., periodic stock investment, pension or 401(k) plans) which are used to purchase Company securities pursuant to the employees' advance instructions. However, Insiders may not alter their instructions regarding the purchase or sale of Company securities in such plans while in the possession of material, non-public information.

ii. ***Stock Option Plans***. The trading prohibitions and restrictions of this Policy apply to all sales of securities acquired through the exercise of stock options granted by the Company.

## 6. POTENTIAL CIVIL, CRIMINAL, AND DISCIPLINARY SANCTIONS

A. ***Civil and Criminal Penalties***. The consequences of prohibited insider trading or "tipping" can be severe. Persons violating insider trading or tipping rules may be required to disgorge the profit made or the loss avoided by the trading, pay the loss suffered by the person who purchased securities from or sold securities to the insider tippee, pay civil penalties up to three (3) times the profit made or loss avoided, pay a criminal penalty of up to five million dollars ($5,000,000.00) and serve a jail term of up to twenty (20) years. The Company and/or supervisors of the person violating the rules may also be required to pay major civil or criminal penalties.

B. ***Company Discipline.*** Violation of this Policy or federal or state insider trading or tipping laws by Employees or their family members, may subject the director to dismissal proceedings and the officer or employee to disciplinary action by the Company up to and including termination for cause.

## 7. INQUIRIES

Please direct all inquiries regarding any of the provisions or procedures of this Policy to a Compliance Officer. Any person covered by this Policy who is unsure whether the information they he or she possesses is material or non-public must consult a Compliance Officer for guidance before trading.

## VI. AUDITING AND MONITORING

The Compliance Officers, in coordination with the Legal department, will periodically monitor the Company to ensure compliance with this Policy, as well as applicable state, federal and country-specific laws. Likewise, Internal Audit may test compliance with this Policy as part of its Internal Audit Plan.

## VII. CONSEQUENCES FOR NON-COMPLIANCE

See Section V.6.

## VIII. REPORTING CONCERNS

It is the responsibility of all Employees to ensure compliance with this Policy. If you have any questions or concerns about past or proposed actions by any Orthofix employee or agent that could violate this Policy or applicable law, report it immediately to your supervisor or the Legal or Compliance department. Any person who violates, or who has knowledge of a violations of, this Policy or any federal or state securities laws must report the violation immediately to a Compliance Officer. Upon learning of any such violation, a Compliance Officer, in consultation with the other Compliance Officer, will determine whether the Company should release any material, non-public information, or whether the Company should report the violation to the SEC or other appropriate governmental authority.

## IX. EXCEPTIONS AND LIMITATIONS

Because the Company cannot account for every situation, the Legal department may exercise discretion where additional local requirements or circumstances must be considered to conform to this Policy. Exceptions to this Policy will only be considered when the action contemplated does not raise significant regulatory, ethical, or legal concerns and can only be made by the Legal department.

## X. REFERENCES

None.

## XI. LANGUAGES

This Policy is available in the following languages: English, French, German, Italian, Portuguese, and Spanish.

**RECEIPT AND ACKNOWLEDGEMENT**

I hereby acknowledge that I have received and read a copy of the Company's *"Insider Trading and Related Matters" Policy* and agree to comply with its terms. I understand that violation of federal and state securities laws and regulations may subject me to severe civil and/or criminal penalties and that violation of the terms of the above-titled policy may subject me to discipline by the Company up to and including termination for cause.

Signature: _____

Printed Name: _____

Date: _____

**APPLICATION AND APPROVAL FORM FOR TRADING EXHIBIT A**
**(Applicable to Section 16 Persons)**

Name: _____

Title: _____

Proposed Trade Date: _____

Type of Security to be Traded: _____

Type of Trade (Purchase/Sale): _____

Number of Shares to be Traded: _____

**CERTIFICATION**

I hereby certify that (i) I am not in possession of any material, non-public information concerning the Company (as defined in the Company's "*Insider Trading and Related Matters*" Policy) and, (ii) to the best of my knowledge, the proposed transaction(s) listed above do not violate the trading restrictions of Section 16, or Rule 144. I understand that, if I enter into such transaction(s) while possessing such information or in violation of such trading restrictions, I may be subject to severe civil and/or criminal penalties, and may be subject to discipline by the Company up to and including termination for cause.

Signature: _____

Printed Name: _____

Date: _____

**REVIEW AND DECISION BY COMPLIANCE OFFICER (OR DESIGNEE)**

The undersigned Compliance Officer hereby certifies that he or she has reviewed the foregoing application and:

(Check One): _____ Approves *or* _____ Does Not Approve

the proposed transaction(s).

Signature: _____

Printed Name: _____

Date: _____

**POWER OF ATTORNEY EXHIBIT B**

Know all by these presents, that the undersigned hereby constitutes and appoints each of the Chief Legal Officer, Chief Financial Officer, Deputy General Counsel, and Chief Accounting Officer of Orthofix Medical Inc. (the "Company"), signing singly, the undersigned's true and lawful attorneys-in-fact to:

(1) execute for and on behalf of the undersigned, in the undersigned's capacity as an officer and/or director of the Company, Forms 3, 4, and 5 in accordance with Section 16(a) of the Securities Exchange Act of 1934 and the rules thereunder;

(2) do and perform any and all acts for an on behalf of the undersigned which may be necessary or desirable to complete and execute any such Form 3, 4, or 5, complete and execute any amendment or amendments thereto, and timely file such form with the United States Securities and Exchange Commission and any stock exchange or similar authority; and

(3) take any other action of any type whatsoever in connection with the foregoing which, in the opinion of such attorneys-in-fact, or any one of them, may be of benefit to, in the best interest of, or legally required by, the undersigned, it being understood that the documents executed by any such attorney-in-fact on behalf of the undersigned pursuant to this Power of Attorney shall be in such form and shall contain such terms and conditions as such attorney-in-fact may approve in such attorney-in-fact's discretion.

The undersigned hereby grants to each such attorney-in-fact full power and authority to do and perform any and every act and thing whatsoever requisite, necessary, or proper to be done in the exercise of any of the rights and powers herein granted, as fully to all intents and purposes as the undersigned might or could do if personally present, with full power of substitution or revocation, hereby ratifying and confirming all that such attorney-in-fact, or such attorney-in-fact's substitute or substitutes, shall lawfully do or cause to be done by virtue of this Power of Attorney and the rights and powers herein granted. The undersigned acknowledges that the foregoing attorneys-in-fact, in serving in such capacity at the request of the undersigned, are not assuming, nor is the Company assuming, any of the undersigned's responsibilities to comply with Section 16 of the Securities Exchange Act of 1934.

This Power of Attorney shall remain in full force and effect until the undersigned is no longer required to file Forms 3, 4 and 5 with respect to the undersigned's holdings of and transactions in securities issued by the Company, unless earlier revoked by the undersigned in a signed writing delivered to the foregoing attorneys-in-fact.

IN WITNESS WHEREOF, the undersigned has caused this Power of Attorney to be executed as of this day of , .

Signature: _____

Printed Name: _____

**Exhibit 21.1**

**The following is a list of our significant subsidiaries:**

| Company | Country of Incorporation | Ultimate Ownership by Parent |
|---|---|---|
| Orthofix Australia Pty. Ltd. | Australia | 100% |
| Orthofix do Brasil Ltda. | Brazil | 100% |
| Orthofix France SAS | France | 100% |
| Orthofix GmbH | Germany | 100% |
| Orthofix Spine GmbH | Germany | 100% |
| Orthofix S.r.l. | Italy | 100% |
| Orthofix Netherlands B.V. | Netherlands | 100% |
| Implantes y Sistemas Medicos, Inc. | Puerto Rico | 100% |
| Orthofix AG | Switzerland | 100% |
| Orthofix Limited | UK | 100% |
| Orthofix US LLC | US | 100% |
| Orthofix Services LLC | US | 100% |
| Spinal Kinetics, LLC | US | 100% |
| IsoTis International SARL | Switzerland | 100% |
| IsoTis OrthoBiologics, Inc. | US | 100% |
| IosTis, Inc. | US | 100% |
| SeaSpine LLC | US | 100% |
| SeaSpine Sales LLC | US | 100% |
| SeaSpine Orthopedics Corporation | US | 100% |
| SeaSpine Orthopedics IntermediateCo, Inc. | US | 100% |
| Project Maple Leaf Holdings ULC | British Columbia | 100% |
| 7D Surgical ULC | British Columbia | 100% |

**Exhibit 23.1**

**Consent of Independent Registered Public Accounting Firm**

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

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

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

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

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

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

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

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

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

(9) Form S-8 No. 333-258569 pertaining to the Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as amended;

(10) Form S-8 No. 333-258571 pertaining to the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan, as amended;

(11) Form S-8 No. 333-268232 pertaining to the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan, as amended;

(12) Form S-8 No. 333-269116 pertaining to the Orthofix Medical Inc. Inducement Plan for SeaSpine Employees;

(13) Post-Effective Amendment on Form S-8 to the Registration Statement (Form S-4 No. 333-268234) pertaining to the Orthofix Medical Inc.'s (i) SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan, as amended, (ii) the SeaSpine Holdings Corporation 2018 Employment Inducement Incentive Award Plan, and (iii) the SeaSpine Holdings Corporation 2020 Employment Inducement Incentive Award Plan;

(14) Form S-8 No. 333-269168 pertaining to the Orthofix Medical Inc.'s SeaSpine Holdings Corporation Amended and Restated 2015 Incentive Award Plan, as amended;

(15) Form S-8 No. 333-275400 pertaining to the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan, as amended, and the Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as amended;

(16) Form S-8 No. 333- 276433pertaining to the Orthofix Medical Inc. 2024 CEO Inducement Plan;

(17) Form S-8 No. 333- 276506pertaining to the Orthofix Medical Inc. 2024 CFO Inducement Plan;

(18) Form S-8 No. 333-278007 pertaining to the Orthofix Medical Inc. 2024 CP&BOO Inducement Plan;

(19) Form S-8 No. 333-278703 pertaining to the Orthofix Medical Inc. 2024 CLO Inducement Plan;

(20) Form S-8 No. 333-280101 pertaining to the Orthofix Medical Inc. 2024 PGS and CIR&CO Inducement Plans;

(21) Form S-8 No. 333-280277 pertaining to the Orthofix Medical Inc. 2024 PGO&Q Inducement Plan;

(22) Form S-8 No. 333-280820 pertaining to the Orthofix Medical Inc. 2024 CHRO Inducement Plan;

(23) Form S-8 No. 333-281580 pertaining to the Orthofix Medical Inc. 2024 PGO Inducement Plan; and

(24) Form S-8 No. 333-281581 pertaining to the Orthofix Medical Inc. Amended and Restated 2012 Long-Term Incentive Plan, as amended, and the Orthofix Medical Inc. Second Amended and Restated Stock Purchase Plan, as amended

of our reports dated February 25, 2025, with respect to the consolidated financial statements of Orthofix Medical Inc. and the effectiveness of internal control over financial reporting of Orthofix Medical Inc. included in this Annual Report (Form 10-K) of Orthofix Medical Inc. for the year ended December 31, 2024.

/s/ Ernst & Young LLP

Dallas, Texas
February 25, 2025

**Exhibit 31.1**

**CERTIFICATION**

I, Massimo Calafiore, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: February 25, 2025

By: /s/ MASSIMO CALAFIORE

Name: Massimo Calafiore

Title: President and Chief Executive Officer, Director

**Exhibit 31.2**

**CERTIFICATION**

I, Julie Andrews, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: February 25, 2025

By: /s/ JULIE ANDREWS

Name: Julie Andrews

Title: Chief Financial Officer

**Exhibit 32.1**

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

In connection with the Annual Report of Orthofix Medical Inc. ("Orthofix") on Form 10-K for the period ended December 31, 2024, (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, Massimo Calafiore, Chief Executive Officer and President of Orthofix, and Julie Andrews, Chief Financial Officer, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to his knowledge:

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

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

Dated: February 25, 2025

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

Dated: February 25, 2025

/s/ JULIE ANDREWS
Name: Julie Andrews
Title: Chief Financial Officer