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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37844

BIOVENTUS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**81-0980861**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
4721 Emperor Boulevard, Suite 100 **Durham, North Carolina** **(Address of Principal Executive Offices)**	**27703** **(Zip Code)**

(919) 474-6700

Registrant's Telephone Number, Including Area Code

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Class A Common Stock, $0.001 par value per share	BVS	The Nasdaq Global Select Market

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of July 3, 2021, the end of the most recently completed second fiscal quarter, the aggregate market value of Class A common stock held by non-affiliates (based upon the closing price of these shares on the Nasdaq) was approximately $263.0 million.

As of March 4, 2022, there were 60,601,858 shares of Class A common stock outstanding and 15,786,737 shares of Class B common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain of the information required to be furnished pursuant to Part III of this Annual Report on Form 10-K will be set forth in, and incorporated by reference from, the registrant's definitive proxy statement for the 2022 annual meeting of stockholders which will be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year ended December 31, 2021.

BIOVENTUS INC.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Annual Report) contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act), and Section 27A of the Securities Act of 1933, as amended (Securities Act), concerning our business, operations and financial performance and condition, as well as our plans, objectives and expectations for our business operations and financial performance and condition. Any statements contained herein that are not statements of historical facts may be deemed to be forward-looking statements including, without limitation, statements regarding our business strategy, including, without limitation, expectations relating to our acquisitions of Misonix and Bioness, potential acquisitions, including CartiHeal, expected expansion of our pipeline and research and development investment, new therapy launches, expected timelines for clinical trial results and other development milestones, expected contractual obligations and capital expenditures, our operations and expected financial performance and condition, and impacts of the COVID-19 pandemic. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “predict,” “potential,” “positioned,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

Forward-looking statements are based on management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management’s beliefs and assumptions are not guarantees of future performance or development and involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control. As a result, any or all of our forward-looking statements in this Annual Report may turn out to be inaccurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Important factors that may cause actual results to differ materially from current expectations include, among other things, those described in *Part I, Item 1A. Risk Factors*. You are urged to consider these factors carefully in evaluating these forward-looking statements. These forward-looking statements speak only as of the date hereof. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future

TRADEMARKS, TRADE NAMES AND SERVICE MARKS

This Annual Report includes our trademarks and trade names that we own or license, and our logos. This Annual Report also includes trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, trademarks and trade names referred to in this Annual Report appear without any “™” or “®” symbol, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights to these trademarks, trade names and service marks. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

SUMMARY OF PRINCIPAL RISK FACTORS

We are subject to several risks, including risks that may prevent us from achieving our business objectives or that may adversely affect our business, results of operations, financial condition, and cash flows. You should carefully consider the risks discussed in the section entitled *Part I, Item 1A. Risk Factors*, including the following principal risks:

- our business may continue to experience adverse impacts as a result of the COVID-19 pandemic;
- we are highly dependent on a limited number of products;
- our long-term growth depends on our ability to develop, acquire and commercialize new products, line extensions or expanded indications;
- we may be unable to successfully commercialize newly developed or acquired products or therapies in the United States;
- demand for our existing portfolio of products and any new products, line extensions or expanded indications depends on the continued and future acceptance of our products by physicians, patients, third-party payers and others in the medical community;
- our commercial success depends on our ability to differentiate the hyaluronic acid (HA) viscosupplementation therapies that we own or distribute from alternative therapies for the treatment of Osteoarthritis (OA);

- the proposed down classification of non-invasive bone growth stimulators, including our Exogen system, by the United States (U.S.) Food and Drug Administration (FDA) could increase future competition for bone growth stimulators and otherwise adversely affect our sales of Exogen;
- if we are unable to achieve and maintain adequate levels of coverage and/or reimbursement for our products, the procedures using our products, or any future products we may seek to commercialize, the commercial success of these products may be severely hindered;
- if we choose to acquire or invest in new businesses, products or technologies, we may be unable to complete these acquisitions or to successfully integrate them in a cost-effective and non-disruptive manner;
- we compete and may compete in the future against other companies, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration or improved operating results;
- our ability to maintain our competitive position depends on our ability to attract, retain and motivate our senior management team and highly qualified personnel, and our failure to do so could adversely affect our business, results of operations and financial condition;
- if our facilities are damaged or become inoperable, we will be unable to continue to research, develop and manufacture our products and, as a result, our business, results of operations and financial condition may be adversely affected until we are able to secure a new facility;
- our products and operations are subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer;
- we may be subject to enforcement action if we engage in improper claims submission practices and resulting audits or denials of our claims by government agencies could reduce our net sales or profits;
- the FDA regulatory process is expensive, time-consuming and uncertain, and the failure to obtain and maintain required regulatory clearances and approvals could prevent us from commercializing our products; our HCT/P products are subject to extensive government regulation and our failure to comply with these requirements could cause our business to suffer;
- if clinical studies of our future products do not produce results necessary to support regulatory clearance, approval or certification in the United States or elsewhere, we will be unable to expand the indications for or commercialize these products; and
- we may be subject to enforcement action if we engage in improper marketing or promotion of our products, that could lead to costly investigations, fines or sanctions by regulatory bodies, any of which could be costly to our business.

PART I

Item 1. Business

Unless the context requires otherwise, in this Annual Report on Form 10-K (Annual Report) the terms "we," "us," "our," the "Company," "Bioventus," "Bioventus Inc." and similar references refer to the combined operations of Bioventus Inc. and its consolidated subsidiaries and affiliates, including Bioventus LLC (BV LLC).

Company overview

We are a global medical device company focused on developing and commercializing clinically differentiated, cost efficient and minimally invasive treatments that engage and enhance the body's natural healing process. We manage our business through two reporting segments, U.S. and International which accounted for 90% and 10%, respectively, of our total net sales during the fiscal year ended December 31, 2021.

Our portfolio of products is grouped into three verticals:

- Pain Treatments is comprised of non-surgical joint pain injection therapies as well as peripheral nerve stimulation (PNS) products to help the patient get back to their normal activities;
- Surgical Solutions is comprised of bone graft substitutes (BGS) to fuse and grow bones, improve results following spinal and other orthopedic surgeries as well as ultrasonic medical devices used for precise bone sculpting, remove tumors and tissue debridement, in various surgeries including spine and neurosurgery; and
- Restorative Therapies is comprised of an Ultrasonic bone healing system for fracture care, skin allografts and products used to support healing of chronic wounds as well as Advanced Rehabilitation devices designed to help patients regain leg or hand function due to stroke, multiple sclerosis or other central nervous system disorders and orthopedic conditions impacting extremity function.

Financial information regarding our reportable business segments is included in *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* and *Note 14. Segments* of the *Notes to the Consolidated Financial Statements* within *Part II, Item 8. Financial Statements and Supplementary Data* of this Annual Report. Our verticals and the products within each vertical are described in additional detail below under "Our products."

COVID-19 Update and Outlook

Refer to *Part I, Item 1A. Risk Factors* and *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* for a discussion of the effects of the global COVID-19 pandemic on our business in 2021 and of its expected impact in 2022 and beyond.

Our growth strategy

We intend to pursue the following strategies to build a market-leading and customer-focused company centered on our three verticals, Pain Treatments, Surgical Solutions and Restorative Therapies, and to continue to grow our net sales and Adjusted EBITDA:

- **Continue to expand market share in HA viscosupplementation**. We intend to increase sales of our HA viscosupplementation therapies and extend our market leadership in this category by building on our unique positioning as the only company to offer a one, three and five injection treatment regimen. We offer the highest molecular weight single injection product known as Durolane.
- **Introduce new pain treatment products as well as complementary products within sports medicine.** We plan to expand our offering beyond HA viscosupplementation, and nerve stimulation into sports medicine by building a comprehensive portfolio for pain and sports medicine treatments for launch over the next several years.
- **Further develop and commercialize our surgical solutions portfolio.** We intend to grow our presence in the surgical solutions market and expand our reach into the operating room in both ambulatory surgical centers (ASCs) and hospitals. In the near-term, we plan to maintain and selectively expand our profitable product lines by adding to our U.S. distributor base in an effort to reach significantly under-penetrated markets. Over time, we intend to launch product line enhancements and invest in the development of next-generation surgical solution therapies to continue to grow our market share.
- **Expand indications for use for our Exogen system**. We are focused on generating incremental clinical data and peer-reviewed publications to expand our indications and continue to grow our market leading share. We are currently underway with the B.O.N.E.S. clinical studies, which are aimed at generating data to support label expansion in additional bone types and expanded reimbursement for the treatment of fresh fractures in patients at risk of nonunion due to certain comorbidities, such as diabetes or obesity.

- **Invest in research and development.** We are focused on internal research and development to broaden our portfolio of Pain Treatments, Surgical Solutions and Restorative Therapies. We rely on a team of highly trained individuals to develop new products, conduct clinical investigations and help educate health care providers using our products. We collaborate with academic centers of excellence, leading contract research organizations and other industry groups to complement and expedite execution of our research and development programs and minimize fixed costs.
- **Pursue business development opportunities.** Consistent with our track record of acquisitions of Bioness and Misonix and strategic investments in CartiHeal and Trice Medical, we intend to continue to pursue business development opportunities in the medium term that leverage our significant customer presence across orthopedics, broaden our portfolio and increase our global footprint. We will continue to search for clinically differentiated and cost-effective products and technologies that also balance our portfolio in terms of risk and time to market.
- **Opportunistically grow our international markets.** We intend to focus our international business on markets where our existing portfolio can maintain profitable growth over time, either through direct or distributor based channels. We plan to selectively expand to new markets and intend to pursue further opportunities in the Asia Pacific markets. In particular, China represents an attractive and exciting market given its large and aging population as well as its rising middle class.

Misonix Acquisition

On October 29, 2021, we acquired Misonix, Inc. (Misonix) in a cash-and-stock transaction (Misonix Merger). Misonix manufactures minimally invasive surgical ultrasonic medical devices used for precise bone sculpting, removal of soft and hard tumors, and tissue debridement, primarily in the areas of neurosurgery, orthopedic surgery, plastic surgery, wound care and maxillo-facial surgery. Misonix also exclusively distributes skin allografts and wound care products used to support healing of wounds.

At the closing of the Misonix Merger, we provided merger consideration totaling $525.3 million, including cash of $183.0 million, the issuance of 18,340,790 shares of our Class A common stock and the assumption or settlement of Misonix stock options having a value of $27.6 million. The remaining consideration consisted of Misonix debt and other liabilities that benefited the seller which we repaid in full. The acquisition includes the entire portfolio of Misonix products as well as its research and development pipeline. The cash consideration was funded through taking on additional debt as well as the use of cash on hand.

Bioness Acquisition

On March 30, 2021, we acquired Bioness, Inc. (Bioness), in a cash transaction (Bioness Merger). Bioness is a global leader in neuromodulation and advanced rehabilitation medical devices through its innovative peripheral nerve stimulator (PNS) therapy and premium advanced rehabilitation solutions. The Bioness Merger gives us access into two large and growing markets: PNS and the advanced rehabilitation market. We believe both of these markets offer attractive growth opportunities driven by demographic trends and the need for safe, effective, treatment options for the many patients suffering from post-surgical pain, stroke, multiple sclerosis, traumatic brain injury, spinal cord injury and cerebral palsy. We estimate Bioness medical devices address total global market opportunities approaching $8 billion per year.

Bioness advanced rehabilitation solutions have a broad portfolio of offerings, including proprietary electrical stimulation exoskeletal devices for both the upper and lower extremities, robotic gait and fall safety systems, and high-tech, interactive software learning and recovery assessment platforms. These products play an essential role in helping patients regain mobility due to stroke, traumatic brain injury, multiple sclerosis and osteoarthritis, and are used by physical or occupational therapists in a clinical setting or by the patient at home, with the guidance of a clinician through telemedicine. Bioness PNS Systems are designed to help patients suffering from pain after surgery on an extremity, which affects over 16 million patients each year globally.

As consideration for the Bioness Merger, we paid $48.9 million in cash at closing and we expect to pay an additional $15.5 million of contingent consideration related to the achievement of certain key milestones. The acquisition included the entire portfolio of Bioness products as well as its research and development pipeline. The up-front consideration was funded exclusively through the use of cash on hand.

For additional information regarding the Misonix and Bioness Mergers, including associated risks and uncertainties, refer to *Part I, Item 1A. Risk Factors—Risks related to our business—We may be unable to complete proposed acquisitions or to successfully integrate proposed or recent acquisitions in a cost-effective and non-disruptive manner* and *Note 4. Acquisitions and investments* of the *Notes to the Consolidated Financial Statements* within *Part II, Item 8. Financial Statements and Supplementary Data* included in this Annual Report.

Our products

We offer a diverse portfolio of products to serve physicians spanning the orthopedic continuum, including sports medicine, total joint reconstruction, hand and upper extremities, foot and ankle, podiatric surgery, trauma, spine and neurosurgery, in the physician's office or clinic, ASCs or in the hospital setting. Our portfolio of products is grouped into three verticals based on clinical use: (i) Pain Treatments, (ii) Surgical Solutions and (iii) Restorative Therapies.

Pain Treatments

Our joint Pain Treatment products are non-surgical alternatives created to work with the body's biological processes, providing a natural lubricant into the joint that relieve mild to moderate pain, improves mobility, and helps the patient get back to their normal activities.

Durolane is an FDA-approved sterile, transparent and viscoelastic gel that is a single injection therapy that is indicated in the United States for the symptomatic treatment of OA in the knee in patients who have failed to respond adequately to conservative non-pharmacological therapy and simple analgesics. Durolane is also indicated for the hip, ankle and shoulder, as well as for treatment of other small orthopedic joints outside the United States. Durolane contains high levels of HA and is injected directly into the joints affected by OA to relieve pain and restore lubrication and cushioning. This may improve joint function and help to potentially avoid or delay knee replacement surgery.

Physicians administer Durolane to the affected knee joint in a single injection and it has been observed to provide a benefit for pain reduction in patients with OA in the knee for up to 26 weeks. Durolane's injection schedule results in economic advantages and greater patient convenience and compliance compared to other HA viscosupplementation therapies which require weekly injections over a period of three to five weeks. Durolane is highly purified and based upon a natural and patented non-animal stabilized HA (NASHA), expanding use to patients who are allergic to animal derived solutions. We currently market Durolane in the United States and Europe.

GELSYN-3 is an FDA-approved sterile, buffered solution of highly purified sodium hyaluronate that is administered as a three injection HA viscosupplementation therapy. It is indicated for the treatment of pain due to knee OA in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics. The solution treats knee OA by providing temporary replacement for the diseased synovial fluid and restoring lubricity of bearing joint surfaces. Physicians administer GELSYN-3 to the affected knee joint once a week for three consecutive weeks. GELSYN-3 provides relief of knee pain and may help delay the need for total knee replacement surgery. GELSYN-3 is derived from bacterial fermentation, is highly purified and does not involve the use of animal products, thereby reducing the potential risk of an immune response following injection. We currently market GELSYN-3 in the United States.

SUPARTZ FX is an FDA-approved sterile and viscoelastic solution of HA that is administered as a five injection HA viscosupplementation therapy. It is indicated for the treatment of pain in patients with knee OA who failed to adequately respond to conservative nonpharmacological therapy and simple analgesics. The solution treats knee OA by providing temporary replacement for the diseased synovial fluid and restoring the lubricity of the bearing joint surfaces. Physicians administer SUPARTZ FX to the affected knee joint once a week for five consecutive weeks. SUPARTZ FX may also delay the need for total knee replacement. SUPARTZ FX is derived from HA extracted from certified and veterinary inspected chicken combs. We currently market SUPARTZ FX in the United States.

Our PNS system is a permanent option that provides relief for chronic peripheral pain including: Nerve Pain, Neuroma, Neuropathic Pain, Post-Stroke Shoulder Pain and Neuralgia. StimRouter is implanted during a minimally invasive outpatient procedure performed under local anesthetic and delivers gentle electrical pulses directly to target peripheral nerve pain at its source. Its small profile allows the system to be implanted in many locations around the body, depending on patient needs. StimRouter is ideally suited for patients with chronic pain of a peripheral origin who are unable to find sustained pain relief with other treatment options such as nerve blocks, nerve ablation, and other temporary treatments. StimRouter is programmed with up to eight different stimulation programs from which the patient is able to select, turn off/on and increase or decrease the stimulation intensity.

Development and clinical pipeline for Pain Treatments (including investments)

We continue to look for and execute on opportunities to expand our Pain Treatments portfolio through business development, product extensions and new market development.

Agili-C. An off-the-shelf aragonite implant designed for implantation into osteochondral defects in the knee currently under development by CartiHeal (2009) Ltd. (CartiHeal), which is subject to our exclusive rights as described below. The Agili-C implant received breakthrough device designation from the FDA in the fourth quarter of 2020. We believe Agili-C is the only product in clinical development in the United States as an off-the-shelf scaffold implant that is designed to regenerate hyaline cartilage and subchondral bone simultaneously. The associated surgical procedure is similar to osteochondral allograft implantation, but is a single-step process and is easier, faster and more cost-effective. We believe this is the first cartilage repair technology to be tested in trials designed for regulatory approval in the United States in non-OA and OA patients, potentially unlocking applications for millions of patients with knee OA and cartilage defects. We also believe Agili-C will enable the treatment of cartilage lesions in a significant population of OA patients, including those younger, active patients for whom available treatment options are limited. We believe the FDA's grant of breakthrough device designation in the fourth quarter of 2020 for the treatment of an International Cartilage Repair Society (ICRS) grade III or above knee-joint surface lesions(s), with a total treatable area of 1-7cm2, without severe osteoarthritis (Kellgren-Lawrence grade 0-3) is a promising development, as such designation may help patients receive more timely access to Agili-C by potentially expediting its development, assessment and review by the FDA. On January 12, 2021, the Centers for Medicare and Medicaid Services (CMS) issued a final rule under which a breakthrough device designation by the FDA also provides a streamlined pathway to national Medicare coverage for a period of four years, beginning as early as the FDA approval for the product. In November 2021, however, CMS rescinded this rule in its entirety, and stated that it plans to work with the FDA and other stakeholders to develop a new process to cover innovative devices that benefit Medicare patients. We believe Agili-C may also have the potential for broader indications for use in other joints, providing entrance into the global market for cartilage repair products.

On July 15, 2020, we entered into an Option Equity Purchase Agreement (Option Agreement) and made a $15.0 million equity investment in CartiHeal, a privately-held company headquartered in Israel and developer of the proprietary Agili-C implant for the treatment of joint surface lesions in traumatic and osteoarthritic joints. CartiHeal submitted the non-clinical module of the PMA in January 2021 and submitted the final, clinical module of a Modular PMA in the August 2021 seeking FDA approval. In September 2021, CartiHeal achieved pivotal clinical trial success, as defined in the Option Agreement, for Agili-C. In accordance with the Option Agreement and upon Board of Director approval, we deposited $50.0 million into escrow for the potential acquisition of CartiHeal. If additional support is needed to complete the CartiHeal product study in response to FDA feedback, we will purchase an additional 338,089 of CartiHeal Series G Preferred Shares for $5.0 million.

We have an exclusive option to acquire the remaining equity in CartiHeal, which may be exercised at any time up to and within 45 days following notice of the FDA approval for Agili-C. In addition, upon the same FDA approval, CartiHeal may exercise an option within 45 days that requires us to complete the acquisition of the remaining equity in CartiHeal.

MOTYS. A placental tissue injectable biologic for knee OA currently in clinical development. Based on our preclinical evidence, we believe the MOTYS formulation holds potential for mitigating OA joint pain while protecting damaged cartilage and promoting anti-catabolic and pro-anabolic events that could ultimately result in delayed disease progression in OA. We have completed extensive in vitro and in vivo studies comparing the effect of MOTYS to the clinical standard of care (steroid injections). In these preclinical studies, MOTYS provided non-inferior pain relief effects to a steroid and showed superiority in protecting cartilage and in promoting new tissue formation.

We began selling MOTYS in the cash pay market during the fourth quarter of 2020 as human cells, tissues and cellular and tissue-based product (HCT/P) pursuant to a temporary FDA policy of enforcement discretion. Following the end of this temporary enforcement discretion policy on May 31, 2021, we were required to cease selling MOTYS and will not be able to resume sales of MOTYS in the United States unless and until such time as we obtain approval of a Biologics License Application (BLA).

Following completion of necessary clinical trials, we plan to pursue submission and approval of the required BLA for this product. On October 29, 2020, we received FDA allowance to proceed with clinical studies under our investigational new drug application (IND). We began randomized clinical trials for MOTYS in the first quarter of 2021 to support submission of a potential BLA to the FDA for the use of MOTYS in pain treatments. We have completed enrollment and 6 months follow-up of all patients in our Phase I study with no material safety findings as assessed by an independent clinical safety review board. Expected completion of this 12 month study is the fourth quarter of 2022. In parallel, we have initiated an international Phase II dose finding clinical investigation. Following national and local regulatory approvals, recruitment has started in Canada and Australia. Study completion is expected in the first quarter of 2023.

PROcuff. An investigational bio-inductive collagen implant for regeneration of tendon tissue in the rotator cuff. Preclinical evidence developed in a sheep model suggest that the material was well tolerated, rapidly integrated and promoted the formation of new tendon tissue at the bone tendon interface.

Further to those encouraging findings, we have initiated a pivotal Good Laboratory Practices sheep implantation study through a collaboration with a prominent academic investigator. The results of this study, together with other ongoing test results, will be part of the request for 510(K) clearance submission, planned for the fourth quarter of 2022.

On August 23, 2019, we entered into an exclusive Collaboration Agreement with Harbor Medtech Inc. (Harbor) to develop and license the rights to commercialize a woven-suture-collagen composite implant product, PROcuff, for the regeneration of tendon tissue. This Collaboration Agreement was terminated on June 8, 2021, and we have acquired all rights to the product.

Surgical Solutions

Our Surgical Solutions product portfolio is comprised of clinically efficacious and cost effective bone graft solutions to meet a broad range of patient needs and procedures. Bone grafting is a surgical procedure used to fuse spinal vertebrae, replace missing bones, fix bones that are damaged from trauma or problem joints, or to facilitate growing bones around an implanted device, such as a total knee replacement. Our products are designed to improve bone fusion rates following spinal and other orthopedic surgeries, including trauma and reconstructive foot and ankle procedures. Our portfolio is also comprised of minimally invasive surgical ultrasonic medical devices. These products are used for precise bone sculpting, removal of soft and hard tumors, and tissue debridement, primarily in the areas of neurosurgery, orthopedic surgery, plastic surgery, wound care and maxillo-facial surgery.

OSTEOAMP is an allograft-derived bone graft with growth factors used for orthopedic, neurosurgical and reconstructive bone grafting procedures. OSTEOAMP is an allogeneic bone graft that is available in multiple formats (fibers, putty, sponge and granules) that is processed with bone marrow cells to maintain the wide array of growth factors present in native bone. We currently market OSTEOAMP in the U.S. We launched OSTEOAMP Flowable in 2021, which is designed to be moldable and easy to use, with a convenient, ready to use syringe.

EXPONENT provides an osteoconductive scaffold with osteoinductive potential while providing optimal handling characteristics indicated for posterolateral spine procedures. EXPONENT is derived from human allograft bone tissue and is combined with a migration-resistant resorbable carrier and formulated into a putty that is ready-to-use out of the syringe. EXPONENT is highly malleable and easy to mold and pack into the surgical defect. Donor bone is sourced from AATB-certified and FDA-registered tissue banks in the U.S. All tissues are screened for the standard panel of infectious viruses. We currently market EXPONENT in the U.S.

PUREBONE provides a natural osteoconductive scaffold that facilitates cellular ingrowth and revascularization which is indicated for orthopedic, neurosurgical and reconstructive bone grafting procedures. PUREBONE is 100% human bone, and is available as demineralized cortical fibers, demineralized cancellous strips and blocks, and mineralized cancellous chips. Demineralized cortical fibers are easy to mold, shape and pack, and provide osteoinductive potential. The fibers demonstrate high fluid retention and expansion properties, which potentially increases the opportunity for bone-on-bone contact. Demineralized block and strip formats provide interconnected porosity with compressible, sponge-like handling characteristics, and provide osteoinductive potential. Mineralized cancellous chips range from 1-4 mm and 4-10 mm granule size for optimal void packing capabilities. Demineralized PUREBONE formats provide osteoinductive potential to recruit and differentiate bone-forming cells. Donor bone is sourced from AATB-certified and FDA-registered tissue banks in the U.S. All tissues are screened for the standard panel of infectious viruses. We currently market PUREBONE in the U.S.

SIGNAFUSE contains a synergistic combination of biomaterials that supports new bone formation which is indicated for standalone posterolateral spine, extremities and pelvis, as well as a bone graft extender in the posterolateral spine. SIGNAFUSE is a synthetic bone graft made up of bioglass and a biphasic mineral (60% hydroxyapatite, 40% β-tricalcium phosphate) available in putty and strip formats. Bioactive synthetic bone graft substitute is comprised of a mixture of calcium phosphate granules and bioglass granules suspended in a resorbable polymer carrier that facilitates handling and delivery of the granule components to fill spaces of missing bone. The unique and synergistic combination of biomaterials in SIGNAFUSE is designed to help accelerate cellular activity and kickstart osteogenesis. We currently market SIGNAFUSE in the U.S.

INTERFACE is designed to facilitate a rapid biologic response that stimulates the bone healing process and is used for posterolateral spine when mixed with autograft, extremities and pelvis. INTERFACE's patented particle technology is designed for enhanced bone graft performance through irregularly shaped synthetic bioglass granules that provide an osteoconductive scaffold for new osseous ingrowth and tissue generation. The patented bioglass component stimulates the formation of an apatite layer as early as seven days on the surface of the granules. The apatite surface layer that is formed is equivalent in composition and structure to the hydroxyapatite found in bone and provides an osteoconductive bioactive scaffold that supports the generation of new osseous tissue. New bone infiltrates around the granules, allowing the repair of the defect as the granules are absorbed. The patented INTERFACE Bioactive Bone Graft particle size of 210-420 microns is designed for a faster speed of bone fill than glass particles with a broader particle size distribution of 90-710 microns and smaller particles below 210 microns. INTERFACE features consistent composition without variability inherently found in particle size and porosity of tissue based grafts. INTERFACE Bioactive Bone Graft conforms to ASTM specification F1538 for 45S5 bioactive glass. INTERFACE is packed in a sterile, single use vial. We currently market INTERFACE in the U.S.

OSTEOMATRIX+ is a synthetic bone graft with exceptional handling, rapid hydration and a biphasic composition for sustained performance used on the posterolateral spine, extremities and pelvis. OSTEOMATRIX+ is a moldable bone graft substitute consisting of biphasic granules designed to produce a reliable, porous scaffold and sustained osteoconductivity throughout bone remodeling. The OSTEOMATRIX+ biphasic granules are composed of 60% hydroxyapatite and 40% beta-tricalcium phosphate (β-TCP), a ratio demonstrated to have advantageous bone remodeling properties. The long-term stability of hydroxyapatite and the solubility of β-TCP provide an osteoconductive graft with an optimal resorption profile. Interconnected macropores provide a porous, osteoconductive matrix that mimics a natural scaffold for cellular ingrowth and revascularization. Three-dimensional micropores enhance the flow and circulation of biological fluids. We currently market OSTEOMATRIX+ in the U.S.

CELLXTRACT is a bone marrow aspirate without dilution or centrifugation. CELLXTRACT provides high levels of cells and their associated signals to deliver optimum clinical results. Independently reviewed clinical data shows the number of stem cells collected by CELLXTRACT, as counted by fibroblast-like colony-forming units (CFU-f), were greater than aspirations from a standard needle of similar volumes and was comparable or greater than final products after centrifugation. Autologous bone marrow aspirate (BMA) contains the needed cells and growth factors to enhance bone healing. There is no waste of biologic material or discard of viable cells compared to inherent inefficiencies in centrifuge-based systems. We believe potential savings can be realized as compared to the centrifuge-based competitors. Generally, the cost of CELLXTRACT is less than the disposable kit associated with those systems. No additional personnel is needed to operate equipment as no centrifugation is required. The aspirated fluid is not required to leave the sterile field for centrifugation, creating less risk for contamination or infection. Traditional needles require repositioning via an additional insertion point(s) or angling in order to access a fresh channel of BMA increasing the risk of infection, blood loss, and operative time. CELLXTRACT, on the other hand, only requires one insertion point minimizing the risks to the patient. We currently market CELLXTRACT in the U.S.

EXTRACTOR is a complementary and cost-effective solution designed to add needed cells and signals to aid in bone healing. EXTRACTOR provides a six-ported cannula with a simplistic design for more flexible positioning and enhanced marrow extraction. The large side port design of EXTRACTOR allows for better access and retrieval of the bone marrow aspirate which contains the cells and signals needed for solid bone formation. The “twin peaks” tip design allows for easy insertion through the hard wall of the cortical bone. An ergonomically designed handle allows the clinician to apply consistent pressure for greater control. We currently market EXTRACTOR in the U.S.

Reficio Demineralized Bone Matrix (Reficio DBM) is a putty comprised of human demineralized bone matrix and a biocompatible bioabsorbable carrier, carboxymethylcellulose, mixed into a putty-like consistency for ease in surgical use. Reficio DBM is indicated for use as a bone void filler and bone graft substitute for voids or gaps that are not intrinsic to the stability to the bony structure, specifically for the treatment of surgically created osseous defects or osseous defects from traumatic injury to the bone. Reficio DBM can be used for extremities, posterolateral spine and pelvis.

neXus is a next generation integrated ultrasonic surgical platform that combines all the features of our existing solutions, including BoneScalpel, SonicOne and SonaStar, into a single fully integrated platform that we believe will also serve to power future solutions. The neXus platform is driven by a new proprietary digital algorithm that results in more power, efficiency, and control. The device incorporates Smart Technology that allows for easier setup and use.

neXus’ increased power has the potential to improve tissue resection rates for both soft and hard tissue removal, which we believe makes it a unique surgical platform for a variety of different surgical specialties. In addition, neXus’ ease of use enables physicians to fully leverage neXus’ capabilities via its digital touchscreen display and smart system setup. Our current ultrasonic applications, which are BoneScalpel, SonaStar and SonicOne, all work on the neXus generator. This allows a hospital to access all of our product offerings on this all-in-one console. We principally sell neXus in the U.S.

The BoneScalpel is a state of the art, ultrasonic bone cutting and sculpting system capable of enabling precise cuts with minimal necrosis, minimal burn artifact, minimal inflammation and minimal bone loss. The device is also capable of preserving surrounding soft tissue structures because of its ability to differentiate soft tissue from rigid bone. This device can make precise linear or curved cuts, on any plane, with precision not normally associated with powered instrumentation. We believe that BoneScalpel offers the speed and convenience of a powered instrument without the dangers associated with conventional rotary devices. The effect on surrounding soft tissue is limited due to the elastic and flexible structure of healthy tissue. We believe this is a significant advantage in anatomical regions like the spine where patient safety is of primary concern. In addition, the linear motion of the blunt, tissue-impacting tips avoids accidental ‘trapping’ of soft tissue while largely eliminating the high-speed spinning and tearing associated with rotary power instruments. We believe the BoneScalpel allows surgeons to improve on existing surgical techniques by creating new approaches to bone cutting, sculpting, and removal, leading to substantial time-savings and increased operation efficiencies.

The SonaStar System provides powerful and precise aspiration following the ultrasonic ablation of soft tissue. The SonaStar has been used for a wide variety of surgical procedures applying both open and minimally invasive approaches, including neurosurgery and general surgery. The SonaStar may also be used with OsteoSculpt® probe tips, which enable the precise shaping or shaving of bony structures that prevent open access to partially or completely hidden soft tissue masses.

Developmental and clinical pipeline for Surgical Solutions (including investments)

As we build the body of clinical evidence supporting our products, we continue to look for and execute on opportunities to innovate in our Surgical Solution portfolio. To meet growing market demand and evolving surgical techniques, we continue to develop product extensions and adjust formulations on all of our surgical technology platforms, including developing new presentations of OsteoAMP, and further refining the Bonescalpel and Sonastar technologies to expand our ability to serve evolving surgical techniques.

On August 23, 2021, we made a strategic investment in Trice Medical, Inc. (Trice). Trice is a privately held company that develops and commercializes minimally invasive technologies for sports medicine and orthopedic surgical procedures. Trice combines their handheld arthroscope and portable ultrasound visualization technologies with its surgical devices to treat a range of sports medicine and orthopedic conditions, including tendinopathy, planter fasciitis and carpel tunnel, in order to improve patient recovery time, reduce pain, minimize scarring and move surgical procedures out of higher cost points of care. Trice’s established and growing presence in sports medicine and orthopedics is directly aligned with our strategy of expanding our offerings.

Our investment resulted in exclusive sales and distribution rights to Trice’s products outside of the U.S. and a seat on the Trice board of directors. We also entered into a co-development arrangement to explore the integration of Trice technologies with our current and future PNS products in order to accelerate the adoption of both of our products.

Restorative Therapies

Our Restorative Therapies product portfolio is comprised of an Ultrasonic bone healing system and skin allografts and products used to support healing of wounds. Our Restorative Therapies product portfolio is also comprised of Advanced Rehabilitation devices designed to help patients regain leg or hand function due to stroke, multiple sclerosis or other central nervous system disorders.

EXOGEN is an ultrasound bone healing system for the non-invasive treatment of established nonunion fractures and certain fresh fractures. A nonunion fracture is considered to be established when the fracture site shows no visibly progressive signs of healing. EXOGEN has been sold commercially for over 25 years and is the only FDA-approved device on the market for the accelerated healing of fresh, closed posteriorly displaced distal fractures of the radius and fresh, closed or grade I open long bone fractures. EXOGEN utilizes low-intensity pulsed ultrasound technology to stimulate the body's natural bone healing process. EXOGEN is used to administer treatment in a location of convenience with an easy to use interface that tracks treatment use and promotes compliance. EXOGEN is indicated in the U.S. for the non-invasive treatment of established nonunions, excluding skull and vertebra, and for accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed or Grade I open long bone fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. EXOGEN is marketed in the U.S., Canada, Europe and Japan. EXOGEN is also approved for marketing in Australia, New Zealand, Saudi Arabia, Turkey and the UAE.

TheraSkin is a biologically active human skin allograft that has all of the relevant characteristics of human skin needed to heal wounds, including living cells, growth factors, and a collagen matrix. TheraSkin is derived from human skin tissue and is an HCT/P. LifeNet processes and supplies TheraSkin to us under a supply and distribution agreement that gives us exclusive rights to sell TheraSkin in the United States. TheraSkin is used on all external skin tissue wounds, including but not limited to difficult to heal diabetic foot ulcers, venous leg ulcers, dehisced surgical wounds, necrotizing fasciitis, burns, Mohs and wounds with exposed structures.

Therion is used as a cover and barrier for homologous use for wound care and surgical procedures. Therion is a dehydrated and terminally sterilized chorioamniotic allograft derived from human placental membrane and is an HCT/P. CryoLife processes and supplies Therion to us under a supply and distribution agreement that gives us exclusive rights to distribute the product in the United States. CryoLife produces Therion using a proprietary process that removes the maternal-derived decidua cells from the placental membrane, leaving the amnion and chorion layers in their native configuration.

TheraGenesis is a Bilayer Wound Matrix and Meshed Bilayer Wound Matrix consisting of a porcine collagen sponge layer and a silicone film layer that provides a scaffold for cellular invasion and capillary growth for management of wounds including partial and full-thickness wounds, chronic wounds, surgical wounds, trauma wounds and draining wounds. We obtain TheraGenesis under an exclusive supply and distribution agreement with Gunze Limited that gives us exclusive rights to distribute the product in the United States.

The SonicOne Ultrasonic Cleansing and Debridement System is a highly innovative, tissue specific approach for the removal of devitalized or necrotic tissue and fibrin deposits while sparing viable, surrounding cellular structures. The tissue specific capability is, in part, due to the fact that healthy and viable tissue structures have a higher elasticity and flexibility than necrotic tissue and are more resistant to destruction from the impact effects of ultrasound. The ultrasonic debridement process separates devitalized tissue from viable tissue layers, allowing for a more defined treatment and, usually, a reduced pain sensation. We believe that SonicOne establishes a new standard in wound bed preparation, the essential first step in the healing process, while contributing to a faster patient healing.

L300 Go Foot Drop System

L300 GO is a functional electrical stimulation that produces measurable mobility improvements for patients living with foot drop and thigh weakness. A 3-axis gyroscope and accelerometer are embedded in the Stimulator to monitor user movement in all three kinematic planes and deploy stimulation in 0.01 seconds of detecting a valid gait event. Through an adaptive, learning algorithm, the L300 Go is designed to detect gait events, providing stimulation precisely when needed making it easier for users to clear their foot at different walking speeds, on stairs, ramps, and while navigating uneven terrain.

H200 WIRELESS Hand Rehabilitation System

H200 Wireless is a hand rehabilitation system that supports the wrist in a functioning position, allowing the fingers and thumb to move efficiently while reaching, grasping and pinching. H200 Wireless has two main parts that communicate wirelessly with each other: the functional stimulation support (orthosis) and the control unit (microprocessor). These designed to increase hand function, increase or maintain hand range of motion, reduce muscle spasms, prevent muscle loss, reeducate muscles and/or increase blood circulation. H200 Wireless is programmed by a clinician to stimulate the appropriate nerves and muscles of the forearm and hand. We believe this helps to reeducate electrical brain signals, stimulating weak or paralyzed muscles.

VECTOR Gait & Safety System®

Vector is a body weight support system designed to accelerate physical rehabilitation of patients with severe gait and/or balance impairment. The system unloads a programmed amount of weight to enable the patient to practice walking with less than his or her full body weight. Vector is designed to alleviate the risk of falling and provides a feeling of security, instilling confidence in patients and empowering clinicians to develop effective and challenging rehabilitation regimens. Vector is designed to reduce safety risks so clinicians can remain focused on their patient's execution of an activity. Designed for both physical and occupational therapy, Vector is designed to provide a safe environment and real-world experience for adult and pediatric patients recovering from stroke, amputations, and orthopedic, brain and spinal cord injuries.

BITS® Bioness Integrated Therapy System

The Bioness Integrated Therapy System (BITS®) is an affordable and versatile solution for vision, motor and balance training for individuals, including those with deficits resulting from traumatic injuries and movement disorders as well as competitive athletes. BITS is a multi-disciplinary therapy solution designed to motivate patients and enhance clinician efficiency. BITS's interactive touchscreen and diverse program options challenge patients to improve performance through the use of visual motor activities, visual and auditory processing, cognitive skills, endurance and balance training. Standardized assessments and progress reports make documenting outcomes quick and easy. With the large variety of BITS programs, therapists can choose activities that are tailored to each individual. BITS programs can be further modified to accommodate varying degrees of difficulties. With hundreds of possible parameter combinations, BITS can be customized even further to provide a unique therapy experience for each patient. BITS is optimized for occupational therapy, physical therapy and speech language pathology.

Developmental and clinical pipeline for Restorative Therapies

In order to evaluate the effectiveness of EXOGEN in mitigating the risk of progression to fracture nonunion, and in an effort to obtain regulatory approval for expanded indications, we are seeking to supplement the body of clinical knowledge in an innovative population-based clinical development program, B.O.N.E.S., which stands for Bioventus Observational Non-interventional EXOGEN Studies. The B.O.N.E.S. clinical study design includes the parallel conduct of three independent study protocols which, taken together, are designed to prospectively include more than 3,000 EXOGEN-treated patients presenting with certain risk factors to be observed over time and propensity matched to one or more untreated controls extracted from a real-world health claims database provided by Truven Healthcare Analytics, generating a total sample size of at least 6,000 patients. The program involves the concurrent execution of three studies on pre-specified anatomical locations, such as the tibia, scaphoid and fifth metatarsal, with the objective of determining if the use of EXOGEN mitigates risk of fracture nonunion in predisposed patients.

We submitted a supplemental PMA to the FDA in December 2020 seeking approval of an expanded indication for EXOGEN, specifically, for the adjunctive treatment of acute and delayed metatarsal fractures to reduce the risk of non-union. This PMA supplement was based on and supported by clinical data in metatarsal fractures from the ongoing B.O.N.E.S. study. In April 2021, we received a letter from the FDA identifying certain deficiencies in the PMA supplement that must be addressed before the FDA can complete its review of the PMA supplement. The deficiencies include concerns about the data and endpoints from the B.O.N.E.S. study, and requests for re-analyses of certain data and provision of other information to support the findings. We are in the process of performing re-analysis of the data as requested by the FDA and are remaining engaged in discussions with the FDA to address the agency's concerns. In addition, in December 2021, we completed the follow up of all patients in the scaphoid fracture portion of the B.O.N.E.S. study. We plan on submitting a PMA supplement for this indication in the fourth quarter of 2022. We can give no assurance that we will be able to resolve the deficiencies identified by the FDA in a timely manner, or at all. Consequently, the FDA's decision on the PMA supplements may be delayed beyond the time originally anticipated. Moreover, if our responses do not satisfy the FDA's concerns, the FDA may not approve our PMA supplements seeking to expand the indications for use of EXOGEN in metatarsal and scaphoid fractures as proposed.

Sales and marketing

Our expansive direct sales and distribution channel across our product portfolio provides us with broad and differentiated customer reach, and allows us to serve physicians spanning the orthopedic continuum, including sports medicine, total joint reconstruction, hand and upper extremities, foot and ankle, podiatric surgery, trauma, spine and neurosurgery. We believe our products or procedures using our products are widely reimbursed by both public and private health insurers and are sold in the physician's office or clinic, ASCs, and in the hospital setting in the United States and across approximately 65 countries. Our sales team and distributors work directly with our physician customers on a frequent basis.

Products from our Pain Treatments, Restorative Therapies and Surgical Solutions verticals are sold by direct sales teams in the United States and a complementary distributor team for Surgical Solutions. That team is supported by a broad management team in addition to a market access team focused on expanding approvals with IDNs, GPOs and payers. Internationally our products are sold through a mix of direct and indirect sales teams. We support our entire sales organization with extensive training to help them excel, and we have a performance culture built on serving our core orthopedic patient customers and delivering our products to a variety of physicians and care settings.

Competition

The medical device industry is highly competitive, subject to change and significantly affected by activities of industry participants. We believe that the principal competitive factors in our markets are product features, value-added solutions, reliability, clinical evidence, reimbursement coverage, and price. Customer support, reputation, and efficient distribution are also important factors. The speed with which we can develop products, complete clinical testing and regulatory clearance processes and supply commercial quantities of our products to the market are therefore important competitive factors. We compete with many companies having more significant capital resources, larger research laboratories and more extensive distribution systems than we do.

Our Pain Treatments that we own or distribute compete with products from Ferring Pharmaceutical Inc., Fidia Farmaceutici S.p.A., DePuy Orthopaedics, Inc. (Johnson & Johnson), and Sanofi S.A, OrthogenRx Inc. and for peripheral nerve stimulation specifically. we compete with SPR Therapeutics, Nalu and Stimwave.

Our Surgical Solution products compete with products from Medtronic, DePuy Orthopaedics, Inc. (Johnson & Johnson), Stryker Corporation, NuVasive, Inc., SeaSpine, Inc., Orthofix Medical Inc., Zimmer Biomet Holdings, Inc. and Globus Medical Inc., Johnson & Johnson, Integra Life Sciences, Inc., and Söering.

Our Restorative Therapies compete with products marketed by Orthofix Medical Inc., Zimmer Biomet Holdings, Inc., DJO Global Inc., MiMedx, Integra Life Sciences, Organogenesis, Hanger Orthopedics, XFT Medical, Rewalk Robotics, Ekso Bionics, Aretech LLC and DIH Medical.

We strive to protect and enhance the proprietary technologies, inventions and improvements that we believe are important to our business, including seeking, maintaining and defending patent rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. We also rely on trademarks, trade secrets and careful monitoring of and contractual obligations with respect to our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Patents, trade secrets, assignments and licenses

We rely on a combination of patents, trade secrets, assignment and license agreements, and non-disclosure agreements to protect our proprietary intellectual property. We own numerous patents and/or patent applications which relate to our material products. Although in the aggregate our intellectual property is of material importance to our business, we do not believe that any single patent is of material importance to our product portfolio. As of December 31, 2021, we owned forty-five issued U.S. patents and twelve pending U.S. patent applications relating to our material products. We also owned seventy-five issued foreign patents and thirty-eight pending foreign patent applications directed to our material products. Our patents and patent applications as of December 31, 2021 directed to our material products are summarized below.

We own three issued U.S. patents and one issued foreign patent in Australia directed to our Exogen system. The U.S. patents are expected to expire between 2025 and 2029, and the foreign patent is expected to expire in 2025.

We own one issued U.S. patent, one pending U.S. patent application, eight issued foreign patents, and ten pending foreign patent applications directed to our OsteoAMP product, including foreign patents and patent applications in Europe, Asia, Canada and Australia. The issued U.S. patent is expected to expire in 2029. The issued foreign patents are expected to expire in 2029. The pending patent applications, if issued, are expected to expire in 2029, without accounting for potential patent term extensions and adjustments.

We also own one pending U.S. patent application and one pending Patent Cooperation Treaty application directed to MOTYS. Patents issuing from these applications, if any, are expected to expire in 2040, without accounting for potential patent term extensions and adjustments.

We also own ten issued U.S. patents and ten issued foreign patents in Australia, Canada, Europe, and Japan directed to our StimRouter system. The U.S. patents are expected to expire between 2026 and 2031, and the foreign patents are expected to expire between 2028 and 2030.

We also own twenty-one issued U.S. patents, three pending U.S. patent applications, forty-three issued foreign patents, and eight pending foreign patent applications directed to our L300 system, including foreign patents and patent applications in Australia, Canada, Europe, and Japan. The U.S. patents are expected to expire between 2026 and 2037, and the foreign patents are expected to expire between 2026 and 2037. The pending patent applications, if issued, are expected to expire between 2026 and 2037, without accounting for potential patent term extensions and adjustments.

We also own eight issued U.S. patents, six pending U.S. patent applications, twelve issued foreign patents, and thirteen pending foreign patent applications directed to our Vector Gait and Safety System, including foreign patents and patent applications in in Australia, Canada, Europe, and Japan. The U.S. patents are expected to expire between 2033 and 2038, and the foreign patents are expected to expire between 2034 and 2036. The pending patent applications, if issued, are expected to expire between 2033 and 2038, without accounting for potential patent term extensions and adjustments.

We also own one issued U.S. patent, one issued foreign patent in Australia and one pending foreign application in Canada directed to our Bioness Integrated Therapy System (“BITS”). The U.S. patent is expected to expire in 2037, and the foreign patent is expected to expire in 2036. The pending patent application, if issued, is expected to expire in 2036, without accounting for potential patent term extensions and adjustments.

We also own one issued U.S. patent and one pending U.S. patent application and five pending foreign patent applications directed to our TalisMann product, including foreign patent applications in Australia, Canada, Europe, Japan and one pending Patent Cooperation Treaty application. The U.S. patent is expected to expire in 2039. The pending patent applications, if issued, are expected to expire between 2039 and 2040, without accounting for potential patent term extensions and adjustments. We also own twenty-four issued U.S. patents and four pending U.S. patent applications directed to our BoneScalpel product.

Our patents and pending patent applications directed to our material products are further detailed in Exhibit 99.1 to this Annual Report on Form 10-K.

Trademarks

We own registered trademarks for Bioventus, Bioness, BITS, Bonescalpel, Cellxtract, Durolane, Exogen, Exponent, Gelsyn-3, LiveOn, L300 Go, Misonix, Ness, Ness L300, Nexus, OsteoAMP, Osteofuse, Prohesion, PureBone, SAFHS, Signafuse, Sonastar, StimRouter, TheraSkin, Therion and Vector Gait and Safety System in the United States.

Trade secrets

We may rely on trade secret law to protect some of our technology. Trade secrets, however, can be difficult to protect. We seek to protect our proprietary technology and manufacturing process, in part, by confidentiality and invention assignment agreements with employees, consultants scientific advisors and contractors, under which they are bound to assign to us certain inventions that are made during the course of performing work for us and relate to our business. These agreements further restrict the use and disclosure of proprietary information belonging to any third-party. These agreements further prohibit our employees from using, disclosing, or bringing onto the premises any proprietary information belonging to any third-party.

In addition to patents, trademarks, and trade secrets, we also rely on assignment and license agreements, pursuant to which we may license rights under patents held by third parties, and non-disclosure agreements, to protect our proprietary intellectual property. We obtain assignments or licenses of varying durations for certain of our products from third parties. We typically acquire rights under such assignments or licenses in exchange for lump-sum payments or arrangements under which we pay a percentage of sales to the licensor. However, while assignments or licenses to us generally are irrevocable, no assurance can be given that these arrangements will continue to be made available to us on terms that are acceptable to us, or at all. The terms of our license and assignment agreements vary in length from a specified number of years to the life of product patents or the economic life of the product. These agreements generally provide for royalty payments and termination rights in the event of a material breach.

We will continue to seek patent, trademark, and copyright protection as we deem advisable to protect the markets for our products and to support our research and development efforts.

Manufacturing and supply

We largely manufacture and assemble our medical device products at our production facilities located in Cordova, TN, Farmingdale, NY, Valencia, CA and Hod Hasharon, Israel. We believe our manufacturing operations are in compliance with regulations mandated by the FDA. We are an FDA-registered medical device manufacturer. Our manufacturing facilities and processes are subject to periodic inspections and audits by various federal, state and foreign regulatory agencies. Our products include components manufactured by other companies in the United States.

Some of our products and product components are manufactured exclusively by single-source third-party manufacturers, pursuant to multi-year supply agreements and may include minimum order volumes. We work closely with each of our manufacturing partners and provide them with a forecast, which enables them to better capacity plan and sequence their production efficiently.

We partnered with and MTF exclusively manufactured and supplied MOTYS to us while we pursue a BLA for the product. MTF was responsible for obtaining and storing all materials, including all tissue materials, required for the manufacture, testing, handling, packaging, labeling, release and delivery of the product to us.

We may encounter difficulty in obtaining materials, supplies and components adequate for our anticipated short-term needs. In addition, supply disruptions resulting from the COVID-19 pandemic may increase the price of, and make more difficult to obtain, materials, supplies or components. We intend to maintain sufficient supplies of the products and components from these single-source suppliers in the event that one or more of these suppliers were to encounter certain interruptions in supply.

Government regulation

Our products and operations are subject to extensive regulation by the FDA and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. In the United States, our products and product candidates are regulated as either medical devices under the Federal Food, Drug, and Cosmetic Act (FDCA), and its implementing regulations, or as drugs or biological products under the FDCA and the Public Health Service Act (PHSA), and their implementing regulations, each as amended and enforced by the FDA. The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices and biological products to ensure that such products distributed domestically are safe and effective for their intended uses and otherwise meet the applicable requirements of the FDCA and PHSA.

U.S. Regulation of Medical Devices

The majority of our products are regulated by the FDA as medical devices in the United States. Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, or approval of a PMA application. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed into Class III.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA's permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Class III devices require approval of a premarket approval application, or PMA, evidencing safety and effectiveness of the device.

To obtain 510(k) clearance, a manufacturer must submit a premarket notification demonstrating to the FDA's satisfaction that the proposed device is "substantially equivalent" to another legally marketed device that itself does not require PMA approval (a predicate device). A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but often takes longer. FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees for medical device establishments.

If the FDA agrees that the device is substantially equivalent to a lawfully marketed predicate device, it will grant 510(k) clearance to authorize the device for commercialization. If the FDA determines that the device is "not substantially equivalent," the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the *de novo* classification process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or *de novo* classification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), *de novo* classification request or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination not to seek a new 510(k) or other form of marketing authorization for the modification to the 510(k)-cleared product, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) clearance or PMA approval is obtained or a *de novo* classification is granted.

The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption (IDE), regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB), for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

In addition to clinical and preclinical data, the PMA must contain a full description of the device and its components, a full description of the methods, facilities, and controls used for manufacturing, and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA's review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel's recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers' or suppliers' facilities to ensure compliance with the QSR.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution, and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval. Certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement, or in some cases a new PMA.

After a device is cleared or approved or otherwise authorized for marketing, numerous pervasive regulatory requirements continue to apply unless explicitly exempt. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling and marketing regulations, which require that promotion is truthful, not misleading, fairly balanced and provide adequate directions for use and that all claims are substantiated, and also prohibit the promotion of products for unapproved or "off-label" uses and impose other restrictions on labeling; FDA guidance on off-label dissemination of information and responding to unsolicited requests for information;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- complying with requirements governing Unique Device Identifiers on devices and also requiring the submission of certain information about each device to the FDA's Global Unique Device Identification Database;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

HCT/Ps

Certain of our products are regulated as HCT/P. Section 361 of the PHSA authorizes the FDA to issue regulations to prevent the introduction, transmission or spread of communicable disease. HCT/Ps regulated as "Section 361" HCT/Ps are subject to requirements relating to registering facilities and listing products with the FDA, screening and testing for tissue donor eligibility, current Good Tissue Practices (cGTPs), when processing, storing, labeling and distributing HCT/Ps, including required labeling information, stringent record keeping and adverse event reporting, among other applicable requirements and laws. Section 361 HCT/Ps do not require 510(k) clearance, PMA approval, BLAs, or other premarket authorization from the FDA before marketing. However, to be regulated as a Section 361 HCT/P, the product must, among other things, be "minimally manipulated," which for structural tissue products means that the manufacturing processes do not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement and for cells or nonstructural tissue products, means that the manufacturing processes do not alter the relevant biological characteristics of cells or tissues. A Section 361 HCT/P must also be intended for "homologous use," which refers to use in the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor. HCT/Ps that do not meet the criteria of Section 361 are regulated under Section 351 of the PHSA. Unlike 361 HCT/Ps, HCT/Ps regulated as "351" HCT/Ps are subject to premarket review and/or approval by the FDA, as required.

In November 2017, the FDA released a guidance document entitled "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue—Based Products: Minimal Manipulation and Homologous Use—Guidance for Industry and Food and Drug Administration Staff." The guidance outlined the FDA's position that all lyophilized amniotic products are more than minimally manipulated and would therefore require a BLA to be lawfully marketed in the United States. The guidance also indicated that the FDA would exercise enforcement discretion, using a risk-based approach, with respect to the IND application and pre-market approval requirements for certain HCT/Ps that had been marketed without marketing authorization, including, among others, lyophilized amniotic products, for a period of 36 months from the issuance date of the guidance to allow manufacturers to pursue INDs and/or seek marketing authorizations. Under this approach, FDA indicated that high-risk products and uses could be subject to immediate enforcement action. In July 2020, the FDA extended its period of enforcement discretion to May 31, 2021. The FDA resumed enforcement of IND and premarket approval requirements with respect to these products as of June 1, 2021.

U.S. Regulation of Drugs and biological products

Certain of our products or product candidates, such as MOTYS, are regulated by the FDA as drugs or biological products, also called biologics. In the United States, the FDA regulates drugs under the FDCA, and its implementing regulations, and biologics under the FDCA and the PHSA and their implementing regulations. The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice requirements;
- submission to the FDA of an IND, which must become effective before clinical trials may begin;
- approval by an IRB or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials to establish the safety, efficacy, purity and potency of the proposed product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA for biologics or New Drug Application (NDA) for small molecule drugs after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA or NDA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMPs and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with Good Clinical Practices (GCPs); and
- FDA review and approval of the BLA or NDA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to beginning clinical trials of a new drug or biologic product in the United States, an IND must be submitted to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. An IND must become effective before human clinical trials may begin. Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. The BLA or NDA must include all relevant data available from preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. The submission of a BLA or NDA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

After the FDA evaluates a BLA or NDA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced and of select clinical trial sites, the FDA may issue an approval letter or a Complete Response Letter (CRL). An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA or NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA or NDA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA or NDA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may include limitations on the indicated uses for which such product may be marketed. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Any drugs or biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program fees for any marketed products. Biologic and drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Post-market Enforcement

The FDA may withdraw marketing authorizations for drugs, biologics (including Section 361 HCT/Ps) or medical devices if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions. Other potential consequences include, among other things: complete withdrawal of the product from the market, product recalls, fines, warning letters, untitled letters, clinical holds on clinical studies, refusal of the FDA to approve pending applications or supplements to approved applications, product seizures or detention, refusal to permit the import or export of products, consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs, the issuance of corrective information, injunctions, or the imposition of civil or criminal penalties.

In addition, the FDA closely regulates the marketing, labeling, advertising and promotion of drugs, biologics (including Section 361 HCT/Ps) and medical devices. A company can make only those claims relating to safety and efficacy, purity and potency that are cleared or approved by the FDA and in accordance with the provisions of the authorized label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties.

International regulation of medical devices

Sales of medical devices outside the United States are subject to foreign government regulations, which vary substantially from country to country. In order to market our products in other countries, we must obtain regulatory approvals or certifications and comply with extensive safety and quality regulations in other countries. The time required to obtain approval or certification by a foreign country may be longer or shorter than that required for FDA approval and the requirements may differ significantly.

EU regulation of medical devices

The European Union (EU) has adopted specific directives and regulations regulating the design, manufacture, clinical investigation, conformity assessment, labeling and adverse event reporting for medical devices.

Until May 25, 2021, medical devices were regulated by Council Directive 93/42/EEC (the EU Medical Devices Directive), which has been repealed and replaced by Regulation (EU) No 2017/745 (the EU Medical Devices Regulation). Our current certificates have been granted under the EU Medical Devices Directive whose regime is described below. However, as of May 26, 2021, some of the EU Medical Devices Regulation requirements apply in place of the corresponding requirements of the EU Medical Devices Directive with regard to registration of economic operators and of devices, post-market surveillance and vigilance requirements. Pursuing marketing of medical devices in the EU will notably require that our devices be certified under the new regime set forth in the EU Medical Devices Regulation when our current certificates expire.

Medical Devices Directive

Under the EU Medical Devices Directive, all medical devices placed on the market in the EU must meet the relevant essential requirements laid down in Annex I to the EU Medical Devices Directive, including the requirement that a medical device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must achieve the performance intended by the manufacturer and be designed, manufactured, and packaged in a suitable manner. The European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with these standards is viewed as the easiest way to satisfy the essential requirements as a practical matter as it creates a rebuttable presumption that the device satisfies that essential requirement.

To demonstrate compliance with the essential requirements laid down in Annex I to the EU Medical Devices Directive, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the essential requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system (the notified body must presume that quality systems which implement the relevant harmonized standards – which is ISO 13485:2016 for Medical Devices Quality Management Systems – conform to these requirements). If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU.

Throughout the term of the certificate of conformity, the manufacturer will be subject to periodic surveillance audits to verify continued compliance with the applicable requirements. In particular, there will be a new audit by the notified body before it will renew the relevant certificate(s).

Medical Device Regulation

The regulatory landscape related to medical devices in the EU recently evolved. On April 5, 2017, the EU Medical Devices Regulation was adopted with the aim of ensuring better protection of public health and patient safety. The EU Medical Devices Regulation establishes a uniform, transparent, predictable and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. Unlike the EU Medical Devices Directive, the EU Medical Devices Regulation is directly applicable in EU member states without the need for member states to implement into national law. This aims at increasing harmonization across the EU.

The EU Medical Devices Regulation became effective on May 26, 2021. The new Regulation among other things:

- strengthens the rules on placing devices on the market (e.g. reclassification of certain devices and wider scope than the EU Medical Devices Directive) and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- establishes explicit provisions on importers' and distributors' obligations and responsibilities;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk;
- sets up a central database (Eudamed) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo a clinical evaluation consultation procedure by experts before they are placed on the market.

Devices lawfully placed on the market pursuant to the EU Medical Devices Directive prior to May 26, 2021 may generally continue to be made available on the market or put into service until May 26, 2025, provided that the requirements of the transitional provisions are fulfilled. In particular, the certificate in question must still be valid. However, even in this case, manufacturers must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation, in particular the obligations described below.

The EU Medical Devices Regulation requires that before placing a device, other than a custom-made device, on the market, manufacturers (as well as other economic operators such as authorized representatives and importers) must register by submitting identification information to the electronic system (Eudamed), unless they have already registered. The information to be submitted by manufacturers (and authorized representatives) also includes the name, address and contact details of the person or persons responsible for regulatory compliance. The new Regulation also requires that before placing a device, other than a custom-made device, on the market, manufacturers must assign a unique identifier to the device and provide it along with other core data to the unique device identifier (UDI) database. These new requirements aim at ensuring better identification and traceability of the devices. Each device – and as applicable, each package – will have a UDI composed of two parts: a device identifier (UDI-DI) specific to a device, and a production identifier (UDI-PI) to identify the unit producing the device. Manufacturers are also notably responsible for entering the necessary data on Eudamed, which includes the UDI database, and for keeping it up to date. The obligations for registration in Eudamed will become applicable at a later date (as Eudamed is not yet fully functional). Until Eudamed is fully functional, the corresponding provisions of the EU Medical Devices Directive continue to apply for the purpose of meeting the obligations laid down in the provisions regarding exchange of information, including, and in particular, information regarding registration of devices and economic operators.

All manufacturers placing medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, serious incidents and Field Safety Corrective Actions (FSCAs) must be reported to the relevant authorities of the EU member states. Manufacturers are required to take FSCAs defined as any corrective action for technical or medical reasons to prevent or reduce a risk of a serious incident associated with the use of a medical device that is made available on the market. An FSCA may include the recall, modification, exchange, destruction or retrofitting of the device.

The advertising and promotion of medical devices is subject to some general principles set forth in EU legislation. According to the EU Medical Devices Regulation, only devices that are CE marked may be marketed and advertised in the EU in accordance with their intended purpose. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices, while not specific to the advertising of medical devices, also apply to the advertising thereof and contain general rules, for example, requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at a national level. EU member states' laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities and many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

The aforementioned EU rules are generally applicable in the European Economic Area (EEA) which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

Other countries

Many other countries have specific requirements for classification, registration and post marketing surveillance that are independent of the countries already listed. We obtain what we believe are the appropriate clearances for our products and conduct our business in accordance with the applicable laws of each country. This landscape is constantly changing and we could be found in violation if we interpret the laws incorrectly or fail to keep pace with changes. In the event of either of these occurrences, we could be instructed to recall products, cease distribution and/or be subject to civil or criminal penalties.

Anti-kickback, false claims and other healthcare laws

We are subject to a number of U.S. laws regulating healthcare fraud and abuse including 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, without limitation, CMS, other divisions of the U.S. Department of Health and Human Services (HHS), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, as well as state and local governments. Among other things, these laws and others generally (1) prohibit the provision of anything of value in exchange for the referral of patients or for the purchase, order, or recommendation of any item or service reimbursed by a federal healthcare program, (including Medicare and Medicaid); (2) require that claims for payment submitted to federal healthcare programs be truthful; and (3) require the maintenance of certain government licenses and permits.

Many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payer, in addition to items and services reimbursed under Medicaid and other state programs.

The federal Anti-Kickback Statute (AKS) prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, in cash or kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Several courts have interpreted the AKS's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the AKS has been violated. The AKS includes statutory exceptions and regulatory safe harbors that protect certain arrangements. Failure to meet the requirements of an applicable AKS safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances, including the parties' intent and the arrangement's potential for abuse, and may be subject to greater scrutiny by enforcement agencies.

The Stark Law prohibits a physician who has a financial relationship, or who has an immediate family member who has a financial relationship, with entities providing designated health services (DHS) from referring Medicare and Medicaid patients to such entities for the furnishing of DHS, unless an exception applies. The Stark Law also prohibits the entity from billing for any such prohibited referral. Unlike the AKS, the Stark Law is violated if the financial arrangement does not meet an applicable exception, regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral.

The Federal False Claims Act (FCA) prohibits a person from knowingly presenting, or caused to be presented, a false or fraudulent request for payment from the federal government, or from making a false statement or using a false record to have a claim approved. A claim includes “any request or demand” for money or property presented to the United States government. Moreover, the government may assert that a claim including items and services resulting from a violation of the AKS or the Stark Law constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Penalties for a violation of the FCA include fines for each false claim, plus up to three times the amount of damages caused by each false claim. Private individuals also have the ability to bring actions under these false claims laws in the name of the government alleging false and fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement.

Further, the Civil Monetary Penalties Statute authorizes the imposition of civil monetary penalties, assessments and exclusion against an individual or entity based on a variety of prohibited conduct, including, but not limited to offering remuneration to a federal healthcare program beneficiary that the individual or entity knows or should know is likely to influence the beneficiary to order or receive healthcare items or services from a particular provider. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the AKS and civil FCA. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The Department of Health and Human Services Office of Inspector General emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, the routine waivers of copayments and deductibles offered to patients covered by commercial payers may implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud.

The Health Insurance Portability and Accountability Act (HIPAA) also established federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payers, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We also participate in state government-managed Medicaid programs as well as certain other qualifying federal and state government programs where discounts and mandatory rebates are provided to participating state and local government entities. In connection with several of these government programs, we are required to report prices to various government agencies. Pricing calculations vary among programs. The calculations are complex and are often subject to interpretation by the reporting entities, government agencies and the courts. Government agencies may also make changes in program interpretations, requirements or conditions of participation, some of which may have implications for amounts previously estimated or paid. By way of example, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), requires that manufacturers report data to CMS on pricing of covered drugs reimbursed under Medicare Part B. These are generally drugs and biologicals, such as injectable products, that are administered “incident to” a physician service and in general are not self-administered. Effective January 1, 2005, ASP became the basis for reimbursement to physicians and suppliers for drugs and biologicals covered under Medicare Part B, replacing the average wholesale price (AWP), provided and published by pricing services. In general, we must comply with all reporting requirements for any drug that is separately reimbursable under Medicare. The SUPARTZ FX product is reimbursed under Medicare Part B and, as a result, we provide ASP data on this product to CMS on a quarterly basis. Several states in which we operate have also adopted similar fraud and abuse laws as described above. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any payer, including patients, employers and commercial insurers, not just those reimbursed by a federally funded healthcare program.

Violation of any of these laws or any other governmental regulations that apply may result in significant penalties, including, without limitation, administrative civil and criminal penalties, damages, disgorgement, fines, additional reporting requirements and compliance oversight obligations, in the event that a corporate integrity agreement or other agreement is required to resolve allegations of noncompliance with these laws, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and/or individual imprisonment.

Foreign Corrupt Practices Act

We are subject to the Foreign Corrupt Practices Act of 1977, as amended (FCPA). The FCPA prohibits U.S. companies and their representatives from processing, offering, or making payments of money or anything of value to foreign officials with the intent to obtain or retain business or seek a business advantage. In certain countries, the health care professionals we or our distributors regularly interact with may meet the definition of a foreign government official for the purposes of the FCPA. Our international activities create the risk of unauthorized payments or offers of payments by our employees, consultants and agents, including distributors, even though they may not always be subject to our control. Our existing safeguards may prove to be less than effective, and our employees, consultants, and agents may engage in conduct for which we might be held responsible. A determination that our operations or activities are not, or were not, in compliance with U.S. or foreign laws or regulations could result in the imposition of substantial fines, interruptions of business, loss of suppliers, vendor or other third-party relationships, termination of necessary licenses or permits, and legal or equitable sanctions. Other internal or governmental investigations or legal or regulatory proceedings, including lawsuits brought by private litigants, may also follow as a consequence.

ISO Standards

We also operate and maintain a Quality Management System that is designed to comply with the requirements of International Standards ISO 13485: 2016 Medical Devices – Quality Management Systems. This system encompasses the principles of enhancing customer satisfaction through the effective application of processes for control, monitoring, and continual improvement, which is designed to ensure that we consistently meet or exceed customer expectations and applicable statutory/regulatory requirements

Privacy and data protection laws

We are subject to a number of federal, state and foreign laws and regulations that govern the collection, use, disclosure, and protection of health-related and other personal information, including health information privacy and security laws, data breach notification laws, and consumer protection laws and regulations (e.g., Section 5 of the Federal Trade Commission Act). For example, HIPAA imposes obligations on “covered entities,” including certain healthcare providers, such as us, health plans, and healthcare clearinghouses, and their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, as well as their covered subcontractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Entities that are found to be in violation of HIPAA, whether as the result of a breach of unsecured protected health information (PHI), a complaint about privacy practices, or an audit by HHS, may be subject to significant civil, criminal, and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance.

In addition, certain state and foreign laws, such as the California Consumer Privacy Act (CCPA) California Privacy Rights Act (CPRA), General Data Protection Regulation (GDPR) and the United Kingdom General Data Protection Regular (UK GDPR) govern the privacy and security of personal information, including health-related information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Coverage and reimbursement

Our products may be reimbursed by third-party payors, such as government programs, including Medicare and Medicaid, or private insurance plans and healthcare networks. As a result, demand for our products is and will continue to be dependent in part on the coverage and reimbursement policies of these payors. The manner in which reimbursement is sought and obtained varies based upon the type of payor involved and the setting in which the product is furnished and utilized. Reimbursement from Medicare, Medicaid and other third-party payors may be subject to periodic adjustments as a result of legislative, regulatory and policy changes, as well as budgetary pressures. Possible reductions in, or eliminations of, coverage or reimbursement by third-party payors, or denial of, or provision of uneconomical reimbursement for new products may affect our customers’ revenue and ability to purchase our products. Any changes in the healthcare regulatory, payment or enforcement landscape relative to our customers’ healthcare services have the potential to significantly affect our operations and revenue. The Medicare program is expected to continue to implement a new payment mechanism for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items via the implementation of its competitive bidding program. Bone growth therapy devices are currently exempt from this competitive bidding process.

Outside of the United States, the pricing of medical devices and prescription pharmaceuticals is subject to governmental control in many countries. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular therapy to currently available therapies or so called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

Employee and Human Capital Resources

As of December 31, 2021, we had approximately 1,200 employees, none of whom were covered by collective bargaining agreements. Most of these employees are located in the United States with approximately 125 located outside the United States. We believe that our relations with our employees are generally good.

We value our employees and regularly benchmark total rewards we provide, such as short and long term compensation, 401(k) contributions, health, welfare and quality of life benefits, paid time off and personal leave, against our industry peers to ensure we remain competitive and attractive to potential new hires. We seek to create a workplace environment that fosters personal and business successes by offering training and development programs, which further assist our current employees in meeting and exceeding our established standards of performance, and a leadership development program specially designed to help our new leaders be successful in their expanded roles.

Additionally, to build on our culture of treating all individuals fairly and respectfully, we have established a Diversity, Equity and Inclusion (DE&I) Council and formed several Employee Resource Groups (ERGs). The DE&I Council and ERGs are voluntary, employee-led groups of employees who come together in their workplace based on shared characteristics or life experiences. The stated mission of the DE&I Council is to foster a culture and identity that drives diversity, equity and inclusion as we engage and develop current employees and recruit future talent, all working together to build a transformative work environment. Our ERGs are generally intended to provide support, enhance career development, and contribute to personal development in the work environment. The goals of these and other similar initiatives is to encourage broad and diverse viewpoints to achieve the best outcomes for the patients, healthcare providers, and employees we serve.

Our Organizational Structure

Bioventus Inc. is a Delaware corporation formed on December 22, 2015 and functions as a holding company with no direct operations and our principal asset is the equity interest in BV LLC. We are headquartered in Durham, North Carolina. On February 16, 2021, we closed an initial public offering (IPO). Our IPO was conducted through what is commonly referred to as an umbrella partnership C corporation (UP-C) structure. In connection with the IPO and the UP-C structure, we completed a series of organizational transactions including, without limitation, the following:

- the limited liability company agreement of BV LLC was amended and restated (Bioventus LLC Agreement) to, among other things, (i) provide for a new single class of common membership interests in BV LLC (LLC Interests), (ii) exchange all of the then existing membership interests of the holders of BV LLC membership interests (Original LLC Owners) for LLC Interests and (iii) appoint Bioventus Inc. as the sole managing member of BV LLC; and
- the acquisition, by merger, of certain members of BV LLC (Former LLC Owners), for which we issued shares of Class A common stock as merger consideration (Merger).
- We amended and restated its certificate of incorporation to authorize Class A common stock, Class B common stock and undesignated preferred stock. Class B common stock has voting rights but no economic rights.

We have a majority economic interest, the sole voting interest in, and control the management of, BV LLC. As a result, we will consolidate the financial results of BV LLC and reports a non-controlling interest representing the LLC Interests held by Smith & Nephew, Inc. (Continuing LLC Owner). Refer to *Note 1. Organization* of the *Notes to the Consolidated Financial Statements* within *Part II, Item 8. Financial Statements and Supplementary Data* of this Annual Report on Form 10-K for additional information about the organizational transactions completed as part of the IPO.

Available Information

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

Item 1A. Risk Factors

Described below are certain risks that we believe apply to our business and the industry in which we operate. You should carefully consider each of the following risk factors in conjunction with other information provided in this Annual Report on Form 10-K (Annual Report) and in our other public disclosures. The risks described below highlight potential events, trends or other circumstances that could adversely affect our business, financial condition, results of operations, cash flows, liquidity or access to sources of financing, and consequently, the market value of our Class A common stock. These risks could cause our future results to differ materially from historical results and from guidance we may provide regarding our expectations of future financial performance. The risks described below are those that we have identified as material and is not an exhaustive list of all the risks we face. There may be others that we have not identified or that we have deemed to be immaterial. All forward-looking statements made by us or on our behalf are qualified by the risks described below.

Risks related to our business

Our business may continue to experience adverse impacts as a result of the COVID-19 pandemic.

In 2020, the COVID-19 pandemic spread around the world and in the U.S. and, more recently, new variants of the virus have emerged, some of which have shown to be more contagious. The COVID-19 pandemic has had widespread, rapidly evolving and unpredictable impacts on global society, economies, financial markets and business practices. Federal and state governments have implemented measures in an effort to minimize the spread of the virus and ongoing effects of the pandemic, including social distancing, travel restrictions, border closures, limitations on public gatherings, mandatory closure or reduced capacity of business, work from home, supply chain logistical changes and other measures, which have caused global business disruptions and significant volatility in U.S. and international debt and equity markets. Our business, results of operations and financial condition have been, and may continue to be, materially impacted due to the decrease in patient visits and elective procedures and any future temporary cessations of elective procedures and could be further impacted by delays in payments from customers, supply chain interruptions, extended “shelter-in-place” orders or advisories, facility closures or other reasons related to the pandemic. Furthermore, the long-term impact of COVID-19 on our business will depend on many factors, including, but not limited to, the duration and severity of the pandemic, new and ongoing measures taken in response to the pandemic, the availability and effectiveness of vaccines and therapeutics to combat COVID-19, future mutations of the virus, the impact on economic activity from the pandemic and actions taken in response and the resulting impact it has on our partners, patients and communities in which we operate, all of which continue to be uncertain. For example, there has been a decrease in patient visits to hospitals due to risk and fear of exposure to COVID-19, as well as decreases in, or temporary moratoriums on, elective procedures, which may be re-imposed in the future. In addition to lower sales, we experienced certain decreased costs as a result of the pandemic including declines in travel and lower compensation related expenses during 2020. We also implemented other various cost reduction initiatives and measures to safeguard liquidity, refer to *Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations*, for further details on the impact of COVID-19 on our business.

To the extent the COVID-19 disruptions continue to adversely impact our business, results of operations and financial condition, it may also have the effect of heightening many of the other risks described in *Part I, Item 1A. Risk Factors*, including risks relating to our ability to successfully commercialize new developed or acquired products or therapies, consolidation in the healthcare industry, disruptions in the supply or manufacturing of our products or their components, intensified pricing pressure as a result of changes in the purchasing behavior of hospitals and maintenance of our numerous contractual relationships.

We are highly dependent on a limited number of products.

Our HA products accounted for 51%, 53% and 54% of our total revenue for the years ended December 31, 2021, 2020 and 2019, respectively. We expect that sales of such products will continue to account for a substantial portion of our revenue, and therefore, our ability to execute our growth strategy and maintain profitability will depend upon the continued demand for these products. If the supply and distribution agreements for any of our HA products were terminated, our revenue would be impaired. If our HA products fail to maintain their market acceptance for any reason, our business, results of operations and financial condition may be adversely affected.

Our long-term growth depends on our ability to develop, acquire and commercialize new products, line extensions or expanded indications.

Our industry is highly competitive and subject to rapid change and technological advancements. Therefore, it is important to our business that we continue to introduce new products and/or enhance our existing product offerings through line extensions or expanded indications. Developing, acquiring and commercializing products is expensive, time-consuming and could divert management's attention away from our existing business. Even if we are successful in developing additional products, the success of any new product offering or enhancements to existing products will depend on several factors, including our ability to:

- properly identify and anticipate the needs of healthcare professionals and patients;
- develop and introduce new products, line extensions and expanded indications in a timely manner;
- distinguish our products from those of our competitors;
- avoid infringing upon the intellectual property rights of third-parties and maintain necessary intellectual property licenses from third-parties;
- demonstrate, if required, the safety and efficacy of new products with data from preclinical studies and clinical trials;
- obtain clearance, approval, or certification, if required, from the FDA and other regulatory agencies or notified bodies, for such new products, line extensions and expanded indications, and maintain full compliance with FDA and other regulatory requirements applicable to new devices or products or modifications of existing devices or products;
- provide adequate training to potential users of our products;
- market acceptance of our newly developed or acquired products or therapies;
- receive adequate coverage and reimbursement for our products; and
- maintain an effective and dedicated sales and marketing team.

If we are unsuccessful in developing, acquiring and commercializing new products or enhancing our existing product offerings through line extensions and expanded indications, our ability to increase our net sales may be impaired.

Additionally, our research and development efforts may require a substantial investment of time and resources before we are adequately able to determine the commercial viability of a new product, technology, material or other innovation. Such efforts may not result in the development of a viable product. In addition, even if we are able to successfully develop new active healing products, line extensions and expanded indications, these products may not produce sales in excess of the costs of development and they may be rendered obsolete by changing customer preferences or the introduction by our competitors of products embodying new technologies or features.

Demand for our existing products and any new products, line extensions or expanded indications depends on the continued and future acceptance of our products by physicians, patients, third-party payers and others in the medical community.

We cannot be certain that our existing products and any new products, line extensions or expanded indications that we develop will achieve or maintain market acceptance. Third-party payers may be reluctant to continue to cover our products at their current prices. Further, new injectable therapies or oral medications may become available that help manage OA joint pain in a more convenient and/or cost effective manner than our HA viscosupplementation therapies. With respect to our Surgical Solutions, new allograft, DBMs, synthetics, growth factors, or other enhancements to our existing implants may never achieve broad market acceptance, which can be affected by a lack of clinical acceptance of Surgical Solutions products and technologies, introduction of competitive treatment options which render Surgical Solutions products and technologies too expensive or obsolete and difficulty training surgeons in the use of Surgical Solutions products and technologies. Media reports or other negative publicity concerning both methods of tissue recovery from donors and actual or potential disease transmission from donated tissue may limit widespread acceptance by the medical community of our allografts, growth factor and DBMs, whether directed at these products generally or our products specifically. Unfavorable reports of improper or illegal tissue recovery practices by any participant in the industry, both in the United States and internationally, as well as incidents of improperly processed tissue leading to transmission of disease, may broadly affect the rate of future tissue donation and market acceptance of allograft based technologies by the medical community.

In addition, we believe that even if the medical community generally accepts our existing portfolio of products and any new products, line extensions or expanded indications, acceptance and recommendations by influential members of the medical community will be important to their broad commercial success. If the medical community does not broadly accept our products, we may not remain competitive in the market, which could adversely affect our business, results of operations and financial condition.

The proposed down-classification of non-invasive bone growth stimulators, including Exogen, by the FDA could increase future competition for bone growth stimulators and otherwise adversely affect our sales of Exogen.

In 2020, the FDA published a Federal Register notice announcing its proposal to reclassify non-invasive bone growth stimulators, such as Exogen, from Class III medical devices to Class II with special controls. Class III devices are subject to the most stringent regulatory pathway for approval for medical devices requiring, among other things, rigorous clinical studies and pre-approval manufacturing review. Class II devices may be cleared for marketing by the FDA under the 510(k) pathway if they are determined to be substantially equivalent to a legally marketed predicate device. The 510(k) clearance process does not always require clinical testing, and is generally less onerous than the premarket approval process applicable to Class III devices. Also in 2020, the Orthopaedic and Rehabilitation Devices Panel of the FDA Medical Devices Advisory Committee met and ultimately voted in favor of FDA's proposal to down-classify non-invasive bone growth stimulators.

While FDA has not yet finalized its proposal to down-classify non-invasive bone growth stimulators, should such down-classification occur now or in the future, we may face additional competition from new market entrants who would be able to pursue marketing authorization through the 510(k) clearance pathway instead of the more onerous and burdensome PMA approval process. Class II devices that qualify as durable medical equipment under the Medicare program may also be eligible for inclusion in Medicare's competitive bidding program for durable medical equipment, prosthetic and orthotic supplies (DEMPOS). As a result of down-classification, Exogen could face additional competition or we could receive lower reimbursement amounts, all of which could adversely affect our business, results of operations and financial condition.

If we are unable to achieve and maintain adequate levels of coverage and/or reimbursement for our products, the procedures using our products, or any future products we may seek to commercialize, the commercial success of these products may be severely hindered.

Our products are purchased by healthcare providers and customers who typically bill third-party payers or private insurance plans and healthcare networks, to cover all or a portion of the costs and fees associated with our products. These third-party payers and insurers may deny reimbursement if they determine that a device or product provided to a patient or used in a procedure does not meet applicable payment criteria or if the policyholder's healthcare insurance benefits are limited.

As required by law, CMS, which administers the Medicare program, has continued efforts to implement a competitive bidding program for selected DEMPOS 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 like Exogen are currently exempt from this competitive bidding process, but may be eligible for inclusion if the FDA's proposed down-classification order becomes effective. 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.

Limits put on reimbursement by third-party payers, whether foreign or domestic, governmental or commercial, could make it more difficult to buy our products and substantially reduce, or possibly eliminate, patient access to our products. The healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control rising healthcare costs by imposing lower payment rates and negotiating reduced contract rates with providers and suppliers. For example, should we consummate the acquisition of CartiHeal, the commercial success of Agili-C may be adversely affected if we are not able to obtain adequate third-party reimbursement for that product.

There is no uniform policy of coverage and reimbursement for our products or procedures using our products among third-party payers in the United States, and coverage and reimbursement for our products and procedures using our products can differ significantly from payer to payer. Further, these payers regularly review new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and treatments. Third-party payers may not consider our products to be medically necessary or cost-effective for certain indications or off-label uses or for all uses, and as a result, may not provide coverage for the products. For example, Blue Cross Blue Shield Association's Evidence Street platform issued a report in April 2017 questioning the efficacy of our Exogen system, which resulted in several non-coverage policies being issued by member organizations in 2018. Additionally, to the extent that third party payers decide that they are no longer willing to provide reimbursement for physician prescribed off-label uses of Exogen, sales may be negatively impacted. See *Part I, Item 1A. Risk Factors—Risks related to government regulation—We may be subject to enforcement action if we engage in improper marketing or promotion of our products, and the misuse or off-label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.*

We may also be required to conduct expensive clinical studies to justify coverage and reimbursement and/or the level of reimbursement relative to other therapies. 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. If third-party payers or insurers that currently cover or reimburse our products or the procedures in which they are used limit their coverage or reimbursement in the future, or if other third-party payers or insurers issue similar policies, this could impact our ability to sell our products, force us to lower the price we charge for our products, and adversely affect our business, results of operations and financial condition.

CMS periodically reviews medical study literature to determine how the literature addresses certain procedures and therapies in the Medicare population. The impact that these assessments could have on Medicare or third-party payer coverage determinations for our products is currently unknown, but we cannot provide assurances that the resulting actions will not restrict Medicare or other insurance coverage for our products. In addition, there can be no assurance that we or our distributors will not experience significant coverage or reimbursement impediments in the future related to these or other programs and policies of CMS. Specifically, drug pricing reform legislation and executive orders, which could negatively affect the reimbursement rates paid our HA viscosupplements, have been issued by the White House and proposed and enacted by Congress. The Consolidated Appropriations Act, 2021 (CAA), was signed into law on December 27, 2020 and, pursuant to implementing regulations promulgated by CMS, expands price reporting obligations for manufacturers of certain products reimbursed under Medicare Part B beginning January 1, 2022. CMS could utilize the new pricing information to adjust Medicare payment for these products, which now include all of our HA viscosupplements, beginning in July 2022. Should CMS choose to use our reported price data to determine the reimbursement rates available to our customers for our HA products such as Durolane and Gelsyn-3, such rates could differ from those currently available, which may affect the commercial success of those products. We cannot predict the extent to which this law, or other proposals that may be enacted in the future, may impact the commercial success of our HA viscosupplements and other products.

Private payers may adopt coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. In addition, for some governmental programs, such as Medicaid, coverage and reimbursement differs from state to state. Medicaid payments to physicians, facilities and other providers are often lower than payments by other third-party payers and some state Medicaid programs may not pay an adequate amount for the procedures performed with our products, if any payment is made at all. If CMS, other government agencies or private payers lower their reimbursement rates, or if any of the proposed drug pricing executive orders or legislative reforms are enacted, the commercial success of our products may be adversely affected.

Our business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if a GPO, third-party payers or other similar entities exclude us from being a supplier.

Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third-party payers. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may increase requests for pricing concessions or risk vendor exclusion. For example, non-clinical staff at hospitals are increasingly involved in the evaluation of products and product purchasing decisions. In order for us to sell our products, we must convince such staff as well as physicians and hospitals that our products are attractive alternatives to competing products for use in surgical procedures. Additionally, GPOs, independent delivery networks and large single accounts may continue to use their market power to consolidate purchasing decisions for physicians. Third-party payers may also continue to use their market power to reduce the reimbursement for our products by increasing the rebates we are required to pay them when our products are covered, which may negatively impact our results. We expect that market demand, government regulation, third-party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our customers, which may exert further downward pressure on the prices of our products.

We may be unable to complete proposed acquisitions or to successfully integrate proposed or recent acquisitions in a cost-effective and non-disruptive manner.

Our success depends on our ability to enhance and broaden our product offerings in response to changing customer demands, competitive pressures and advances in technologies. We continue to search for viable acquisition candidates or strategic alliances that would expand our market sector and/or global presence, as well as additional products appropriate for current distribution channels. Accordingly, we have previously and may in the future pursue the acquisition of, or joint ventures relating to, new businesses, products or technologies instead of developing them internally. Our future success will depend, in part, upon our ability to manage the expanded business following these acquisitions, including challenges related to the management and monitoring of new operations and associated increased costs and complexity associated with the acquisition of Misonix, Bioness and other acquisitions. In addition, we have entered into an Option and Equity Purchase Agreement with CartiHeal providing for, among other things, an exclusive option to acquire CartiHeal under certain terms and conditions. Other risks involving potential future and completed acquisitions and strategic investments include:

- risks associated with conducting due diligence;
- problems integrating the purchased technologies, products or business operations;
- inability to achieve the anticipated synergies and overpaying for acquisitions or unanticipated costs associated with acquisitions;
- invalid net sales assumptions for potential acquisitions;
- issues maintaining uniform standards, procedures, controls and policies;
- diversion of management’s attention from our core business;
- adverse effects on existing business relationships with suppliers, distributors and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential loss of key employees of acquired businesses; and
- increased legal, accounting and compliance costs.

We compete with other companies for these opportunities, and we may be unable to consummate such acquisitions or joint ventures on commercially reasonable terms, or at all. In addition, acquired businesses may have ongoing or potential liabilities, legal claims (including tort and/or personal injury claims) or adverse operating issues that we fail to discover through due diligence prior to the acquisition. Even if we are aware of such liabilities, claims or issues, we may not be able to accurately estimate the magnitude of the related liabilities and damages. In particular, to the extent that prior owners of any acquired businesses or properties failed to comply with or otherwise violated applicable laws or regulations, failed to fulfill their contractual obligations to their customers, or failed to satisfy legal obligations to employees or third parties, we, as the successor, may be financially responsible for these violations and failures and may suffer reputational harm or otherwise be adversely affected. Acquisitions also frequently result in the recording of goodwill and other intangible assets which are subject to potential impairment in the future that could harm our financial results. If we were to issue additional equity in connection with such acquisitions, this may dilute our stockholders.

Pricing pressure from our competitors or hospitals may affect our ability to sell our products at prices necessary to support our current business strategies.

Medical device companies, healthcare systems and GPOs have intensified competitive pricing pressure as a result of industry trends and new technologies. Purchasing decisions are gradually shifting to hospitals, IDNs and other hospital groups, with surgeons and other physicians increasingly acting only as “employees.” Changes in the purchasing behavior of hospitals or the amount third-party payers are willing to reimburse our customers for procedures using our products, including those as a result of healthcare reform initiatives, could create additional pricing pressure on us. In addition to these competitive forces, we continue to see pricing pressure as hospitals introduce new pricing structures into their contracts and agreements, including fixed price formulas, capitated pricing and episodic or bundled payments intended to contain healthcare costs. If such trends continue to drive down the prices we are able to charge for our products, our profit margins will shrink, adversely affecting our business, results of operations and financial condition.

If we fail to successfully enter into purchasing contracts for our Surgical Solutions products or engage in contract bidding processes internationally, we may not be able to receive access to certain hospital facilities and our sales may decrease.

In the United States, the hospital facilities where physicians treat patients with our Surgical Solution products typically require us to enter into purchasing contracts. The process of securing a satisfactory contract can be lengthy and time-consuming and require extensive negotiations and management time. In certain international jurisdictions, from time to time, certain institutions require us to engage in a contract bidding process in the event that such institutions are considering making purchase commitments that exceed specified cost thresholds, which vary by jurisdiction. These processes are only open at certain periods of time, and we may not be successful in the bidding process. If we do not receive access to hospital facilities through these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, our sales may stagnate or decrease and our operating results may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

Governments outside the United States may not provide coverage or reimbursement of our products, which may adversely affect our business, results of operations and financial condition.

Acceptance of our products in international markets 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, and include both government-sponsored healthcare and private insurance. Our products may not obtain international coverage and reimbursement approvals in a timely manner, if at all, which may require consumers desiring our products to purchase them directly. Third-party coverage and reimbursement for our products or any of our products in development for which we may receive regulatory approval may not be available or adequate in international markets, which could adversely affect our business, results of operations and financial condition.

Our future growth depends on physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products.

We focus our sales, marketing and training efforts on physicians, surgeons and other health care professionals. The acceptance of our products depends in part on our ability to educate physicians as to the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products compared to alternative products, procedures and therapies. If physicians, surgeons or other healthcare professionals 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 physicians, surgeons or other healthcare professionals regarding our products may impair our ability to achieve market acceptance of our products.

We compete and may compete in the future against other companies, some of which have longer operating histories, more established products or greater resources than we do, which may prevent us from achieving increased market penetration or improved operating results.

The medical device industry is characterized by intense competition, subject to rapid change and significantly affected by market activities of industry participants, new product introductions and other technological advancements. We believe that our competitors have historically dedicated and will continue to dedicate significant resources to promote their products or to develop new products. We have competitors in the United States and internationally, including major medical device and pharmaceutical companies, biotechnology companies and universities and other research institutions.

These companies and other industry participants may develop alternative treatments, products or procedures that compete directly or indirectly with our products. If alternative treatments are, or are perceived to be, superior to our products, sales of our products could be adversely affected and our results of operations could suffer. Our competitors may also develop and patent processes or products earlier than we can or obtain regulatory clearances, approvals or certifications for competing products more rapidly than we can, which could impair our ability to develop and commercialize similar processes or products.

Many of our current and potential competitors are major medical device and pharmaceutical companies that have substantially greater financial, technical and marketing resources than we do, and they may succeed in developing products that would render our products obsolete or noncompetitive. It is also possible that our competition will be able to leverage their large market share to set prices at a level below that which is profitable for us.

Some of our competitors enjoy several competitive advantages over us, including:

- greater financial, human and other resources for product research and development, sales and marketing and litigation;
- significantly greater name recognition;
- control of intellectual property and more expansive portfolios of intellectual property rights, which could impact future products under development;

- greater experience in obtaining and maintaining regulatory clearances, approvals or certifications for products and product enhancements;
- established relationships with hospitals and other healthcare providers, physicians, suppliers, customers and third-party payers;
- additional lines of products, and the ability to bundle products to offer greater incentives to gain a competitive advantage; and
- more established sales, marketing and worldwide distribution networks.

The potential introduction by competitors of products that compete with our existing or planned products may also make it difficult to market or sell our 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 market generally.

As a result, our ability to compete successfully will depend on our ability to develop proprietary products that reach the market in a timely manner, receive adequate coverage and reimbursement from third-party payers, and are safer, less invasive and more effective than alternatives available for similar purposes. If we are unable to do so, our sales or margins could decrease, which would adversely affect our business, results of operations and financial condition.

The reclassification of our HA products from medical devices to drugs in the United States by the FDA could negatively impact our ability to market these products and may require that we conduct costly additional clinical studies to support current or future indications for use of those products.

On December 18, 2018, the FDA published notice in the Federal Register announcing its intention to reconsider the appropriate classification of HA intra-articular products intended for the treatment of pain in OA of the knee. Although HA products intended for this use have previously been regulated as medical devices, in its notice the FDA stated that current published scientific literature supports that HA products achieve their primary intended purpose of treatment of pain in OA of the knee through biological action in the body which would require such products being classified as drugs. The FDA has encouraged organizations intending to submit applications for changes in indications for use, formulation, or route of administration of their HA products to obtain from the FDA an informal or formal classification and jurisdiction determination as a drug or device through a pre-request for designation or request for designation, respectively, prior to submission of such application. However, the FDA to date has taken no action to reclassify HA products from medical devices to drugs, or indicated what the potential ramifications would be for currently marketed HA products if a reclassification were to occur.

If the reclassification of HA products were to occur, the FDA may not allow us to continue to market our HA products without submitting additional clinical trial data, obtaining approval of a NDA for these products, or without otherwise complying with new conditions or limitations on how those products are marketed. Clinical testing can take years to complete, can be expensive and carries uncertain outcomes, and there is no guarantee that would be able to successfully obtain and maintain any required regulatory approvals. These new regulatory obligations could result in increased regulation and would subject our HA products to a new set of regulatory requirements to which they have not been previously subject. These changes could ultimately increase our costs and adversely impact our business, results of operations and financial condition if they were to be implemented. See *Part I, Item 1A. Risk Factors—Risks related to our business—If we are unable to achieve and maintain adequate levels of coverage and/or reimbursement for our products, the procedures using our products, or any future products we may seek to commercialize, the commercial success of these products may be severely hindered*.

Our ability to maintain our competitive position depends on our ability to attract, retain and motivate our senior management team and highly qualified personnel, and our failure to do so could adversely affect our business, results of operations and financial condition.

We believe that our continued success depends to a significant extent upon the skill, experience and performance of members of our senior management team, who have been critical to the management of our operations and implementation of our strategy, as well as our ability to continue to attract, retain and motivate additional executive officers, and other key employees and consultants, such as those individuals who are engaged in our research and development efforts. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and could therefore adversely affect our business, results of operations and financial condition. In addition, we do not carry any “key person” insurance policies that could offset potential loss of service under applicable circumstances.

Competition for experienced employees in the medical device industry can be intense. To attract, retain and motivate qualified employees, we may utilize equity-based incentive awards such as employee stock options. If the value of such equity incentive awards does not appreciate as measured by the performance of the price of our Class A 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 adversely affect our business, results of operations and financial condition and/or require us to increase the amount we expend on cash and other forms of compensation.

If we fail to properly manage our anticipated growth, our business could suffer.

We have been growing steadily in recent periods, prior to the impact of COVID-19. We intend to continue to grow and may experience periods of rapid growth and expansion, which could place a significant additional strain on our limited personnel, information technology systems and other resources. In particular, our sales force and distributor network requires significant management, training, financial and other supporting resources. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals.

To achieve our revenue goals, we must also successfully increase supply of our products to meet expected customer demand. In the future, we may experience difficulties with yields, quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability and increases in expenses which could adversely affect our ability to generate revenue.

Future growth will also impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure.

In order to manage our operations and growth we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our operating results and business could suffer.

We may not be able to strengthen our brand and the brands associated with our products.

We believe that strengthening the Bioventus brand and the brands associated with our products is critical to achieving widespread acceptance of our products, particularly because of the rapidly developing nature of the market for active healing products as well as the recent expansion of our product portfolio due to our recent acquisitions. Promoting and positioning our brand will depend largely on the success of our marketing efforts and the reliability of our products. Historically, our efforts to build our brand have involved marketing expenses, and it is likely that our future marketing efforts will require us to incur additional expenses. These brand promotion activities may not yield increased sales and, even if they do, any sales increases may not offset the expenses we incur to promote our brand and our products. If we fail to successfully promote and maintain our brand, or if we incur substantial expenses in an unsuccessful attempt to promote and maintain our brand and the brands of our products, our products may not be accepted by healthcare providers, which would cause our sales to decrease and would adversely affect our business, results of operations and financial condition.

We face the risk of product liability claims that could be expensive, divert management's attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance.

Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of our products. This risk exists even if a product is cleared, approved or certified for commercial sale by the FDA, foreign regulatory authorities or notified bodies and manufactured in facilities regulated by the FDA or an applicable foreign regulatory authority. Our products are designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our products in development could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot assure you that we will not face product liability claims. We may be subject to product liability claims if our products or products in development cause, or merely appear to have caused, patient injury or death, even if such injury or death was as a result of supplies or components that are produced by third-party suppliers. Product liability claims may be brought against us by consumers, healthcare providers or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- costs of litigation;
- distraction of management's attention from our primary business;
- the inability to commercialize existing or new products;
- decreased demand for our products or, if cleared or approved, products in development;

- damage to our business reputation;
- product recalls or withdrawals from the market;
- withdrawal of clinical trial participants;
- substantial monetary awards to patients or other claimants; and
- loss of net sales.

While we have attempted and may continue to attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products may delay the supply of those products to our customers and may impact our reputation. For example, we have in the past instituted a voluntary recall for certain of our products. We cannot assure you that we will be successful in initiating appropriate market recall or market withdrawal efforts that may be required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for product safety or be perceived by patients as a safety risk when considering the use of our products, either of which could adversely affect our business, results of operations and financial condition.

In addition, although we have product liability and clinical study liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could adversely affect our business, results of operations and financial condition.

Fluctuations in the demand for our products or our inability to forecast demand accurately may influence the ability of our suppliers to meet our delivery needs or result in excess product inventory.

We are required by some of our contracts with suppliers of our products to forecast future product demand or meet minimum purchase requirements. Our HA product supply agreements are subject to minimum volumes based in part on forecasts, annual minimum purchase requirements and purchase amounts based on rolling annual forecasts. Our forecasts are based on multiple assumptions of product and market demand, which may cause our estimates to be inaccurate. If we underestimate demand, we may not have adequate supplies and could have reduced control over pricing, availability and delivery schedules with our suppliers, which could prevent us from meeting increased customer or consumer demand and harm our business. However, if we overestimate our demand, we may have underutilized assets and may experience reduced margins. If we do not accurately align our supplies with demand and/or fail to meet contractual minimum purchase requirements, our business, results of operations and financial condition may be adversely affected.

We may face issues with respect to the supply of our products or their components, including increased costs, disruptions of supply, shortages, contamination or mislabeling.

We are dependent on a limited number of suppliers for our products and components used in the manufacturing process of our products. Our top three single-source third-party manufacturers supply us with our HA products and constituted 51%, 53% and 54% of total net sales for the years ended December 31, 2021, 2020 and 2019, respectively. Exogen undergoes final assembly with components procured from various suppliers, including a transducer, which is a key component that is supplied by a single source supplier. Many of the acquired Bioness and Misonix products are also dependent on a limited number of suppliers for these products and their components. We may not be able to renew or enter into new contracts with our existing suppliers following the expiration of such contracts on commercially reasonable terms, or at all. Additionally, our PNS, advanced rehabilitation and Surgical Ultrasonic devices require ciruit boards and other electronic components that are periodically in short supply. The unavailability of such components from our suppliers may impact our ability to meet the customer demand for these products.

The success of certain Surgical and Wound solution products, depends on our suppliers continuing to have access to donated human cadaveric tissue, as well as the maintenance of high standards in their processing methodology. The supply of such donors can fluctuate over time. We cannot be certain that our current suppliers who rely on allograft bone, skin and amniotic tissue, plus any additional sources that our suppliers identify in the future, will be sufficient to meet our product needs. Our dependence on a limited number of third-party suppliers and the challenges that they may face in obtaining adequate supplies of allograft bone tissue involve several risks, including limited control over pricing, availability, quality and delivery schedules. We may be unable to find an alternative supplier in a reasonable time period or on commercially reasonable terms, if at all, which would adversely affect our business, results of operations and financial condition.

If any of our products or the components used in our products are alleged or proven to include quality or product defects, including as a result of improper methods of tissue recovery from donors and disease transmission from donated tissue or illegal harvesting, we may need to find alternate supplies, delay production of our products, discard or otherwise dispose of our products, or engage in a product recall, all of which may adversely affect our business, results of operations and financial condition. If our products or the components in our products are affected by adverse prices or quality or other concerns, we may not be able to identify alternate sources of components or other supplies that meet our quality controls and standards to sustain our sales volumes or on commercially reasonable terms, or at all.

We rely on a limited number of third-party manufacturers to manufacture certain of our products.

Third-party manufacturers generally manufacture our HA products, Exogen components and certain Surgical Solutions products. We have developed in-house assembly capabilities for our Exogen system. We and our third-party manufacturers are required to comply with the QSR which is a set of FDA regulations that establishes cGMP requirements for medical devices and covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of such devices. Moreover, certain of our products may be re-classified as drugs, and we are planning to seek approval of a product pursuant to the BLA pathway. In each case, such products would be required to comply with the cGMP requirements that apply to drugs and biologics, respectively.

There are a limited number of suppliers and third-party manufacturers that operate under FDA's QSR requirements and that have the necessary expertise and capacity to manufacture our products or components for our products. As a result, it may be difficult for us to locate manufacturers for our anticipated future needs, and our anticipated growth could strain the ability of our current suppliers and third-party manufacturers to deliver products, materials and components to us. Upon expiration of our existing agreements with these third-party manufacturers, we may not be able to renegotiate the terms of our agreements with these third-party manufacturers on a commercially reasonable basis, or at all.

If we or our third-party manufacturers fail to maintain facilities in accordance with the FDA's QSR, the noncomplying party could lose the ability to manufacture our products on a commercial scale. Loss of this manufacturing capability would limit our ability to sell some of our products.

The manufacturing of our products may not be easily transferable to other sites in the event that any of our third-party manufacturers experience breakdown, failure or substandard performance of equipment, disruption of supply or shortages of, or quality issues with, components of our products and other supplies, labor problems, power outages, adverse weather conditions, natural disasters, global pandemics, such as COVID-19, or the need to comply with environmental and other directives of governmental agencies. From time to time, a third-party manufacturer may experience financial difficulties, bankruptcy or other business disruptions, which could disrupt our supply of finished goods or require that we incur additional expense by providing financial accommodations to the third-party manufacturer or taking other steps to seek to minimize or avoid supply disruption, such as establishing a new third-party manufacturing arrangement with another provider. The loss of any of these third-party manufacturers or the failure for any reason of any of these third-party manufacturers to fulfill their obligations under their agreements with us, including a failure to meet our quality controls and standards, may result in disruptions to our supply of finished goods. We may be unable to locate an additional or alternate third-party manufacturing arrangement that meets our quality controls and standards in a timely manner or on commercially reasonable terms, if at all. If this occurs, our business, results of operations and financial condition will be adversely affected.

If our facilities are damaged or become inoperable, we will be unable to continue to research, develop and manufacture our products and, as a result, our business, results of operations and financial condition may be adversely affected until we are able to secure a new facility.

We do not have redundant manufacturing facilities. Our other facilities and equipment would be costly to replace and could require substantial lead-time to repair or replace. Our facilities may be harmed or rendered inoperable by natural or man-made disasters, including, but not limited to, tornadoes, flooding, fire and power outages. Such disasters may render it difficult or impossible to manufacture and commercialize our products and conduct our research and development activities for new products, line extensions and expanded indications. The inability to perform those activities, combined with our limited inventory of supplies, components and finished product, may result in the inability to continue manufacturing or supplying our products during such periods and the loss of customers or harm to our reputation. Although we possess insurance for damage to our facilities and the disruption of our business, this insurance may not be sufficient to cover all of our potential losses and this insurance may not continue to be available to us on acceptable terms, or at all.

If we fail to maintain our numerous contractual relationships, our business, results of operations and financial condition could be adversely affected.

We are party to numerous contracts in the normal course of our business, including our supply and distribution agreements. We have contractual relationships with suppliers, distributors and agents, as well as service providers. In the aggregate, these contractual relationships are necessary for us to operate our business. From time to time, we amend, terminate or negotiate our contracts. We may also periodically be subject to, or make claims of breach of contract, or threaten legal action relating to our contracts. These actions may result in litigation. At any one time, we have a number of negotiations under way for new or amended commercial agreements. We devote substantial time, effort and expense to the administration and negotiation of contracts involved in our business. However, these contracts may not continue in effect past their current term or we may not be able to negotiate satisfactory contracts in the future with current or new business partners, which may adversely affect our business, results of operations and financial condition.

Actual or attempted breaches of security, unauthorized disclosure of information, denial of service attacks or the perception that personal and/or other sensitive or confidential information in our possession or control is not secure, could result in a material loss of business, substantial legal liability or significant harm to our reputation.

We receive, collect, process, use and store a large amount of information, including personally identifiable, protected health and other sensitive and confidential information. This data is often accessed by us through transmissions over public and private networks, including the Internet. The secure transmission of such information over the Internet and other mechanisms is essential to maintain confidence in our information technology systems. Despite the privacy and security measures we have in place to ensure compliance with applicable laws, regulations and contractual requirements, our facilities and systems, and those of our third-party vendors and service providers, are vulnerable to privacy and security incidents including, but not limited to, computer hacking, breaches, acts of vandalism or theft, computer viruses and other malware, including ransomware or other forms of cyber-attack, misplaced or lost data, programming and/or human errors or other similar events. A party, whether internal or external, that is able to circumvent our security systems could, among other things, misappropriate or misuse sensitive or confidential information, user information or other proprietary information, or cause significant interruptions in our operations. Internal or external parties have and will continue to attempt to circumvent our security systems, and we expect that we may in the future experience external attacks on our network, such as, reconnaissance probes, denial of service attempts, malicious software attacks and phishing attacks.

Because the techniques used to circumvent security systems can be highly sophisticated and change frequently, and often are not recognized until launched against a target and may originate from less regulated and remote areas around the world, we may be unable to proactively address all possible techniques or implement adequate preventive measures for all situations. Attacks upon information technology systems are also increasing in their frequency, levels of persistence, and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. Recent, well-publicized attacks on prominent companies have resulted in the theft of significant amounts of sensitive and personal information and demonstrate the sophistication of the perpetrators and magnitude of the threat posed to companies across the nation, including the health care industry.

If someone is able to circumvent or breach our security systems, they could steal any information located therein or cause interruptions to our operations. Security breaches or attempts thereof could also damage our reputation and expose us to a risk of monetary loss and/or litigation, fines and sanctions. We also face risks associated with security breaches affecting third parties that conduct business with us or our customers and others who interact with our data. While we maintain insurance that covers certain security and privacy breaches, we may not carry appropriate insurance or maintain sufficient coverage to compensate for all potential liability. Additionally, the costs incurred to remediate any data security or privacy incident could be substantial.

We cannot assure you that our third-party service providers with access to our or our customers', suppliers', trial patients', and employees' personally identifiable and other sensitive or confidential information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security breaches or attempts thereof, which could have a corresponding effect on our business including putting us in breach of our obligations under privacy laws and regulations and/or which could in turn adversely affect our business, results of operations and financial condition. While we attempt to address the associated risks by performing security assessments and detailed due diligence, we cannot assure you that these contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information.

Failure of a key information technology and communication system, process or site could adversely affect our business, results of operations and financial condition.

We rely extensively on information technology and communication systems and software and hardware products, including those of external providers, to conduct business. These systems and software and hardware impact, among other things, ordering and managing components of our products from suppliers, shipping products to customers on a timely basis, processing transactions, coordinating our sales activities across all of our products, summarizing and reporting results of operations, complying with regulatory, legal or tax requirements, data security and other processes necessary to manage our business.

Despite any precautions we may take, our systems and software and hardware could be exposed to damage or interruption from circumstances beyond our control, such as fire, natural disasters, systems failures, power outages, cyber-attacks, terrorism, energy loss, telecommunications failure, security breaches and attempts thereof, computer viruses and similar disruptions affecting the global Internet. Although we have taken steps to prevent system failures and have back-up systems and procedures to prevent or reduce disruptions, such steps may not prevent an interruption of services and our disaster recovery planning may not be adequate or account for all contingencies. Additionally, our insurance may not adequately compensate us for all losses or failures that may occur. If our systems or software and hardware are damaged or cease to function properly and our business continuity plans do not effectively compensate on a timely basis, we may suffer interruptions in our operations, which could adversely affect our business, results of operations and financial condition.

We will need to improve and upgrade our systems and infrastructure as our operations grow in scale in order to maintain the reliability and integrity of our systems and infrastructure. The expansion of our systems and infrastructure will require us to commit substantial financial, operational and technical resources before the volume of our business increases, with no assurance that the volume of business will increase. Any 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 could adversely affect our business, results of operations and financial condition.

Our business subjects us to economic, political, regulatory and other risks associated with international sales and operations that could adversely affect our business, results of operations and financial condition.

Since we sell our products in many different jurisdictions outside the United States, our business is subject to risks associated with conducting business internationally. We anticipate that net sales from international operations will continue to represent a portion of our total net sales. In addition, a number of our third-party manufacturing facilities and suppliers of our products are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- customers in some foreign countries potentially having longer payment cycles;
- disadvantages of competing against companies from countries that are not subject to U.S. laws and regulations, including the U.S. Foreign Corrupt Practices Act (FCPA), regulations of the U.S. Office of Foreign Assets Controls, and U.S. anti-money laundering regulations, as well as exposure of our foreign operations to liability under these regulatory regimes;
- training of third-parties on our products and the procedures in which they are used;
- reduced protection for and greater difficulty enforcing our intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements, export licensing requirements or other restrictive actions by foreign governments;
- difficulty in staffing and managing widespread operations, including compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- international regulators and third-party payers requiring additional clinical studies prior to approving or allowing reimbursement for our products;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- production shortages resulting from any events affecting material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geopolitical actions, including war and terrorism, global pandemics or natural disasters including earthquakes, typhoons, floods and fires. If the current conflict between Russia and Ukraine escalates or spills over to or otherwise impacts additional regions, it could heighten many of the other risk factors included in this Item 1A.

In addition, further expansion into new international markets may require significant resources and the efforts and attention of our management and other personnel, which may divert resources from our existing business operations. As we expand our business internationally, our success will depend, in large part, on our ability to anticipate and effectively manage these and other risks associated with our operations outside of the United States.

We are exposed to foreign currency risks, which may adversely affect our business, results of operations and financial condition.

External events such as the withdrawal by the United Kingdom from the EU, global pandemics, the ongoing uncertainty regarding actual and potential shifts in U.S. and foreign trade, economic and other policies and the passage of U.S. taxation reform legislation have caused, and may continue to cause, significant volatility in currency exchange rates. Because some of our revenue, expenses, assets and liabilities are denominated in foreign currencies, we are subject to exchange rate and currency risks. Our financial statements are presented in U.S. dollars which may result in currency gain or loss, the outcome of which we cannot predict. Furthermore, to the extent that we incur expenses or earn revenue in currencies other than in U.S. dollars, 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 face potential foreign exchange exposure.

To minimize such exposures, we have entered, and may in the future enter, into derivative instruments related to forecasted foreign currency transactions or currency hedges from time to time. Losses from changes in the value of the Euro or other foreign currencies relative to the U.S. dollar could adversely affect our business, results of operations and financial condition.

We are subject to differing tax rates in several jurisdictions in which we operate, which may adversely affect our business, results of operations and financial condition.

We will be subject to taxes in the United States and certain foreign jurisdictions. Due to economic and political conditions, tax rates in various jurisdictions, including the United States, may be subject to change. Our future effective tax rates could be affected by changes in the mix of earnings in countries with differing statutory tax rates, changes in the valuation of deferred tax assets and liabilities and changes in tax laws or their interpretation. In addition, we may be subject to income tax audits by various tax jurisdictions. Although we believe our income tax liabilities are reasonably estimated and accounted for in accordance with applicable laws and principles, an adverse resolution by one or more taxing authorities could have a material impact on the results of our operations.

International tariffs applied to goods traded between the United States and China for restrictions on goods imported from certain regions of China may adversely affect our business, results of operations and financial condition.

International tariffs, including tariffs applied to goods traded between the United States and China, may adversely affect our business, results of operations and financial condition. Since the beginning of 2018, there has been increasing rhetoric, in some cases coupled with legislative or executive action, from several U.S. and foreign leaders regarding the possibility of instituting tariffs against foreign imports of certain materials. The institution of trade tariffs both globally and between the U.S. and China specifically carries the risk of adversely affecting overall economic condition, which could have a negative impact on us as imposition of tariffs could cause an increase in the cost of our products and the components for our products, specifically with respect to our Exogen system, which may adversely affect our business, results of operations and financial condition. In addition, the U.S. has previously enacted and it or other countries may in the future enact legislation that limits or prohibits the use of foreign manufactured equipment or supplies from China, such as Uyghur Forced Labor Prevention Act, which imposes a ban on virtually all imports from the Xinjiang region of China unless companies are able to prove that the products were not made with forced labor, which is expected to have an adverse effect on our ability to conduct our business and our results of operations.

Our Credit Agreement contains financial and operating restrictions that may limit our access to credit. If we fail to comply with its financial or other covenants, we may be required to repay the indebtedness, which may harm our liquidity.

We are subject to certain covenants under our Credit and Guaranty Agreement dated December 6, 2019 (as amended, the Credit Agreement), including, but not limited to:

- a minimum interest coverage ratio and a maximum debt leverage ratio requirement as defined in the Credit Agreement;
- restrictions on the declaration or payment of certain distributions on or in respect of our equity interests;
- restrictions on acquisitions, investments and certain other payments;
- limitations on the incurrence of new indebtedness;

- limitations on the incurrence of new liens on property or assets;
- limitations on transfers, sales and other dispositions;
- limitations on entering into transactions with affiliates; and
- limitations on making any material change in any of our business objectives that could reasonably be expected to have a material adverse effect on the repayment of our credit agreement.

Our indebtedness could have significant consequences, including:

- requiring a substantial portion of our cash flows to be dedicated to debt service payments instead of funding growth, working capital, capital expenditures, investments or other cash requirements;
- reducing our flexibility to adjust to changing business conditions or obtain additional financing;
- exposing us to the risk of increased interest rates as certain of our borrowings, including borrowings under our term loan, are at variable rates, making it more difficult for us to make payments on our indebtedness;
- restricting us from making strategic acquisitions or causing us to make non-strategic divestitures;
- subjecting us to restrictive covenants that may limit our flexibility in operating our business; and
- limiting our ability to obtain additional financing for working capital, capital expenditures, debt service requirements and general corporate or other purposes.

We are subject to certain covenants with which we may not be able to comply in the future. In the absence of a waiver from our lenders, any failure by us to comply with these covenants in the future may result in the declaration of an event of default, which could adversely affect our business, results of operations and financial position. See *Part II, Item 7. Management's discussion and analysis of financial condition and results of operations—Indebtedness*.

Uncertainty relating to the LIBOR calculation process and potential phasing out of LIBOR in the future may adversely affect our financing costs.

Our Credit Agreement utilizes the London Interbank Offered Rate (LIBOR), or various alternative methods to calculate interest on any borrowings, which may be subject to regulatory guidance and/or reform that could cause interest rates under our current or future debt agreements to perform differently than in the past or cause other unanticipated consequences. Some tenors of LIBOR were discontinued on December 31, 2021. Although we expect that the capital and debt markets will cease to use LIBOR as a benchmark in the near future and the administrator of LIBOR has announced its intention to extend the publication of most tenors of LIBOR for U.S. dollars through June 30, 2023, we cannot predict whether or when LIBOR will actually cease to be available, whether the Secured Overnight Funding Rate (SOFR), will become the market benchmark in its place or what impact such a transition may have on our business, financial condition and results of operations.

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.

We believe that our current cash and cash equivalents, in combination with the borrowing availability under our credit facility and our expected cash from operations, will be sufficient to meet our projected operating requirements for the foreseeable future. However, we may seek additional funds from public and private stock offerings, borrowings under our existing or new credit facilities or other sources in order to fund future initiatives related to the expansion of our business, which financing may not be available on acceptable or commercially reasonable terms, if at all. For example, pursuant to the Option and Equity Purchase Agreement with CartiHeal and its shareholders, CartiHeal has a put option that would require us to purchase 100% of CartiHeal's shares, excluding those we already own, for $314.9 million under certain conditions. Upon achievement of certain sales milestones, an additional $135.0 million would become payable after closing. See *Part II, Item 7. Management's discussion and analysis of financial condition and results of operations—Strategic transactions—CartiHeal* (developer of Agili-C) investment and option and equity purchase agreement.

Furthermore, if we issue equity or debt securities to raise additional capital, our existing stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. In addition, if we raise additional capital through collaboration, licensing or other similar arrangements, it may be necessary to relinquish valuable rights to our products, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If we cannot raise capital on acceptable terms, including the capital necessary to consummate the CartiHeal transaction, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures, changes in our supplier relationships, or unanticipated customer requirements. Any of these events could adversely affect our business, results of operations and financial condition.

Risks related to government regulation

The risk factors listed below describe the risks we face related to government regulation. The companies who manufacture or produce certain of the products we distribute face similar risks with respect to government regulation relating to such products. If such suppliers are unable to comply with government regulations, they may not be able to continue to supply us with products, which could adversely affect our business, results of operations and financial condition.

Our products and operations are subject to extensive governmental regulation, and our failure to comply with applicable requirements could cause our business to suffer.

The healthcare industry, and in particular the medical device industry, are regulated extensively by governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies and authorities. The FDA and other U.S. and foreign governmental agencies and authorities regulate and oversee, among other things:

- design, development and manufacturing;
- testing, labeling, content and language of instructions for use and storage;
- clinical trials;
- product safety;
- marketing, sales and distribution;
- premarket clearance, approval and certification;
- conformity assessment procedures;
- record-keeping procedures;
- advertising and promotion;
- recalls and other field safety corrective actions;
- postmarket surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- postmarket studies; and
- product import and export.

The regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

The failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as:

- administrative or judicially imposed sanctions;
- unanticipated expenditures to address or defend such actions;
- injunctions, consent decrees or the imposition of civil penalties or fines;
- recall or seizure of our products;
- total or partial suspension of production or distribution;
- refusal to grant pending or future clearances, approvals or certifications for our products;
- withdrawal or suspension of regulatory clearances, approvals or certifications;
- clinical holds;
- untitled letters or warning letters;
- refusal to permit the import or export of our products; and
- criminal prosecution of us or our employees.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and harm our reputation, business, results of operations and financial condition.

Moreover, governmental authorities outside the United States 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 adversely affect our business, results of operations and financial condition. The European Commission has harmonized national regulations for the control of medical devices through European Medical Device Directives with which manufacturers must comply. Under these new regulations, manufacturing plants must have received a full Quality Assurance Certification from a "Notified Body" in order to be able to sell products within the member states of the EU. This certification allows manufacturers to stamp the products of certified plants with a "CE" mark. Products covered by European Commission regulations that do not bear the CE mark cannot be sold or distributed within the EU.

We may be subject to enforcement action if we engage in improper claims submission practices and resulting audits or denials of our claims by government agencies could reduce our net sales or profits.

In connection with our Exogen system, we submit claims directly to, and receive payments directly from, the Medicare and Medicaid programs and private payers. Therefore, we are subject to extensive government regulation, including detailed requirements for submitting claims under appropriate codes and maintaining certain documentation, including evidence that all medical necessity requirements are met to support our claims. Billing for our Exogen system is complex, time-consuming and expensive, particularly for items and services provided to government healthcare program beneficiaries, such as Medicare and Medicaid. Reimbursement claims may be adversely affected by improper completion of the CMN required in connection with Medicare claims for the Exogen system and we may be subject to investigations by governmental authorities or third party payers and required to prove the validity of the claims or the authenticity of the signatures on the CMNs under investigation. Reimbursement claims may also be adversely affected by the promotion of our devices for unapproved or off-label uses or assistance with the reimbursement process that could result in false or fraudulent claims for reimbursement being submitted to government or private payers. Depending on the billing arrangement and applicable law, we bill various payers, all of which may have different prior authorization, patient qualification and medical necessity requirements, as well as patients for any applicable co-payments or co-insurance amounts. In addition, we may also face increased risk in our collection efforts, including potential write-offs of doubtful accounts and long collection cycles, any of which could adversely affect our business, results of operations and financial condition.

We are also required to implement compliance procedures and oversight, train and monitor our employees, appeal coverage and payment denials, and perform internal audits periodically to assess compliance with applicable laws and regulations as well as internal compliance policies and procedures. We are required to report and return any overpayments received from government payers within 60 days of identification and exercise of reasonable diligence to investigate credible information regarding potential overpayments. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. For example, in February 2021 we entered into a settlement agreement with the United States Attorney's Office for the Middle District of North Carolina and the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) to resolve potential liabilities associated with a self-disclosure we made to the OIG in November 2018 regarding violations of certain Medicare claim submission requirements. See *Part I, Item 1A. Risk Factors—Risks related to government regulation—We are subject to federal, state and foreign laws and regulations relating to our healthcare business, and could face substantial penalties if we are determined not to have fully complied with such laws, which would adversely affect our business, results of operations and financial condition.* Moreover, Medicare contractors and Medicaid agencies periodically conduct pre- and post-payment reviews and other audits of claims and are under increasing pressure to more closely scrutinize healthcare claims and supporting documentation. We may be subject to prepayment and post-payment reviews, as well as audits of claims in the future. Private payers may from time to time conduct similar reviews and audits. Any third-party payer reviews and audits of our claims could result in material delays in payment, material recoupments, overpayments, claim denials, fines, revocations of billing privileges, bars on re-enrollment in federal or state healthcare programs, cancellation of our agreements or damage to our reputation, any of which would reduce our net sales and profitability.

The FDA regulatory process is expensive, time-consuming and uncertain, and the failure to obtain and maintain required regulatory clearances and approvals could prevent us from commercializing our products.

Before we can market or sell a new medical device or other product or a new use of or a claim for or significant modification to an existing medical device in the United States, we must obtain either clearance from the FDA under 510(k) pathway or approval of a PMA, unless an exemption applies. In the United States, we have obtained 510(k) clearance from the FDA to market certain of our products such as Signafuse Bioactive Bone Graft Putty, Interface Bioactive Bone Graft and Signafuse Mineralized Collagen Scaffold. Our OA joint pain treatment and joint preservation products, including Durolane, GELSYN-3 and SUPARTZ FX, and our Exogen system, have obtained PMA approval. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed predicate device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. In the PMA process, the FDA must determine that a proposed product is safe and effective for our intended use based, in part, on extensive data, including, but not limited to, technical, preclinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for products that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to twelve months, but can last longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from six to eighteen months, or even longer, from the time the application is filed with the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, we cannot assure you that any particular device will be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory approvals could harm our business.

Any modification to one of our 510(k) cleared products that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device would require us to obtain a new 510(k) marketing clearance and may even, in some circumstances, require the submission of a PMA application, if the change raises complex or novel scientific issues or the product has a new intended use. The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. We may make changes to our 510(k)-cleared products in the future that we may determine do not require a new 510(k) clearance or PMA approval. If the FDA disagrees with our decision not to seek a new 510(k) or PMA approval for changes or modifications to existing devices and requires new clearances or approvals, we may be required to recall and stop marketing our products as modified, which could require us to redesign our products, conduct clinical trials to support any modifications, and pay significant regulatory fines or penalties. If there is any delay or failure in obtaining required clearances or approvals or if the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, our ability to introduce new or enhanced products in a timely manner would be adversely affected, which in turn would result in delayed or no realization of revenue from such product enhancements or new products and could also result in substantial additional costs which could decrease our profitability.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that the product or modification is substantially equivalent to the proposed predicate device or safe and effective for its intended use;
- the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared or approved products on a timely basis. Even after clearance or approval for our products is obtained, we and the products are subject to extensive postmarket regulation by the FDA, including with respect to advertising, marketing, labeling, manufacturing, distribution, import, export, and clinical evaluation.

We are also required to timely file various reports with regulatory agencies. If these reports are not timely filed, regulators may impose sanctions and sales of our products may suffer, and we may be subject to product liability or regulatory enforcement actions, all of which could harm our business. In addition, if we initiate a correction or removal for one of our devices, issue a safety alert, or undertake a field action or recall to reduce a risk to health posed by the device, we may be required to submit a report to the FDA, and in many cases, to other regulatory agencies. Such reports could lead to increased scrutiny by the FDA, other international regulatory agencies and our customers regarding the quality and safety of our devices and to negative publicity, including FDA alerts, press releases, or administrative or judicial actions. Furthermore, the submission of these reports has been and could be used by competitors against us in competitive situations and cause customers to delay purchase decisions or cancel orders, which would harm our reputation and business.

The FDA, state and foreign authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recalls, termination of distribution, administrative detention or seizures of our products;
- operating restrictions, partial suspension or total shutdown of production;
- customer notifications or repair, replacement or refunds;
- refusing our requests for 510(k) clearance or PMA approvals or foreign regulatory approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current 510(k) clearances or PMAs or foreign regulatory approvals, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could also result in higher than anticipated costs or lower than anticipated sales and adversely affect our business, results of operations and financial condition.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance as a result of a changing regulatory landscape, we may lose any marketing approvals or clearances that we have already obtained or fail to obtain new marketing approvals or clearances, and we may not be able to achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Legislative or regulatory reforms, including those currently under consideration by FDA, could make it more difficult or costly for us to obtain regulatory clearance, approval or certification of any future products and to manufacture, market and distribute our products after clearance, approval or certification is obtained, which could adversely affect our competitive position and materially affect our business and financial results.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, propose new reclassification orders, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to market or modify our currently cleared products on a timely basis. For example, over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the 510(k) premarket notification pathway, including plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway. In September 2019, the FDA also issued revised final guidance establishing a "Safety and Performance Based Pathway" for "manufacturers of certain well-understood device types" allowing manufacturers to rely on objective safety and performance criteria recognized by the FDA to demonstrate substantial equivalence, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA has developed and maintains a list of device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria and recommended testing methodologies for each such device type, where feasible. Some of these proposals have not yet been finalized or adopted, and the FDA announced that it would seek public feedback prior to publication of any such proposals, and may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any changes could impose additional regulatory requirements on us that could delay our ability to obtain clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The EU Medical Devices Regulation (MDR) which require changes in the clinical evidence for medical devices, post-market clinical follow-up evidence, annual reporting of safety information for Class III products, and bi-annual reporting for Class II products, Unique Device Identification (UDI) for all products, submission of core data elements to a European UDI database prior to placement of a device on the market, reclassification of medical devices, and multiple other labeling changes. While we are able to continue marketing our currently CE-marked products in the EEA after the EU MDR enters into full effect and until the associated CE mark certificates expire, acquiring certifications for new products or renewing our existing CE mark certificates once these expire could be more challenging and costly. Additionally, even if we can continue marketing our currently CE marked products in the EEA, we must comply with a number of new or reinforced requirements set forth in the EU Medical Devices Regulation.

Our HCT/P products are subject to extensive government regulation and our failure to comply with these requirements could cause our business to suffer.

In the United States, we sell human tissue-derived Surgical Solutions products, which are referred to by the FDA as human cells, tissues and cellular or tissue-based products (HCT/Ps). In the U.S., we are marketing our HCT/Ps pursuant to Section 361 of the PHSA and 21 CFR Part 1271 of FDA's regulations. We do not manufacture these HCT/P products, but serve as a distributor for them. So-called Section 361 HCT/Ps are not currently subject to the FDA requirements to obtain marketing authorizations as long as they meet certain criteria provided in FDA's regulations. HCT/Ps regulated as "361 HCT/Ps" are currently subject to requirements relating to registering facilities and listing products with the FDA, screening and testing for tissue donor eligibility, cGTP, when processing, storing, labeling and distributing HCT/Ps, including required labeling information, stringent record keeping and adverse event reporting. If we or our suppliers fail to comply with these requirements, we could be subject to FDA enforcement action, including, for example, warning letters, fines, injunctions, product recalls or seizures, and, in the most serious cases, criminal penalties. To be regulated as Section 361 HCT/Ps, these products must meet FDA's criteria to be considered "minimally manipulated" and intended for "homologous use," among other requirements. HCT/Ps that do not meet the criteria to be considered Section 361 HCT/Ps are subject to the FDA's regulatory requirements applicable to medical devices, biologics or drugs. Device, biologic or drug HCT/Ps must comply both with the requirements exclusively applicable to Section 361 HCT/Ps and, in addition, with other requirements, including requirements for marketing authorization, such as 510(k) clearance or PMA or BLA approvals before marketing. Except as described below with regard to MOTYS, we believe our HCT/Ps are regulated solely under Section 361 of the PHSA, and therefore, we have not sought or obtained 510(k) clearance, PMA approval, or licensure through a BLA for such HCT/Ps.

The FDA could disagree with our determination that these human tissue products are Section 361 HCT/Ps and could determine that these products are biologics requiring a BLA or medical devices requiring 510(k) clearance or PMA approval, and could require that we cease marketing such products and/or recall them pending appropriate clearance, approval or licensure from the FDA. If we have to cease marketing and/or have to recall any of our Surgical Solutions products our net sales would decrease, which would adversely affect our business, results of operations and financial condition.

HCT/Ps that do not meet the criteria of Section 361 are regulated under Section 351 of the PHSA. HCT/Ps regulated as "351" HCT/Ps are subject to premarket review and approval by the FDA. In November 2017, the FDA released a guidance document entitled "Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue—Based Products: Minimal Manipulation and Homologous Use—Guidance for Industry and Food and Drug Administration Staff." The guidance outlined the FDA's position that all lyophilized amniotic products are more than minimally manipulated and would therefore require a BLA to be lawfully marketed in the United States. The FDA resumed enforcement of IND and premarket approval requirements with respect to these products as of June 1, 2021. As a result, we were required to cease selling MOTYS. We expect the cost to develop and manufacture MOTYS will be higher than our other HCT/Ps because of the costs to comply with the more stringent requirements that apply to products regulated as biologics for which a BLA is required (and not just as Section 361 HCT/Ps). If we do receive BLA approval for MOTYS, changes such as adding new indications, manufacturing changes and additional labeling claims, will be subject to further testing requirements and FDA review and approval.

In addition, the FDA may in the future modify the scope of its enforcement discretion with respect to Section 361 HCT/Ps or change its position on which current or future products qualify as Section 361 HCT/Ps, or determine that some or all of our HCT/P products may not be lawfully marketed under the FDA's policy of enforcement discretion. Any regulatory changes could have adverse consequences for us and make it more difficult or expensive for us to conduct our business by requiring pre-market clearance or approval and compliance with additional post-market regulatory requirements with respect to those products.

If clinical studies of our future products do not produce results necessary to support regulatory clearance, approval or certification in the United States or elsewhere, we will be unable to expand the indications for or commercialize these products.

We will likely need to conduct additional clinical studies in the future to support new indications for our products or for clearances, approvals or certifications of new product lines, or for the approval or certification of the use of our products in some foreign countries. Clinical testing can take many years, can be expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons. Conducting successful clinical studies requires the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects, the availability of appropriate clinical trial investigators and support staff, proximity of patients to clinical sites, patient ability to meet the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in clinical trials may die before completion of the trial or suffer adverse medical events unrelated to investigational products.

Clinical failure can occur at any stage of testing. Our clinical studies may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical studies in addition to those we have planned. In addition, failure to adequately demonstrate the safety and efficacy of any of our devices would prevent receipt of regulatory clearance, approval or certification and, ultimately, the commercialization of that device or indication for use. Even if our future products are cleared in the United States, commercialization of our products in foreign countries would require approval or certification by regulatory authorities or notified bodies in those countries. Approval and certification procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials. Any of these occurrences could adversely affect our business, results of operations and financial condition.

Interim, "top-line" and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, "top-line" or preliminary data from our clinical trials. Interim, top-line, or preliminary data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary, "top-line," or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, "top-line," and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, interim, or "top-line" data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, "top-line," or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

We may be subject to enforcement action if we engage in improper marketing or promotion of our products, and the misuse or off-label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Certain products that we currently market have been cleared, approved or certified by the FDA and other foreign regulatory authorities and notified bodies for specific treatments. We cannot prevent a physician from using our products outside of such cleared or approved indications for use, known as off-label uses. While we do not analyze the ordering practices of physicians with respect to off-label uses, we are aware of certain off-label uses of our EXOGEN product. As a result, we could be subject to regulatory or enforcement actions if we were determined to have engaged in promotion of our products for off-label uses, or otherwise determined to have made false or misleading statements about our products. There may be increased risk of injury to patients if physicians attempt to use our products off-label. Furthermore, the use of our products for indications other than those cleared, approved or certified by the FDA or any foreign regulatory authority or notified body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients.

In addition, physicians may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Further, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of off-label use. If the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, the FDA could request that we modify our training, promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. Such enforcement actions may include, but are not limited to, criminal, civil and administrative penalties, treble damages, fines, disgorgement, exclusion from participation in government healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations.

Our products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could materially harm our business.

Some of our marketed products are subject to MDR obligations, which require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. The timing of our obligation to report under the MDR regulations is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA could take action including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearances, seizure of our products, or delay in clearance of future products.

We and our third-party manufacturers and suppliers are subject to various governmental regulations related to the manufacturing of our products.

Our products and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such products, will be subject to continued regulatory review, oversight and periodic inspection by the FDA and other domestic and foreign regulatory bodies. In particular, the methods used in, and the facilities used for, the manufacture of the products that we own and distribute that are regulated as medical devices must comply with the FDA's QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of medical devices. The FDA enforces the QSR through periodic announced or unannounced inspections of manufacturing facilities, and both we and our third-party manufacturers and suppliers are subject to such inspections. Similarly, the devices we distribute on behalf of third-party manufacturers that are regulated as Section 361 HCT/Ps must be manufactured in compliance with cGTP requirements and other related requirements. Moreover, should any of our HA products be re-classified as drugs, such products would be required to comply with a different set of manufacturing requirements under FDA's cGMP requirements for drugs. Similarly, if we are successful in obtaining BLA approval for MOTYS, that product will need to comply with the cGMP requirements for biologics. The need to comply with different manufacturing requirements may require us to seek new suppliers.

Failure to comply with applicable FDA requirements, or later discovery of previously unknown problems with our products or the manufacturing processes of our third-party manufacturers and suppliers, including any failure to take satisfactory corrective action in response to an adverse regulatory inspection, can result in, among other things:

- administrative or judicially imposed sanctions;
- injunctions or the imposition of civil penalties or fines;
- recall or seizure of our products;
- total or partial suspension of production or distribution;
- refusal to grant pending or future clearances, approvals or certifications for our products;
- withdrawal or suspension of regulatory clearances, approvals or certifications;
- clinical holds;
- untitled letters or warning letters;
- refusal to permit the import or export of our products; and
- criminal prosecution of us or our employees.

Any of these actions could prevent or delay us from marketing, distributing or selling our products and would likely harm our business. Furthermore, our suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Our products may be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could adversely affect us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in their design or manufacture. For example, the FDA's authority to require a recall for medical devices must be based on a finding that there is reasonable probability that the device would cause serious injury or death. We have in the past and may in the future decide to voluntarily recall our products if certain deficiencies are found. For example, we are currently undertaking a voluntary Class II recall of certain vials of ultrasound gel that we provide with our Exogen system due to particulates, which were microbial in nature, found in the gel. The gel is manufactured by a third-party supplier, and we have discontinued the use of that suppliers' gel and have replaced that gel with that of another manufacturer. We have identified the affected lots and have notified patients to discard gel bottles from those lots. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and could adversely affect our reputation and business, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that could adversely affect our business, results of operations and financial condition.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA or foreign regulatory authorities. We may initiate voluntary recalls or corrections for our products in the future that we determine do not require notification of the FDA or foreign regulatory authorities. If the FDA or foreign regulatory authorities disagree with our determinations, they could require us to report those actions as recalls and we may be subject to enforcement action.

As we conduct clinical studies designed to generate long-term data on some of our existing products, the data we generate may not be consistent with our existing data and may demonstrate less favorable safety or efficacy. Data we generate may ultimately not be favorable, or could even hurt the commercial prospects for our products.

We are currently collecting and plan to continue collecting long-term clinical data regarding the quality, safety and effectiveness of some of our existing products. The clinical data collected and generated as part of these studies will further strengthen our clinical evaluation concerning safety and performance of these products. If the results of these clinical studies are negative, these results could reduce demand for our products and significantly reduce our ability to achieve expected net sales. Surgeons and physicians could be less likely to purchase our products than competing products for which longer-term clinical data are available. Also, we may not choose or be able to generate the comparative data that some of our competitors have or are generating and we may be subject to greater regulatory and product liability risks. If we are unable to or unwilling to collect sufficient long-term clinical data supporting the quality, safety and effectiveness of our existing products, our business, results of operations and financial condition could be adversely affected.

We may rely on third parties to conduct our clinical studies and to assist us with preclinical development and if they fail to perform as contractually required or expected, we may not be able to obtain regulatory clearance, approval or certification to commercialize our products.

We have relied upon and may continue to rely upon third parties, such as contract research organizations (CROs), medical institutions, clinical investigators and contract laboratories to assist in conducting our clinical studies, which must be conducted in accordance with applicable regulations, including GCP and our preclinical development activities. We rely on these parties for execution of our studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our clinical studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. GCPs are regulations and guidelines enforced by the FDA and other regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, trial sites, and CROs. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable manufacturing requirements.

If these third parties fail to successfully carry out their contractual duties, comply with applicable regulatory obligations, including GCP requirements, or meet expected deadlines, or if these third parties must be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to clinical protocols or applicable regulatory requirements or for other reasons, our pre-clinical development activities or clinical studies may be extended, delayed, suspended or terminated. Under these circumstances we may not be able to obtain regulatory clearance, approval or certification for, or successfully commercialize, our products on a timely basis, if at all, and our business, results of operations and financial condition may be adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or to do so on commercially reasonable terms. In addition, our third parties are not our employees, and except for remedies available to us under our agreements with them, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical and preclinical programs. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO or other third party vendor commences work. As a result, delays occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our third party vendors including CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Healthcare regulatory reform may affect our ability to sell our products profitably and could adversely affect our business, results of operations and financial condition.

In the United States and in certain foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the regulatory and healthcare systems in ways that could prevent or delay marketing approval or certification of our products in development, restrict or regulate post-approval or certification activities of our products and impact our ability to sell our products profitably. In the United States in recent years, new legislation has been proposed and adopted at the federal and state level that is effecting major changes in the healthcare system. In addition, new regulations and interpretations of existing healthcare statutes and regulations are frequently adopted.

By way of example, the Affordable Care Act (ACA) substantially changed the way healthcare is financed by both governmental and private insurers, encourages improvements in the quality of healthcare items and services and significantly impacts the medical device industry. Among other things, the ACA:

- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;

- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extended manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs;
- established a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and
- 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.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, from February 15, 2021 through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. We cannot predict with certainty what impact any U.S. federal and state health reforms will have on us, but such changes could impose new and/or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Budget Control Act of 2011, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020, through March 31, 2022, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Third-party payers also regularly update payments to physicians and hospitals where our products are used. By way of example, the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs, such as MACRA, may have on our business, financial condition, results of operations or cash flows. These and other payment updates could directly impact the demand for our products or any products we may develop in the future, if cleared or approved.

We expect that other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we receive for any cleared or approved products. Furthermore, we believe that many individuals who have obtained insurance coverage through the health insurance exchanges which arose as a result of the ACA have done so with policies that have significantly higher deductibles than policies they may have obtained prior to its enactment. Because the out-of-pocket costs of undergoing certain procedures for patients who have not met their deductible for a given year would be significantly higher than they historically would have been, these patients may be discouraged from undergoing certain procedures due to the cost. Any reluctance on the part of patients to undergo procedures utilizing our products due to cost could impact our ability to expand sales of our products and could adversely impact our business, results of operations and financial condition.

We are subject to federal, state and foreign laws and regulations relating to our healthcare business, and could face substantial penalties if we are determined not to have fully complied with such laws, which would adversely affect our business, results of operations and financial condition.

Both in our capacity as a pharmaceutical and medical device manufacturer and/or as a supplier of covered items and services to federal health care program beneficiaries, with respect to which items and services we submit claims for reimbursement from such programs, we are subject to healthcare fraud and abuse regulation and enforcement by federal, state and foreign governments, which could adversely impact our business, results of operations and financial condition. Healthcare fraud and abuse and health information privacy and security laws potentially applicable to our operations include:

- the federal Anti-Kickback Statute (AKS), which prohibits the knowing and willful offer, payment, solicitation or receipt of any bribe, kickback, rebate or other remuneration for referring an individual, in return for ordering, leasing, purchasing or recommending or arranging for or to induce the referral of an individual or the ordering, purchasing or leasing of items or services covered, in whole or in part, by any federal healthcare program, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;;
- the federal physician self-referral law, the Stark Law, which, subject to limited exceptions, prohibits physicians from referring Medicare or Medicaid patients to an entity for the provision of certain designated health services, or DHS, if the physician or a member of such physician's immediate family has a direct or indirect financial relationship (including an ownership interest or a compensation arrangement) with the entity, and prohibits the entity from billing Medicare or Medicaid for such DHS;
- the False Claims Act, or FCA, which imposes civil and criminal liability on individuals or entities that knowingly submit false or fraudulent claims for payment to the government or knowingly make, or cause to be made, a false statement in order to have a false claim paid, including qui tam or whistleblower suits. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS or Stark Law constitutes a false or fraudulent claim for purposes of the FCA;
- the Civil Monetary Penalties Law, which prohibits, among other things, an individual or entity from offering remuneration to a federal healthcare program beneficiary that the individual or entity knows or should know is likely to influence the beneficiary to order or receive healthcare items or services from a particular provider;
- the criminal healthcare fraud provisions of Health Insurance Portability and Accountability Act, or HIPAA, and related rules that prohibit knowingly and willfully executing a scheme or artifice to defraud any healthcare benefit program or falsifying, concealing or covering up a material fact or making any material false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;;
- the federal Physician Payments Sunshine Act, which requires certain applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under certain federal healthcare programs, to monitor and report to CMS, certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare providers (physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives) and teaching hospitals, and applicable manufacturers and group purchasing organizations, to report annually ownership and investment interests held by such physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers;
- federal government price reporting laws; and
- analogous state law equivalents of each of the above federal laws, state anti-kickback and false claims laws; state laws requiring device companies to comply with specific compliance standards, restrict payments made to healthcare providers and other potential referral sources, and report information related to payments and other transfers of value to healthcare providers or marketing expenditures; and state laws related to insurance fraud in the case of claims involving private insurers.

The risk of us being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We are unable to predict what additional federal, state or foreign legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal, state or foreign governments may impose additional restrictions or adopt interpretations of existing laws that could adversely affect us.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, it is possible that some of our business activities, including certain sales and marketing practices and financial arrangements with physicians and other healthcare providers, some of whom recommend, use, prescribe or purchase our products, and other customers, could be subject to challenge under one or more of such laws. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, additional reporting requirements and oversight if we become subject to a Corporate Integrity Agreement or similar agreement to resolve allegations of non-compliance with these laws, exclusion from governmental healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely impact our business, results of operations and financial condition.

In 2018, we identified non-compliance with certain U.S. federal statutes and requirements governing the Medicare program in related to improper completion of Certificate for Medical Necessity (CMN) forms. In November 2018, we made a voluntary self-disclosure to the Office of Inspector General of the U.S. Department of Health and Human Services (OIG) pursuant to the OIG's Provider Self-Disclosure Protocol related to this matter. After settlement discussions with the Office of the United States Attorney in the Middle District of North Carolina (USAO) and OIG, on February 22, 2021, we entered into a formal settlement agreement, which included releases from associated False Claims Act liability and further Civil Monetary Penalties that are customary in self-disclosures of this type, and agreed to pay $3.6 million.

We are subject to governmental regulation and other legal obligations, particularly related to privacy, data protection and information security, and we are subject to consumer protection laws that regulate our marketing practices and prohibit unfair or deceptive acts or practices. Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security, including, in the United States, HIPAA and, in the EU, the GDPR. New privacy rules are being enacted in the United States and globally, and existing ones are being updated and strengthened. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any privacy laws or data security laws or any security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, whether by us, one of our business associates or another third-party, could adversely affect our business, results of operations and financial condition, including but not limited to: investigation costs, material fines and penalties; compensatory, special, punitive, and statutory damages; litigation; reputational damage; consent orders regarding our privacy and security practices; requirements that we provide notices, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals; adverse actions against our licenses to do business; and injunctive relief.

In the United States, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and regulations implemented thereunder (collectively referred to as "HIPAA") imposes, among other things, certain standards relating to the privacy, security, transmission and breach reporting of individually identifiable health information on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities, such as us, as well as business associates to develop and maintain policies with respect to the protection of, use and disclosure of PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and certain notification requirements in the event of a breach of unsecured PHI.

Additionally, under HIPAA, covered entities must report breaches of unsecured PHI to affected individuals without unreasonable delay, not to exceed 60 days following discovery of the breach by a covered entity or its agents. Notification also must be made to the U.S. Department of Health and Human Services Office for Civil Rights and, in certain circumstances involving large breaches, to the media. Business associates must report breaches of unsecured PHI to covered entities within 60 days of discovery of the breach by the business associate or its agents.

Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices or an audit by the U.S. Department of Health and Human Services (HHS), may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Certain states have also adopted comparable privacy and security laws and regulations, some of which may be more stringent than HIPAA. Such laws and regulations will be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us and our future customers and strategic partners. For example, the CCPA went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the CPRA recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging.

The Federal Trade Commission (FTC) and many state Attorneys General also continue to enforce federal and state consumer protection laws against companies for online collection, use, dissemination and security practices that appear to be unfair or deceptive. For example, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure can constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.

In Europe, the GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield. In July 2020, the Court of Justice of the EU (CJEU) limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on the use of standard contractual clauses (SCCs). The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the United Kingdom; the United Kingdom's Information Commissioner's Office launched a public consultation on its draft revised data transfers mechanisms in August 2021. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

Additionally, from January 1, 2021, following the United Kingdom's departure from the EU, we have had to comply with the GDPR and the UK GDPR (i.e. the GDPR as implemented into UK law). Failure to comply with the UK GDPR can result in fines up to the greater of £17.5 million (approximately $20 million), or 4% of global revenue. However, the relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision.

Failure to comply with the FCPA and laws associated with our activities outside the United States could adversely affect our business, results of operations and financial condition.

We are subject to the FCPA and other anti-bribery legislation around the world. The FCPA generally prohibits covered entities and their intermediaries from engaging in bribery or making other prohibited payments, offers or promises to foreign officials for the purpose of obtaining or retaining business or other advantages. In addition, the FCPA imposes recordkeeping and internal controls requirements on publicly traded corporations and their foreign affiliates, which are intended to, among other things, prevent the diversion of corporate funds to the payment of bribes and other improper payments, and to prevent the establishment of "off books" slush funds from which such improper payments can be made. As we conduct our business in jurisdictions outside of the United States, we face significant risks if we fail to comply with the FCPA and other laws that prohibit improper payments, offers or promises of payment to foreign governments and their officials and political parties by us and other business entities for the purpose of obtaining or retaining business or other advantages. In many foreign countries, it may be a local custom that businesses operating in such countries engage in business practices that are prohibited by the FCPA or other laws and regulations. Although we have implemented a company policy requiring our employees and consultants to comply with the FCPA and similar laws, such policy may not be effective at preventing all potential FCPA or other violations. Although our agreements with our international distributors clearly state our expectations for our distributors' compliance with U.S. laws, including the FCPA, and provide us with various remedies upon any non-compliance, including the ability to terminate the agreement, we also cannot guarantee our distributors' compliance with U.S. laws, including the FCPA. Therefore, there can be no assurance that our employees and agents, or those companies to which we outsource certain of our business operations, have not and will not take actions that violate our policies or applicable laws, for which we may be ultimately held responsible. Any violation of the FCPA and related policies could result in severe criminal or civil sanctions, which could adversely affect our business, results of operations and financial condition.

Furthermore, we are subject to the export controls and economic embargo rules and regulations of the United States, 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. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries or persons. A determination that we have failed to comply, whether knowingly or inadvertently, may result in substantial penalties, including fines, enforcement actions, civil and/or criminal sanctions, the disgorgement of profits, the imposition of a court-appointed monitor, as well as the denial of export privileges, and may adversely affect our business, results of operations and financial condition.

If we fail to meet Medicare accreditation and surety bond requirements or DMEPOS supplier standards, it could adversely affect our business, results of operations and financial condition.

Our Exogen system is classified by CMS and third-party payers as durable medical equipment. Suppliers of Medicare durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) must be accredited by an approved accreditation organization as meeting DMEPOS quality standards adopted by CMS and are required to meet surety bond requirements. In addition, Medicare DMEPOS suppliers must comply with Medicare supplier standards in order to obtain and retain billing privileges, including meeting all applicable federal and state licensure and regulatory requirements. CMS periodically expands or otherwise clarifies the Medicare DMEPOS supplier standards, and states periodically change licensure requirements, including licensure rules imposing more stringent requirements on out-of-state DMEPOS suppliers. We believe we are currently in compliance with these requirements. If we fail to maintain our Medicare accreditation status and/or do not comply with Medicare surety bond or supplier standard requirements or state licensure requirements in the future, or if these requirements are changed or expanded, it could adversely affect our business, results of operations and financial condition.

Our operations involve the use of hazardous and toxic materials, and we must comply with environmental, health and safety laws and regulations, which can be expensive, and could adversely affect our business, results of operations and financial condition.

We are subject to a variety of federal, state, local and foreign laws and regulations relating to the protection of the environment or of human health and safety, including laws pertaining to the use, handling, storage, disposal and human exposure to hazardous and toxic materials. Liability under environmental laws can be imposed on a joint and several basis (which could result in an entity paying more than its fair share) and without regard to comparative fault, and environmental laws are likely to become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations, which could adversely affect our business, results of operations and financial condition.

Our employees, independent distributors, independent contractors, suppliers and other third parties may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could expose us to liability and hurt our reputation.

We are exposed to the risk that our employees, independent distributors, independent contractors, suppliers and others may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) FDA laws and regulations, including those laws that require the reporting of true, complete and accurate information to the FDA, (2) manufacturing standards, (3) healthcare fraud and abuse laws, or (4) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our preclinical studies or clinical trials or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred.

If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our business, results of operations and financial condition.

Risks related to intellectual property matters

Protection of our intellectual property rights may be difficult and costly, and our inability to protect our intellectual property could adversely affect our competitive position.

Our success depends in part on our ability to protect our proprietary rights to the technologies and inventions used in, or embodied by, our products. To protect our proprietary technology, we rely on patent protection, as well as a combination of copyright, trade secret and trademark laws, as well as nondisclosure, confidentiality and other contractual restrictions in our consulting and employment agreements. These legal means afford only limited protection, however, and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Our existing confidentiality and/or invention assignment agreements with employees, contractors, and others who participate in IP development activities could be breached, or we may not enter into sufficient and adequate agreements with those individuals in the first instance, and we may not have adequate remedies for such breaches. Furthermore, we may be subject to, and forced to defend against, third-party claims of ownership to our intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or rights to use, valuable intellectual property. Such an outcome could adversely affect our business, results of operations and financial condition. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

The process of applying for patent protection is time-consuming and expensive and we cannot assure you that all of our patent applications will issue as patents or that, if issued, they will issue in a form that will be advantageous to us. The rights granted to us under our patents may not be meaningful or provide us with any commercial advantage, and they could be opposed, contested, narrowed, or circumvented by our competitors or declared invalid or unenforceable in judicial or administrative proceedings. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. As a result, some of our products are not, and in the future may not be, protected by patents. We generally apply for patents in those countries where we intend to make, have made, use, offer for sale, or sell products and where we assess the risk of infringement to justify the cost of seeking patent protection. However, we do not seek protection in all countries where we sell products and we may not accurately predict all the countries where patent protection would ultimately be desirable. If we fail to timely file a patent application in any such country or major market, we may be precluded from doing so at a later date. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection but where such protection may not be sufficient to terminate infringing activities. Furthermore, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed to us by third-parties. Therefore, these patents and applications may not be prosecuted or enforced in a manner consistent with the best interests of our business. If such licensors fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, which could also adversely affect our business, results of operations and financial condition.

The rights granted to us under these patents, including prospective rights sought in our pending patent applications, could be opposed, contested or circumvented by our competitors or declared invalid or unenforceable in judicial or administrative proceedings. If any of our patents are challenged, invalidated or legally circumvented by third-parties, and if we do not own other enforceable patents protecting our products, competitors could market products and use processes that are substantially similar to, or superior to, those of ours, and our business will suffer. In addition, the patents we own may not be of sufficient scope or strength to provide us with any meaningful protection or commercial advantage, and competitors may be able to design around our patents or develop products that provide outcomes comparable to those of ours without infringing on our intellectual property rights.

Further, our patents may not be drafted or interpreted sufficiently broadly to prevent others from marketing products and services similar to ours or designing around our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our commercial technology or the future products and services that we develop. We may not have freedom to operate unimpeded by the patent rights of others. Third parties may have dominating, blocking or other patents relevant to our technology of which we are not aware. In addition, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications or published information which could invalidate our patents or a portion of the claims of our patents. Any such patent applications may have priority over our patent applications or issued patents, which could require us to obtain rights from third parties to issued patents or pending patent applications covering such technologies to allow us to commercialize our technology. If another party has filed a U.S. patent application on inventions similar to ours, depending on when the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the USPTO to determine priority of invention in the United States. Further, we may not develop additional proprietary technologies and, even if we do, they may not be patentable.

In addition, patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. We may be subject to a third-party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third-parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Moreover, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. In some cases, noncompliance with such requirements can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to our products, which would adversely affect our business, results of operations and financial condition.

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries may not protect our intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories in which we have patent protection that may not be sufficient to terminate infringing activities.

Furthermore, we do not have patent rights in certain foreign countries in which a market may exist in the future. We may need to expend additional resources to protect or defend our intellectual property rights in these countries, and the inability to protect or defend the same could impair our brand or adversely affect the growth of our business internationally. For example, we may not be able to stop a competitor from marketing and selling in foreign countries products that are the same as or similar to our products.

Patents have a limited lifespan, and the protection patents affords is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Even if patents covering our products are obtained, once the patent life has expired for patents covering a product, we may be open to competition from competitive products and services. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours.

Trademarks

We rely on our trademarks as one means to distinguish our products from the products of our competitors, and have registered or applied to register many of these trademarks. However, we may not be able to successfully secure trademark registrations for all such applications. Third-parties may oppose our trademark applications, or otherwise challenge our use of both registered and unregistered trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively and our business, results of operations and financial condition may be adversely affected.

Trade secrets and know-how

We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees or current employees, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property will be effective. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Our competitors could use any of the information we may be required to disclose by the FDA to develop independently technology similar to ours. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business, results of operations and financial condition. If we were to enforce a claim that a third-party had illegally obtained, misappropriated or was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may adversely affect our business, results of operations and financial condition. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

We depend on certain technologies that are licensed to us. We do not control the intellectual property rights covering these technologies and any loss of our rights to these technologies or the rights licensed to us could prevent us from selling our products, which could adversely impact our business, results of operations and financial condition.

We are a party to license agreements under which we are granted rights to intellectual property that is material to our business, and we may need to enter into additional license agreements in the future. Our rights to use these technologies and the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those licenses. Our existing license agreements impose, and we expect that future license agreements will impose on us, various diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which case we would not be able to market products covered by the license, which would adversely affect our business, results of operations and financial condition.

As we have done previously, we may need to obtain licenses from third parties to advance our research or allow commercialization of our products and technologies. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In the event that we are not able to acquire a license, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected products and technologies, which could materially harm our business. In addition, the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties or other forms of compensation and damages.

In some cases, we may not have the right to control the prosecution, maintenance, or filing of the patents that are licensed to us, or the enforcement of these patents against infringement by third parties. Some of our patents and patent applications were not filed by us, but were either acquired by us or are licensed from third parties. Thus, these patents and patent applications were not drafted by us or our attorneys, and we did not control or have any input into the prosecution of these patents and patent applications prior to our acquisition of, or our entry into a license with respect to, such patents and patent applications. We cannot be certain that the drafting or prosecution of the patents and patent applications licensed to us will result or has resulted in valid and enforceable patents. Further, we do not always retain complete control over our ability to enforce our licensed patent rights against third-party infringement. In those cases, we cannot be certain that our licensor will elect to enforce these patents to the extent that we would choose to do so, or in a way that will ensure that we retain the rights we currently have under our license. If our licensor fails to properly enforce the patents subject to our license in the event of third-party infringement, our ability to retain our competitive advantage with respect to our products may be materially and adversely affected.

Licensing of intellectual property is an important part of our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property that is subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products and technologies, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

In addition, we may become the owner of intellectual property that was obtained through assignments which may be subject to re-assignment back to the original assignor upon our failure to prosecute or maintain such intellectual property, upon our breach of the agreement pursuant to which such intellectual property was assigned, or upon our bankruptcy. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or if intellectual property is re-assigned back to the original assignor, we may be unable to successfully develop and commercialize the affected products and technologies.

Our intellectual property agreements with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology.

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, either of which could adversely affect our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact conceives or develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may in the future be a party to patent and other intellectual property litigation and administrative proceedings that could be costly and could interfere with our ability to successfully market our products.

The medical device industry has been characterized by frequent and extensive intellectual property litigation and is highly competitive. Our competitors or other patent holders may assert that our products and/or the methods employed in our products are covered by their patents or that we are infringing, misappropriating, or misusing their trademark, copyright, trade secret, and/or other proprietary rights.

If our products or methods are found to infringe, we could be prevented from manufacturing or marketing our products. In the event that we become involved in such a dispute, we may incur significant costs and expenses and may need to devote resources to resolving any claims, which would reduce the cash we have available for operations and may be distracting to management and other employees, including those involved in the development of intellectual property. We do not know whether our competitors or potential competitors have applied for, will apply for, or will obtain patents that will prevent, limit or interfere with our ability to make, use, sell, import or export our products. Because patent applications can take many years to issue, third parties may have currently pending patent applications which may later result in issued patents that our products and technologies may infringe, or which such third parties claim are infringed by the use of our products or technologies. There is no guarantee that patents will not issue in the future from currently pending applications that may be infringed by our technology or products. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and difficulty in assessing the meaning of patent claims. We cannot assure you that we will prevail in such actions, or that other actions alleging misappropriation or misuse by us of third-party trade secrets or infringement by us of third-party patents, copyrights, trademarks or other rights or challenging the validity of our patents, copyrights, trademarks or other rights will not be asserted against us.

We may also initiate litigation against third-parties to enforce our patent and proprietary rights or to determine the scope, enforceability or validity of the proprietary rights of others. Our intellectual property has not been tested in litigation. If we initiate litigation to protect our rights, we run the risk of having our patents and other proprietary rights invalidated, canceled or narrowed, which could undermine our competitive position. Further, if the scope of protection provided by our patents or patent applications or other proprietary rights is threatened or reduced as a result of litigation, it could discourage third parties from entering into collaborations with us that are important to the commercialization of our products.

We may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our product. Furthermore, if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate its patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business, results of operations and financial condition. Any such claim could also force use to do one or more of the following:

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the product, service, or technology at issue infringes or violates the third-party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third-party's attorneys' fees;
- pay substantial damages to our customers or end users to discontinue use or replace infringing technology with non-infringing technology;
- stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the product or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such product, service, or technology;
- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our products, services, and technology so they do not infringe or violate the third-party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with our competitors, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing products and technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims, if our claims are held invalid or otherwise unenforceable.

Some of our competitors may be able to sustain the costs of complex intellectual property litigation more effectively than we can. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact prospective customers, cause product shipment delays, divert the time, attention and resources of management, or prohibit us from manufacturing, marketing or otherwise commercializing our products, services and technology. Any uncertainties resulting from the initiation and continuation of any litigation could adversely affect our ability to raise additional funds or otherwise adversely affect our business, results of operations and financial condition.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If these results are perceived to be negative, the price of our Class A common stock could be adversely affected.

In addition, certain of our agreements with suppliers, distributors, customers and other entities with whom we do business may require us to defend or indemnify these parties to the extent they become involved in infringement claims relating to our technologies or products, or rights licensed to them by us. If we are required or agree to defend or indemnify any of these third parties in connection with any infringement claims, we could incur significant costs and expenses that could adversely affect our business, results of operation and financial condition.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or former employers or are in breach of non-competition or non-solicitation agreements with our competitors or former employers.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. In addition, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the competitors or former employers. An inability to incorporate technologies or features that are important or essential to our products could adversely affect our business, results of operations and financial condition, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could adversely affect our business, results of operations and financial condition.

Any product candidates that we develop as biologics subject to the BLA pathway may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when processes intended to implement BPCIA may be fully adopted by the FDA, any of these processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any of the product candidates we develop that is approved in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

Intellectual property rights do not necessarily address all potential threats to our business.

Once granted, patents may remain open to invalidity challenges including opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

In addition, the degree of future protection afforded by our intellectual property rights is uncertain because even granted intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors or permit us to maintain our competitive advantage. Moreover, if a third-party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights.

The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;

- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- our pending patent applications may not lead to issued patents;
- issued patents that we own or exclusively license may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may adversely affect our business.

Should any of these events occur, they could adversely affect our business, results of operations and financial condition.

Risks related to our organizational structure and the Tax Receivable Agreement

Our principal asset is our interest in BV LLC, and, accordingly, we depend on distributions from BV LLC to pay our taxes and expenses, including payments under the Tax Receivable Agreement. BV LLC's ability to make such distributions may be subject to various limitations and restrictions.

We are a holding company and have no material assets other than our ownership of LLC Interests of BV LLC. As such, we have no independent means of generating net sales or cash flow, and our ability to pay our taxes and operating expenses or declare and pay dividends in the future, if any, will be dependent upon the financial results and cash flows of BV LLC and its subsidiaries and distributions we receive from BV LLC. There can be no assurance that BV LLC and its subsidiaries will generate sufficient cash flow to distribute funds to us or that applicable state law and contractual restrictions, including negative covenants in our debt instruments, will permit such distributions.

BV LLC will continue to be treated as a partnership for U.S. federal income tax purposes and, as such, generally will not be subject to any entity-level U.S. federal income tax. Instead, taxable income will be allocated to holders of LLC Interests, including us. Accordingly, we will incur income taxes on our allocable share of any net taxable income of BV LLC. Under the terms of the Bioventus LLC Agreement, BV LLC will be obligated to make tax distributions to holders of LLC Interests, including us, subject to any limitations or restrictions in our debt arrangements. In addition to tax expenses, we will also incur expenses related to our operations, including payments under the Tax Receivable Agreement (TRA), which we expect could be significant. See *Part III, Item 13. Certain Relationships and Related Transactions, and Director Independence-Tax Receivable Agreement* for further information. We intend, as its managing member, to cause BV LLC to make cash distributions to the owners of LLC Interests, including us, in an amount sufficient to (i) fund their or our tax obligations in respect of allocations of taxable income from BV LLC and (ii) cover our operating expenses, including payments under the TRA. However, BV LLC's ability to make such distributions may be subject to various limitations and restrictions, such as restrictions on distributions that would either violate any contract or agreement to which BV LLC is then a party, including debt agreements, or any applicable law, or that would have the effect of rendering BV LLC insolvent. If we do not have sufficient funds to pay taxes or other liabilities or to fund our operations, we may have to borrow funds, which could materially adversely affect our liquidity and financial condition and subject us to various restrictions imposed by any such lenders. To the extent that we are unable to make payments under the TRA for any reason, such payments generally will be deferred and will accrue interest until paid; provided, however, that nonpayment for a specified period may constitute a material breach of a material obligation under the TRA and therefore accelerate payments due under the TRA. In addition, if BV LLC does not have sufficient funds to make distributions, our ability to declare and pay cash dividends will also be restricted or impaired.

The TRA with the Continuing LLC Owner requires us to make cash payments to it in respect of certain tax benefits to which we are or may become entitled, and we expect that the payments we will be required to make could be significant.

We are a party to a TRA with Smith & Nephew, Inc. (Continuing LLC Owner). Under the TRA, we are required to make cash payments to the Continuing LLC Owner equal to 85% of the tax benefits, if any, that we actually realize, or in certain circumstances are deemed to realize, as a result of (1) increases in the tax basis of assets of BV LLC resulting from (a) any future redemptions or exchanges of LLC Interests and (b) certain distributions (or deemed distributions) by BV LLC and (2) certain other tax benefits arising from payments under the TRA. We expect the amount of the cash payments that we will be required to make under the TRA will be significant. The actual amount and timing of any payments under the TRA will vary depending upon a number of factors, including the timing of redemptions or exchanges by the Continuing LLC Owner, the amount of gain recognized by the Continuing LLC Owner, the amount and timing of the taxable income we generate in the future, and the federal tax rates then applicable. Any payments made by us to the Continuing LLC Owner under the TRA will generally reduce the amount of overall cash flow that might have otherwise been available to us. To the extent that we are unable to make timely payments under the TRA for any reason, the unpaid amounts will be deferred and will accrue interest until paid by us. Furthermore, our obligation to make payments under the TRA could make us a less attractive target for an acquisition, particularly in the case of an acquirer that cannot use some or all of the tax benefits that are the subject of the TRA.

Payments under the TRA are not conditioned on the Continuing LLC Owner's continued ownership of LLC Interests or our Class A common stock. The amounts we will be required to pay under the TRA will depend on, among other things, the timing of subsequent redemptions or exchanges of LLC Interests by the Continuing LLC Owner, the price of our shares of Class A common stock at the time of each such redemption or exchange, and the amounts and timing of our future taxable income, and may be significantly different from the amounts described in the preceding sentence. Additionally, in certain cases such payments may be accelerated or significantly exceed the actual benefits we realize. Moreover, our organizational structure, including the TRA, confers certain tax benefits upon the Continuing LLC Owner that may not benefit the holders of our Class A common stock to the same extent as they will benefit the Continuing LLC Owner. Refer to risk factor—*In certain cases, payments under the TRA to the Continuing LLC Owners may be accelerated or significantly exceed the actual benefits we realize in respect of tax attributes subject to the TRA.*

In certain cases, payments under the TRA to the Continuing LLC Owner may be accelerated or significantly exceed the actual benefits we realize in respect of the tax attributes subject to the TRA.

The TRA provides that if (i) we materially breach any of our material obligations under the TRA, (ii) we undertake certain mergers, assets sales, other forms of business combinations or other changes of control or (iii) we elect an early termination of the TRA, then our obligations or our successor's obligations under the TRA to make payments thereunder would be based on certain assumptions, including an assumption that we would have sufficient taxable income to fully utilize all potential future tax benefits that are subject to the TRA (or, in the case of certain mergers, assets sales, other forms of business combinations or other charges of control, that we would have taxable income at least equal to four times the highest taxable income in any of the four fiscal quarters ending prior to the closing date of such transaction (increased by 10% for each taxable year beginning with the second taxable year following the closing date)). As a result of the foregoing, (i) we could be required to make payments under the TRA that are greater than the specified percentage of the actual benefits we ultimately realize in respect of the tax benefits that are subject to the TRA and (ii) if we materially breach any of our material obligations under the TRA or if we elected to terminate the TRA early, we would be required to make an immediate cash payment equal to the present value of the anticipated future tax benefits that are the subject of the TRA, which payment may be made significantly in advance of the actual realization, if any, of such future tax benefits.

In these situations, our obligations under the TRA could have a substantial negative impact on our liquidity and could have the effect of delaying, deferring or preventing certain mergers, asset sales, other forms of business combinations or other changes of control. There can be no assurance that we will be able to fund or finance our obligations under the TRA. We may elect to completely terminate the TRA early only with the written approval of a majority of our directors other than any directors that have been appointed or designated by the Continuing LLC Owner or any of such person's affiliates.

We may make payments to the Continuing LLC Owner under the TRA that exceed the tax benefits actually realized by us in the event that any tax benefits are disallowed by a taxing authority.

Payments under the TRA are be based on the tax reporting positions that we determine, and the Internal Revenue Service (IRS) or another tax authority may challenge all or part of the tax basis increases, as well as other related tax positions we take, and a court could sustain such challenge. Pursuant to the TRA, the Continuing LLC Owner is required to reimburse us for any cash payments previously made to it under the TRA in the event that any tax benefits actually realized by us and for which payment has been made under the TRA are subsequently challenged by a taxing authority and are ultimately disallowed. In addition, but without duplication of any amounts previously reimbursed by the Continuing LLC Owner, any excess cash payments made by us to the Continuing LLC Owner will be netted against any future cash payments that we might otherwise be required to make to the Continuing LLC Owner under the terms of the TRA. However, we might not determine that we have effectively made an excess cash payment to the Continuing LLC Owner for a number of years following the initial time of such payment. Moreover, there can be no assurance that any excess cash payments for which the Continuing LLC Owner has a reimbursement obligation under the TRA will be repaid to us. As a result, payments could be made under the TRA in excess of the tax savings that we realize in respect of the tax attributes with respect to the Continuing LLC Owner that are the subject of the TRA.

Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our results of operations and financial condition.

We are subject to taxes by the U.S. federal, state, local and foreign tax authorities, and our tax liabilities will be affected by the allocation of expenses to differing jurisdictions. Our future effective tax rates could be subject to volatility or adversely affected by a number of factors. In addition, we may be subject to audits of our income, sales and other transaction taxes by U.S. federal, state, local and foreign taxing authorities. Outcomes from these audits could adversely affect our business, results of operations and financial condition.

If we were deemed to be an investment company under the Investment Company Act of 1940, as amended, or the 1940 Act, as a result of our ownership of BV LLC, applicable restrictions could make it impractical for us to continue our business as contemplated and could adversely affect our business, results of operations and financial condition.

As the sole managing member of BV LLC, we control and operate BV LLC. On that basis, we believe that our interest in BV LLC is not an “investment security” as that term is used in the 1940 Act. However, if we were to cease participation in the management of BV LLC, our interest in BV LLC could be deemed an “investment security” for purposes of the 1940 Act.

We and BV LLC intend to conduct our operations so that we will not be deemed an investment company. However, if we were to be deemed an investment company, restrictions imposed by the 1940 Act, including limitations on our capital structure and our ability to transact with affiliates, could make it impractical for us to continue our business as contemplated and could adversely affect our business, results of operations and financial condition.

Bioventus is controlled by the Original LLC Owners, whose interests may differ from those of our public stockholders.

As of March 4, 2022, the Original LLC Owners control approximately 58.7% of the combined voting power of our common stock through their ownership of both Class A common stock and Class B common stock. The Original LLC Owners will, for the foreseeable future, have the ability to substantially influence us through their ownership position over corporate management and affairs, and will be able to control virtually all matters requiring stockholder approval. The Original LLC Owners are able to, subject to applicable law, and the voting arrangements, elect a majority of the members of our Board, control actions to be taken by us and our Board, including amendments to our certificate of incorporation and bylaws and approval of significant corporate transactions, including mergers and sales of substantially all of our assets. The directors so elected will have the authority, subject to the terms of our indebtedness and applicable rules and regulations, to issue additional stock, implement stock repurchase programs, declare dividends and make other decisions. It is possible that the interests of the Original LLC Owners may in some circumstances conflict with our interests and the interests of our other stockholders, including you. For example, the Continuing LLC Owner may have different tax positions from us, especially in light of the TRA that could influence our decisions regarding whether and when to dispose of assets, whether and when to incur new or refinance existing indebtedness, and whether and when Bioventus should terminate the TRA and accelerate its obligations thereunder. In addition, the determination of future tax reporting positions and the structuring of future transactions may take into consideration the Continuing LLC Owner’s tax or other considerations, which may differ from the considerations of us or our other stockholders.

Failure to establish and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could adversely affect our business and stock price.

We are required to comply with the SEC's rules implementing Sections 302 and 404 of the Sarbanes-Oxley Act, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal controls over financial reporting. Though we will be required to disclose changes made in our internal controls and procedures on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting pursuant to Section 404 until the year following our first annual report required to be filed with the SEC. However, as an emerging growth company, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating.

To comply with the requirements of being a public company, we have undertaken various actions, and may need to take additional actions, such as implementing new internal controls and procedures and hiring additional accounting or internal audit staff. We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to prevent or avoid potential future material weaknesses and we have identified material weaknesses in the past. If we identify any material weaknesses in the future, the accuracy and timing of our financial reporting may be adversely affected. Testing and maintaining internal controls can also divert our management's attention from other matters that are important to the operation of our business. Additionally, when evaluating our internal controls over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404. If we identify any material weaknesses in our internal controls over financial reporting or are unable to comply with the requirements of Section 404 in a timely manner or assert that our internal controls over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our Class A common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other regulatory authorities, which could require additional financial and management resources.

Our amended and restated certificate of incorporation, to the extent permitted by applicable law, contains provisions renouncing our interest and expectation to participate in certain corporate opportunities identified or presented to certain of our Original LLC Owners.

Certain of the Original LLC Owners are in the business of making or advising on investments in companies and these Original LLC owners may hold, and may, from time to time in the future, acquire interests in or provide advice to businesses that directly or indirectly compete with certain portions of our business or the business of our suppliers. Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, none of the Original LLC Owners or any director who is not employed by us or his or her affiliates will have any duty to refrain from engaging in a corporate opportunity in the same or similar lines of business as us. The Original LLC Owners may also pursue acquisitions that may be complementary to our business, and, as a result, those acquisition opportunities may not be available to us. As a result, these arrangements could adversely affect our business, results of operations, financial condition or prospects if attractive business opportunities are allocated to any of the Original LLC Owners instead of to us.

Anti-takeover provisions in our governing documents and under Delaware law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management, and depress the market price of our common stock.

Our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law contain provisions that could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our Board and include the following provisions:

- authorizing the issuance of "blank check" preferred stock that could be issued by our Board to increase the number of outstanding shares and thwart a takeover attempt;
- establishing a classified Board so that not all members of our Board are elected at one time;
- the removal of directors only for cause;
- prohibiting the use of cumulative voting for the election of directors;
- limiting the ability of stockholders to call special meetings or amend our bylaws;
- requiring all stockholder actions to be taken at a meeting of our stockholders; and

- establishing advance notice and duration of ownership requirements for nominations for election to the Board or for proposing matters that can be acted upon by stockholders at stockholder meetings.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the DGCL, which prevents interested stockholders, such as certain stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations unless (i) prior to the time such stockholder became an interested stockholder, the board approved the transaction that resulted in such stockholder becoming an interested stockholder, (ii) upon consummation of the transaction that resulted in such stockholder becoming an interested stockholder, the interested stockholder owned 85% of the common stock or (iii) following board approval, the business combination receives the approval of the holders of at least two-thirds of our outstanding common stock not held by such interested stockholder. Because we have "opted out" of Section 203 of the DGCL in our amended and restated certificate of incorporation, the statute will not apply to business combinations involving us.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying, preventing or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for: (a) any derivative action, suit or proceeding brought on our behalf; (b) any action, suit or proceeding asserting a claim of breach of fiduciary duty owed by any of our directors, officers or stockholders to us or to our stockholders; (c) any action, suit or proceeding arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or amended bylaws (as either may be amended from time to time); or, (d) any action, suit or proceeding asserting a claim governed by the internal affairs doctrine; provided that the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal executive offices are located on leased property in Durham, North Carolina. We also occupy leased office and manufacturing space in Cordova, Tennessee, Farmingdale, New York, Newport News, Virginia and Valencia, California. In addition, our international operations occupy leased office spaces in Hoofddorp, Netherlands, Mississauga, Canada and Hod Hasharon, Israel. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed on acceptable terms.

Item 3. Legal Proceedings

On March 23, 2017, Misonix's former distributor in China, Cicel (Beijing) Science & Technology Co., Ltd., filed a lawsuit against Misonix and certain of its officers and directors in the United States District Court for the Eastern District of New York. The complaint alleged that Misonix improperly terminated its contract with the former distributor. The complaint sought various remedies, including compensatory and punitive damages, specific performance and preliminary and post judgment injunctive relief, and asserted various causes of action, including breach of contract, unfair competition, tortious interference with contract, fraudulent inducement, and conversion. On October 7, 2017, the court granted Misonix's motion to dismiss each of the tort claims asserted against Misonix, and also granted the individual defendants' motion to dismiss all claims asserted against them. On January 23, 2020, the Court granted Cicel's motion to amend its complaint, to include claims for alleged defamation and theft of trade secrets in addition to the breach of contract claim. Discovery in the matter ended on August 5, 2021. On January 20, 2022, the Court granted Misonix's summary judgment motion on Cicel's breach of contract and defamation claims. We believe that we have various legal and factual defenses to the remaining trade secret claim and intend to defend the action vigorously. There is no trial date currently set.

Prior to the closing of our acquisition of Bioness, Bioness had been named as a defendant in a lawsuit, for which we are indemnified under the indemnification provisions contained in the Bioness Merger Agreement. The case relates to an action brought in February 2021 in the Delaware State Court of Chancery by a former minority shareholder and director of Bioness, seeking a temporary restraining order contesting our acquisition of Bioness. While the complaint to block the Bioness acquisition was dismissed by the court, a separate action was brought against the Company under the indemnification provisions of the Bioness Certificate of Incorporation to recover approximately $2.0 million in attorney fees and other expenses incurred by the director and shareholder in connection with the dismissed case.

On August 19, 2021, the court issued a ruling granting, in part, plaintiff's motion for summary judgment, awarding plaintiff attorney's fees and related expenses incurred in connection with performance of the plaintiff's directorial duties, and denying fees and expenses incurred in a non-director capacity. In its ruling, the Court's order also directed the parties to agree upon a process that will govern the payment of and challenges to plaintiff's payment requests and required Bioness to pay 50% of the demanded amount into escrow if more than 50% of the total invoiced amount was in dispute. Pursuant to the court's order, to date, Bioness has paid approximately $1.0 million into escrow. We await the court's final ruling on the appropriateness of these fees.

On February 8, 2022, the above referenced minority shareholder of Bioness filed another action in the Delaware State Court of Chancery in connection with our acquisition of Bioness. This action names the former Bioness directors, the Alfred E. Mann Trust (Trust), which was the former majority shareholder of Bioness, the trustees of the Trust and Bioventus as defendants. The complaint alleges, among other things, that the individual directors, the Trust, and the trustees breached their fiduciary duty to the plaintiff in connection with their consideration and approval of our transaction. The complaint also alleges that we aided and abetted the other defendants in breaching their fiduciary duties to the plaintiff and that we breached the Merger Agreement by failing to pay the plaintiff its pro rata share of the merger consideration. We believe that we are indemnified under the indemnification provisions contained in the Bioness Merger Agreement for these claims. We also believe that there are various legal and factual defenses to the claims plaintiff made against us and intend to defend ourselves vigorously.

On September 15, 2021, a purported stockholder of Misonix filed an action in the United States District Court for the Eastern District of New York, captioned Stein v. Misonix, Inc., et al., Case No. 2:21-cv-05127 (E.D.N.Y.) (the Stein Complaint). The Stein Complaint names Misonix and members of its board of directors as defendants. On September 16, 2021, a purported stockholder of Misonix filed an action in the United States District Court for the Southern District of New York, captioned Ciccotelli v. Misonix, Inc. et al., Case No. 1:21-cv-07773 (S.D.N.Y.) (the Ciccotelli Complaint) against Misonix, members of its board of directors, the Company, and its subsidiaries, Merger Sub I and Merger Sub II, as defendants. Plaintiff voluntarily dismissed the Ciccotelli Complaint on November 10, 2021. On October 12, 2021, another purported stockholder of Misonix filed an action in the United States District Court for the Eastern District of New York, captioned Rubin v. Misonix, Inc. et al., Case No. 1:21-cv-05672 (S.D.N.Y.) (the Rubin Complaint) and on October 15, 2021, another purported stockholder of Misonix filed an action in the United States District Court for the Southern District of New York, captioned Taylor v. Misonix, Inc. et al., Case No. 1:21-cv-08513 (S.D.N.Y.) (the Taylor Complaint). The Rubin Complaint and the Taylor Complaint name Misonix and members of its board of directors as defendants.

Each of the pending complaints asserts claims under Section 14(a) and Section 20(a) of the Exchange Act and SEC Rule 14a-9, challenging the adequacy of disclosures in the proxy statement/prospectus filed with the SEC on September 8, 2021 or the Definitive Proxy Statement filed with the SEC on September 24, 2021, regarding Misonix and/or Bioventus' projections and J.P. Morgan's financial analysis. The complaints seek, among other relief, (i) injunctive relief preventing the parties from proceeding with the merger, (ii) rescission in the event that the merger is consummated, and (iii) an award of costs, including attorneys' and experts' fees.

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 Information

On February 11, 2021, we closed an initial public offering (IPO) and Class A common stock began trading on the Nasdaq Global Select Market under the symbol "BVS". Prior to that time, there was no public market for our stock. There is no established public trading market for our Class B common stock. As of March 4, 2022, we had 1 holder of record of our Class B common stock.

As of March 4, 2022, we had approximately 204 holders of record of our Class A common stock. This amount does not take into account shareholders whose shares are held in "street name" by brokerage houses or other intermediaries. The closing price of our common stock on March 4, 2022 was $13.51.

Dividends

We do not anticipate declaring or paying any cash dividends to holders of our Class A common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to finance the growth of our business. If we decide to pay cash dividends in the future, the declaration and payment of such dividends will be at the sole discretion of our board of directors (Board) and may be discontinued at any time. Holders of our Class B common stock are not entitled to participate in any dividends declared by our Board. In determining the amount of any future dividends, our Board will take into account any legal or contractual limitations, our actual and anticipated future earnings, cash flow, debt service and capital requirements and other factors that our Board may deem relevant.

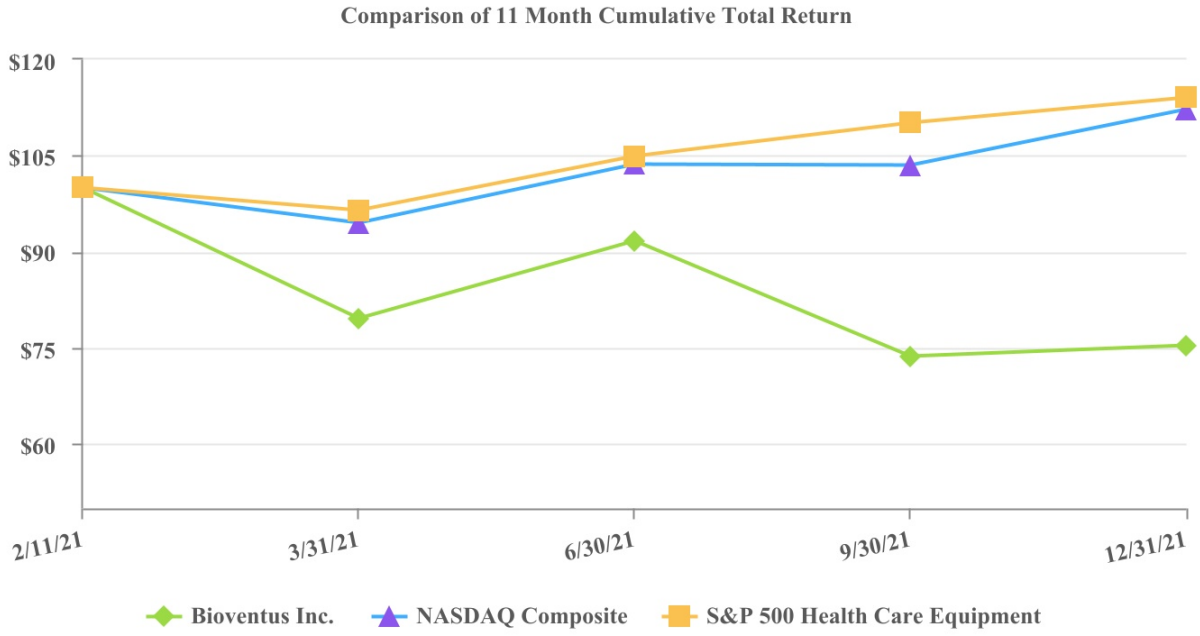
In the event Bioventus Inc. declares any cash dividend, we intend to cause Bioventus LLC (BV LLC) to make distributions to Bioventus Inc., in an amount sufficient to cover such cash dividends declared by us. If BV LLC makes such distributions to Bioventus Inc., the Class B common stock owner will also be entitled to receive the respective equivalent pro rata distributions in accordance with the percentages of their respective LLC Interests.

In addition, the terms of our financing arrangements contain covenants that may restrict BV LLC and its subsidiaries from paying such distributions, subject to certain exceptions. Any financing arrangements that we enter into in the future may include restrictive covenants that limit our ability to pay dividends. In addition, BV LLC is generally prohibited under Delaware law from making a distribution to a member to the extent that, at the time of the distribution, after giving effect to the distribution, liabilities of BV LLC (with certain exceptions) exceed the fair value of its assets. Subsidiaries of BV LLC are generally subject to similar legal limitations on their ability to make distributions to BV LLC.

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 performance graph compares the cumulative 11 months cumulative total return to stockholders on our Class A common stock relative to the cumulative total returns on the Nasdaq Composite Index and the S&P 500 Health Care Equipment Index for the period commencing on February 11, 2021 (the date our Class A common stock commenced trading on Nasdaq) through December 31, 2021 assuming an initial investment of $100. Nasdaq Composite Index and S&P 500 Health Care Equipment Index will not be deemed incorporate by reference into any other filings under the Exchange Act or the Securities Act of 1933, as amended, except to the extent we specifically incorporate. Note that historic stock price performance is not necessarily indicative of future stock price performance.



	2/11/21	3/31/21	6/30/21	9/30/21	12/31/21
Bioventus Inc.	$ 100.00	$ 79.54	$ 91.62	$ 73.71	$ 75.43
NASDAQ Composite	$ 100.00	$ 94.54	$ 103.69	$ 103.46	$ 112.20
S&P 500 Health Care Equipment	$ 100.00	$ 96.41	$ 104.95	$ 110.16	$ 113.99

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 results of operations should be read in conjunction with Part I, Item 1A, Risk Factors and our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K (Annual Report). In addition to historical consolidated financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Some of the numbers included herein have been rounded for the convenience of presentation. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including those discussed under Part 1, Item 1A. Risk Factors and elsewhere in this Annual Report. A discussion of the year ended December 31, 2020 compared to the year ended December 31, 2019 has been reported previously in our 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 26, 2021, under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Executive Summary

We are a global medical device company focused on developing and commercializing clinically differentiated, cost efficient and minimally invasive treatments that engage and enhance the body's natural healing process. We operate our business through two reportable segments, U.S. and International, and our portfolio of products is grouped into three verticals:

- Pain Treatments is comprised of non-surgical joint pain injection therapies as well as peripheral nerve stimulation (PNS) products to help the patient get back to their normal activities.
- Surgical Solutions is comprised of bone graft substitutes (BGS) to fuse and grow bones, improve results following spinal and other orthopedic surgeries as well as minimally invasive ultrasonic medical devices used for precise bone sculpting, removing tumors and tissue debridement, in various surgeries.
- Restorative Therapies is comprised of a bone healing system, skin allografts and products used to support healing of wounds as well as devices designed to help patients regain leg or hand function due to stroke, multiple sclerosis or other central nervous system disorders.

The following table sets forth notable financial results in 2021 and 2020:

	Years Ended December 31,	
	2021	2020
Net sales	$ 430,898	$ 321,161
Net income	$ 9,586	$ 14,722
Adjusted EBITDA[(1)]	$ 80,759	$ 72,443
Loss per share, basic and diluted	$ (0.15)	NM

(1) See below under results of operations-Adjusted EBITDA for a reconciliation of net income to Adjusted EBITDA.

Strategic transactions

We have pursued and continue to pursue business development opportunities that leverage our significant customer presence across orthopedics, broaden our portfolio and increase our global footprint. Below is a summary of some of our recent transactions:

Misonix Acquisition

On October 29, 2021, we acquired Misonix, Inc. (Misonix) in a cash-and-stock transaction. We provided merger consideration totaling $525.3 million, including Class A common stock valued at $274.6 million, cash of $183.0 million, fully vested Bioventus stock options valued at $27.6 million and additional cash used to pay debt and expenses on Misonix's behalf totaling $40.1 million. The cash consideration was primarily funded through taking on additional debt.

The acquisition includes the entire portfolio of Misonix products as well as its research and development pipeline. Misonix manufactures minimally invasive surgical ultrasonic medical devices used for precise bone sculpting, removal of soft and hard tumors, and tissue debridement, primarily in the areas of neurosurgery, orthopedic surgery, plastic surgery, wound care and maxillo-facial surgery. Misonix also exclusively distributes skin allografts and wound care products used to support healing of wounds.

The Misonix Acquisition provided additional net sales in 2021 totaling $15.4 million since the date of acquisition. We incurred transaction costs of $8.0 million. We expect to benefit from the Misonix Acquisition by capitalizing on the processes below:

- Accelerating Misonix's BoneScalpel and Nexus adoption through our extensive spine surgical solutions footprint;
- Augmenting our leading lower extremity offerings and commercial footprint to accelerate growth in this call point;
- Significantly expanding the direct wound salesforce that covers the entire customer continuum, including physicians' offices, ambulatory surgical centers, wound clinics, and hospitals; and
- Extending Misonix's international access through our direct channels and infrastructure in the Netherlands, Canada, Germany, and the UK.

Bioness Acquisition

On March 30, 2021, we acquired Bioness, Inc. (Bioness), in a cash transaction. We provided upfront cash of $48.9 million funded exclusively through the use of cash on hand and we could be required to pay up to an additional $50.0 million related to the achievement of certain key milestones. This discounted contingent consideration is currently valued at $15.5 million based on the probability of reaching the key milestones. We currently estimate the payments to be made in 2024 and 2025.

The acquisition includes the entire portfolio of Bioness products as well as its research and development pipeline. Bioness manufactures neuromodulation and advanced rehabilitation medical devices through its PNS system and premium advanced rehabilitation solutions. PNS Systems help patients suffering from pain after surgery on an extremity, which affects over 16 million patients each year globally, and addresses the growing need to reduce opioid usage. Rehabilitation solutions includes electrical stimulation exoskeletal devices for both the upper and lower extremities, robotic gait and fall safety systems, and high-tech, interactive software learning and recovery assessment platforms.

The Bioness acquisition provided additional net sales in 2021 totaling $34.0 million since the date of acquisition. We incurred transaction costs of $8.0 million and restructuring charges of $2.5 million related to the Bioness Acquisition during 2021. We expect total restructuring expenses related to the Bioness Acquisition to be $2.9 million. We expect to benefit significantly from the Bioness Acquisition by capitalizing on the processes below:

- Accelerating Bioness' revenue growth by leveraging our existing global network of sales representatives calling on orthopedic, pain and podiatric physicians; and
- Expanding market access and reimbursement processing capabilities as we estimate Bioness medical devices address total global market opportunities approaching $8 billion per year.

CartiHeal

On July 15, 2020, we entered into an Option and Equity Purchase Agreement (Option Agreement) with CartiHeal (2009) Ltd. (CartiHeal), a privately-held company headquartered in Israel and the developer of the proprietary Agili-C™ implant for the treatment of joint surface lesions in traumatic and osteoarthritic joint, and its shareholders. The agreement provides us with an exclusive option to acquire 100% of CartiHeal's shares under certain conditions (Call Option), and provides CartiHeal with a put option that would require us to purchase 100% of CartiHeal's shares under certain conditions (Put Option).

On August 2, 2021, CartiHeal provided us the required evidence of the Agili-C device clinical trial's success demonstrating the superiority of the Agili-C implant over the surgical standard of care, including microfracture and debridement, for the treatment of cartilage or osteochondral defects, in both osteoarthritic knees and knees without degenerative changes. As a result, with Board of Director approval, we deposited $50.0 million into escrow towards the potential purchase price of CartiHeal. In order to support the completion, if needed, we will purchase an additional 338,089 of CartiHeal Series G Preferred Shares for $5.0 million.

We intend to exercise our Call Option upon FDA approval of the Agili-C device with a label consistent in all respects with the clinical trial. CartiHeal submitted the non-clinical module of the PMA in January 2021 and submitted the final, clinical module of a Modular PMA in the August 2021 seeking FDA approval. The review process is progressing according to plan and regulatory feedback received to date from the FDA has been addressed in a timely manner. We currently believe the required FDA approval will occur in the first half of 2022 and expect to acquire all of the shares of CartiHeal, excluding those we already own, for $314.9 million, payable at closing in the second quarter of 2022. Upon the achievement of certain sales milestones, an additional $135.0 million could become payable after closing.

B.O.N.E.S. Trial

In April 2021, we received a letter from the FDA identifying certain deficiencies in the PMA supplement that must be addressed before the FDA can complete its review of the PMA supplement. The deficiencies include concerns about the data and endpoints from the B.O.N.E.S. study, and requests for re-analyses of certain data and provision of other information to support the findings. We are in the process of performing ancillary analysis on the data as requested by the FDA and remain engaged in discussions with the FDA to address the agency's concerns. In addition, in December 2021, we completed the follow up of all patients in the scaphoid B.O.N.E.S. study. We plan on submitting a PMA supplement for this indication in the fourth quarter of 2022. We can give no assurance that we will be able to resolve the deficiencies identified by the FDA in a timely manner, or at all. Consequently, the FDA's decision on the PMA supplements may be delayed beyond the time originally anticipated. Moreover, if our responses do not satisfy the FDA's concerns, the FDA may not approve our PMA supplements seeking to expand the indications for use of EXOGEN in metatarsal and scaphoid fractures as proposed.

Other

We continue to make equity investments in companies that commercialize or could in the future commercialize technologies for sports medicine, wound healing and orthopedic surgical procedures to align with our strategy of expanding our offerings. Our investments totaling $11 million in 2021 permit, in certain cases, exclusive sales and distribution rights, co-development arrangements, and/or insight into the research and development progress.

COVID-19 pandemic impact

In 2020, the COVID-19 pandemic spread around the world and in the United States. New variants of the virus have emerged, some of which have shown to be more contagious. The COVID-19 pandemic has had widespread, rapidly evolving and unpredictable impacts on global society, economies, financial markets and business practices. Federal and state governments have implemented measures in an effort to prevent or minimize the spread of the virus, and ongoing effects of the pandemic, including social distancing, travel restrictions, border closures, limitations on public gatherings, mandatory closure or reduced capacity of businesses, work from home, supply chain logistical changes and other measures, which caused global business disruptions and significant volatility in U.S. and international debt and equity markets. Our business, results of operations and financial condition have been and may continue to be, materially impacted by fluctuations in patient visits and elective procedures and any future temporary cessations of elective procedures and could be further impacted by delays in payments from customers, supply chain interruptions, extended "shelter-in-place" orders or advisories, facility closures or other reasons related to the pandemic. Furthermore, the long-term impact of COVID-19 on our business will depend on many factors, including, but not limited to, the duration and severity of the pandemic, the spread of new variants of the virus, new and ongoing measures taken in response to the pandemic, the availability, adoption and effectiveness of vaccines and treatments, the impact on economic activity from the pandemic and actions taken in response and the resulting impact it has on our partners, patients and communities in which we operate, all of which continue to be uncertain. As of the date of this Annual Report on Form 10-K, the extent to which COVID-19 could materially impact our financial conditions, liquidity or results of operations is uncertain.

To the extent COVID-19 disruptions continue to adversely impact our business, results of operations and financial condition, it may also have the effect of heightening risks relating to our ability to successfully commercialize newly developed or acquired products or therapies, consolidation in the healthcare industry, intensified pricing pressure as a result of changes in the purchasing behavior of hospitals and maintenance of our numerous contractual relationships. For additional information on the risks we may face as a result of COVID-19, refer to *Part I, Item 1A. Risk Factors – Our business may continue to experience adverse impacts as a result of the COVID-19 pandemic* in our 2021 10-K.

Components of our results of operations

Net sales

We generate net sales from a portfolio of active healing products that serve physicians spanning the orthopedic continuum, including sports medicine, total joint reconstruction, hand and upper extremities, foot and ankle, podiatric surgery, trauma, spine and neurosurgery. We report sales net of contractual allowances, rebates and returns.

We sell our products primarily through our direct sales team, who manage and maintain the sales relationship with healthcare providers, distribution centers or specialty pharmacies. Certain surgical products are sold through independent distributors to hospitals so our neurosurgeon and orthopedic spine surgeon customers can use them in procedures. In certain international markets, we also sell to independent distributors on prearranged business terms, who manage or maintain the sales relationship with their physician customers. Refer to *Note 2. Summary of significant accounting policies* to our *Notes to consolidated financial statements* for further information.

We generally recognize revenue at the point in time when control is transferred to the customer, for example, when the product are shipped to the customer, when the patient has accepted the product or upon consumption in a surgical procedure.

Cost of sales

Our cost of sales primarily consist of costs of products purchased from our third-party suppliers, direct labor and allocated overhead associated with manufacturing and assembly, excess and obsolete inventory charges, shipping, inspection and related costs incurred in making our products available for sale or use. In addition, cost of sales includes depreciation related to production as well as amortization of product-related intellectual property and distribution rights associated with commercialized products. Certain products are manufactured by or obtained from third-party suppliers primarily located in Japan, Switzerland, Sweden and the United States. We receive the components for our Exogen system from suppliers and assemble each system in-house at our Cordova, Tennessee facility. In the future, we expect our cost of sales to increase due to increased sales volume.

Gross profit and gross margin

Gross profit consists of net sales less cost of sales. We calculate gross margin as gross profit divided by net sales. Our gross margin has been and will continue to be affected by a variety of factors, including costs of products purchased from our third-party suppliers, manufacturing costs, product mix and implementation over time of cost-reduction strategies. We expect net sales and product mix to vary quarter by quarter and therefore our gross profit will likely fluctuate from quarter to quarter.

Selling, general and administrative expense

Selling, general and administrative expense primarily consists of salaries, benefits and other related costs, including equity-based compensation, for personnel employed in sales, marketing, finance, legal, compliance, administrative, information technology, medical education and training, quality and human resource departments. Selling, general and administrative expense also includes third-party marketing, supply chain and distribution, product recall costs, information technology, legal, human resources, insurance and facilities expenses, selling, general and administrative expenses also include commissions, generally based on a percentage of sales, to our direct sales team and independent distributors. We expect our selling, general and administrative expenses will increase with the continued expansion of our sales organization and commercialization of our current and pipeline products. We plan to hire more personnel to support the growth of our business. However, over time, as we grow our net sales, we expect selling, general and administrative expenses to decline as a percentage of net sales.

Research and development expense

Research and development expense primarily consists of employee compensation, equity compensation and related expenses, as well as contract research organization service expenses related to clinical trials. We expense internal research and development costs as incurred and research and development costs incurred by third parties as they perform contracted work. Our research and development expenses may vary substantially from period to period based on the timing of research and development activities. We are focused on internal research and development to broaden our product portfolio across all verticals, expand our Exogen system product label and undertake clinical research to support commercialization of all of our products. As a result, we expect our research and development expenses to increase to the mid-single digits as a percentage of net sales as we introduce new products, extend existing product lines and expand indications. We see significant opportunity to develop innovative and clinically differentiated products in-house with our experienced research and development team. In addition, we are planning preclinical and animal model studies for MOTYS and PROcuff. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations.

Restructuring costs

Restructuring costs primarily consist of employee severance, legal, consulting and temporary labor expenses. During the periods presented, restructuring costs were associated in 2021 with headcount reductions related to 2021 acquisitions and in 2020 with restructuring efforts in our international business to improve operating efficiency. Key assumptions in determining the restructuring costs include headcount reductions, as well as terms and negotiated payments to terminate certain contractual obligations.

Depreciation and amortization

Depreciation expense primarily consists of depreciation of computer equipment and software as well as demonstration and consignment inventory, leasehold improvements, furniture, fixtures, machinery and equipment. Amortization expense primarily consists of amortization expense related to customer relationships and other intangible assets.

Interest expense

Interest expense primarily consists of interest on our indebtedness, which currently consists of our term loan and revolving credit facility, which was incurred pursuant to the Credit Agreement, as amended. We have entered into interest rate swaps to limit our exposure to changes in the variable interest rate on our term loan. Interest expense includes any fair value gain or losses on these swaps. Interest expense also includes the revaluation for the liability related to our Equity Participation Right (EPR) Unit. The EPR Unit’s entitlement is 0.55% of available distributions arising from a distribution event as defined in the Bioventus LLC Agreement and was settled in cash as part of our IPO.

Other expense (income)

Other expense (income) primarily consists of foreign currency transaction and remeasurement gains and losses on transactions denominated in currencies other than our functional currency. Our foreign currency transaction and remeasurement gains and losses are primarily related to foreign currency denominated cash, liabilities and intercompany receivables and payables. Other expense (income) may also include certain nonrecurring items.

Income tax expense

Bioventus LLC (BV LLC) is a partnership for U.S. federal tax purposes. Accordingly, the members include the profits and losses of BV LLC in their income tax returns. Certain wholly-owned subsidiaries of BV LLC are taxable entities for U.S. or foreign tax purposes and file tax returns in their local jurisdictions. Bioventus Inc. is subject to U.S. federal, state and local income taxes at the prevailing corporate tax rates with respect to our taxable income. In addition to tax expenses, we are obligated to make payments under the TRA, which could be significant. The TRA, obligates us to pay to the Continuing LLC Owner 85% of the amount of any realized tax benefits, (or in some circumstances are deemed to realize) resulting from (i) increases in the tax basis of assets of BV LLC as a result of (a) any future redemptions or exchanges of LLC Interests and (b) certain distributions (or deemed distributions) by BV LLC and (ii) certain other tax benefits arising from our making payments under the TRA. For more information, see *Part II. Item 8. Financial Statements—Note 11. Income Taxes* to our consolidated financial statements for additional information.

Income tax expense includes U.S. federal, state and international income taxes, including certain taxes applicable to BV LLC. Certain income and expense items in income tax returns are not reported in the same year as financial statements. We report the income tax effects of these differences as deferred income taxes. Valuation allowances recognized reduce the related deferred tax assets to an amount which will, more likely than not, be realized. We recognize interest and penalties related to unrecognized tax benefits as a component of income tax expense.

Non-GAAP Financial Measures - Adjusted EBITDA

We present Adjusted EBITDA, a non-GAAP financial measure because we believe it is a useful indicator of our operating performance. Our management uses Adjusted EBITDA principally as a measure of our operating performance and believes that Adjusted EBITDA is useful to our investors because it is frequently used by securities analysts, investors and other interested parties in their evaluation of the operating performance of companies in industries similar to ours. Our management also uses Adjusted EBITDA for planning purposes, including the preparation of our annual operating budget and financial projections. We define Adjusted EBITDA as net income from continuing operations before depreciation and amortization, provision of income taxes and interest expense, adjusted for the impact of certain cash, non-cash and other items that we do not consider in our evaluation of ongoing operating performance. These items include equity compensation, change in fair value of contingent consideration, COVID-19 benefits, succession and transition charges, loss on impairment of intangible assets, losses associated with debt refinancing, restructuring costs, acquisition and integration costs, inventory step-up costs, equity loss in non-consolidated investments, change in fair value of contingent consideration, impairments related to variable interest entity, foreign currency impact and other costs. Adjusted EBITDA by segment is comprised of net sales and costs directly attributable to a segment, as well as an allocation of corporate overhead costs. The allocation of corporate overhead costs is determined based on various methods but is primarily based on a ratio of net sales by segment to total consolidated net sales. See table within results of operations for a reconciliation of net income to Adjusted EBITDA.

Results of Operations

The following table sets forth components of our consolidated statements of operations as a percentage of net sales for the periods presented:

	Years Ended December 31,	
	2021	2020
Net sales	100.0 %	100.0 %
Cost of sales (including depreciation and amortization)	29.7 %	27.3 %
Gross profit	70.3 %	72.7 %
Selling, general and administrative expense	59.0 %	60.1 %
Research and development expense	4.4 %	3.5 %
Change in fair value of contingent consideration	0.2 %	— %
Restructuring costs	0.6 %	0.2 %
Depreciation and amortization	2.0 %	2.3 %
Impairment of variable interest entity assets	1.3 %	— %
Operating income	2.8 %	6.6 %

The following table presents a reconciliation of net income to Adjusted EBITDA for the periods presented:

(in thousands)	Years Ended December 31, 2021	2020
Net income	**$ 9,586**	**$ 14,722**
Income tax (benefit) expense	(1,966)	1,192
Interest expense	1,112	9,751
Depreciation and amortization[(a)]	34,875	28,643
Acquisition and related costs[(b)]	21,978	—
Restructuring and succession charges[(c)]	3,717	6,172
Impairments related to variable interest entity[(d)]	7,043	—
Equity compensation[(e)]	(4,512)	10,103
COVID-19 benefits, net[(f)]	—	(4,123)
Equity loss in unconsolidated investments[(g)]	1,868	467
Foreign currency impact[(h)]	132	(117)
Other items[(i)]	6,926	5,633
Adjusted EBITDA	**$ 80,759**	**$ 72,443**

(a) Includes depreciation and amortization of $26,471 and $21,169 in cost of sales and $8,363 and $7,439 in operating expenses, with the balance in research and development, presented in the consolidated statements of operations and comprehensive income.

(b) Includes acquisition and integration costs related to completed acquisitions, amortization of inventory step-up associated with acquired entities, and changes in fair value of contingent consideration.

(c) Costs incurred during 2021 were the result of adopting acquisition related restructuring plans to reduce headcount, reorganize management structure, consolidate certain facilities, and costs related to executive transitions. Costs incurred during 2020 related to a shift from direct to an indirect distribution model in our International business to improve performance. Various international subsidiaries were dissolved and/or merged into other BV LLC entities.

(d) Represents loss on impairment of Harbor's long-lived assets and the Company's investment in Harbor.

(e) The year ended December 31, 2021 includes compensation expense resulting from awards granted under the Company's equity based compensation plans in effect after its IPO. These expenses were entirely offset and resulted in income due to the change in fair market value of the BV LLC Phantom Profits Interest Plan (Phantom Plan) accrued liability due to expected pricing with our IPO. The year ended December 31, 2020 includes compensation expense resulting from the BV LLC's management incentive plan and Phantom Plan as well as the change in fair market value of the associated liability due to the impact of the COVID-19 pandemic on our business.

(f) Includes income resulting from the CARES Act offset by additional cleaning and disinfecting expenses and contract termination fees for canceled events.

(g) Includes CartiHeal equity investment losses.

(h) Includes realized and unrealized gains and losses from fluctuations in foreign currency.

(i) Other items primarily includes charges associated with strategic transactions, such as potential acquisitions, debt retirement and modification costs and public company preparation costs, which primarily includes accounting and legal fees.

We present Adjusted EBITDA, a non-GAAP financial measure, because we believe it is a useful indicator that management uses as a measure of operating performance as well as for planning purposes, including the preparation of our annual operating budget and financial projections. We believe that Adjusted EBITDA is useful to our investors because it is frequently used by securities analysts, investors and other interested parties in their evaluation of the operating performance of companies in industries similar to ours. We define Adjusted EBITDA as net income before depreciation and amortization, provision of income taxes and interest expense, adjusted for the impact of certain cash, non-cash and other items that we do not consider in our evaluation of ongoing operating performance. These items include acquisition and related costs, restructuring and succession charges, impairments related to variable interest entity, equity compensation, COVID-19 expense (benefit), equity loss in unconsolidated investments, foreign currency impact, and other items. Adjusted EBITDA by segment is comprised of net sales and costs directly attributable to a segment, as well as an allocation of corporate overhead costs primarily based on a ratio of net sales by segment to total consolidated net sales.

Net sales

(in thousands, except for percentage)	Years Ended December 31, 2021	2020	Change $	%
U.S.	$ 387,553	$ 293,697	$ 93,856	32.0 %
International	43,345	27,464	15,881	57.8 %
Net Sales	$ 430,898	$ 321,161	$ 109,737	34.2 %

U.S.

Net sales increased $93.9 million, or 32.0%, of which acquisitions contributed $39.4 million. Revenue also increased due to volume growth as revenue in 2020 was negatively affected by the economic impact of the COVID-19 pandemic. These increases were partially offset by more treatments being sold under contracts with major insurers at lower prices. Revenue increases by vertical were: i) Pain Treatments—$44.5 million; ii) Restorative Therapies—$26.4 million; and iii) Surgical Solutions—$23.0 million.

International

Net sales increased $15.9 million, or 57.8%, of which acquisitions contributed $10.0 million. Revenue also increased due to sales volume growth, as revenue in 2020 was negatively affected by the economic impact of the COVID-19 pandemic.

Gross profit and gross margin

(in thousands, except for percentage)	Years Ended December 31, 2021	2020	Change $	%
U.S.	$ 273,690	$ 214,572	$ 59,118	27.6 %
International	29,016	18,947	10,069	53.1 %
Total	$ 302,706	$ 233,519	$ 69,187	29.6 %

Gross margin	Years Ended December 31, 2021	2020	Change
U.S.	70.6 %	73.1 %	(2.5 %)
International	66.9 %	69.0 %	(2.1 %)
Total	70.3 %	72.7 %	(2.4 %)

U.S.

Gross profit increased $59.1 million, or 27.6%, primarily due to the increase in net sales. Gross margin decreased due to product mix including products introduced as a result of acquisitions. Gross margin was also negatively impacted by 1.3% from additional amortization of acquisition related assets in 2021 compared with the prior year. In addition, we have experienced higher expense related to supply chain delays.

International

Gross profit increased $10.1 million, or 53.1%, primarily due to the increase in net sales. Gross margin decreased due to product mix including products introduced as a result of acquisitions.

Selling, general and administrative expense

(in thousands, except for percentage)	Years Ended December 31, 2021	2020	Change $	%
Selling, general and administrative expense	$ 254,253	$ 193,078	$ 61,175	31.7 %

Selling, general and administrative expenses increased $61.2 million, or 31.7%, primarily due to: i) the impact of the COVID-19 pandemic on our business in 2020 compared to normalized spending in 2021; ii) costs incurred as a result of being a public company in 2021 and iii) acquisitions. The rise in expenses were primarily within increased compensation related expenses of $38.0 million, increased equity compensation excluding the change in fair value of $16.0 million, increased legal and accounting expenses of $13.5 million, increased consulting and travel related expenses of $11.0 million and increased corporate insurance and employee health insurance of $7.5 million. These increases were partially offset by a higher change in fair value of our accrued equity-based compensation resulting in an increased net recovery of $29.9 million in expense compared to the prior year. The change in fair value for 2021 was due to adjustments to reflect the difference between the expected pricing from the then-pending IPO and the actual offering price. The change in fair value for 2020 was due to the impact of the COVID-19 pandemic on our business.

Research and development expenses

	Years Ended December 31,		Change	
(in thousands, except for percentage)	2021	2020	$	%
Research and development expense	$ 19,039	$ 11,202	$ 7,837	70.0 %

Research and development expense increased by $7.8 million, or 70.0%, partially due to our 2021 acquisitions contributing an additional $3.8 million as well as more normalized spending versus our cost reduction efforts implemented during 2020 as a result of the COVID-19 pandemic. In addition, compensation related expenses increased $3.1 million and equity compensation excluding the change in fair value increased by $1.2 million in 2021 compared to prior year. These increases were partially offset by a higher change in fair value of our accrued equity-based compensation resulting in an increased net recovery of $2.0 million in expense. The change in fair value during 2021 was due to adjustments to reflect the difference between the expected pricing from the then-pending IPO and the actual offering price. The change in fair value during 2020 was due to the impact of the COVID-19 pandemic on our business.

Change in fair value of contingent consideration

The $0.8 million change in fair value of Bioness Acquisition contingent consideration for the year ended December 31, 2021 resulted from the change in present value of discounted cash flows due to the passage of time.

Depreciation and amortization

	Years Ended December 31,		Change	
(in thousands, except for percentage)	2021	2020	$	%
Depreciation and amortization	$ 8,363	$ 7,439	$ 924	12.4 %

Depreciation and amortization increased primarily due to acquisitions.

Impairment of variable interest entity assets

We terminated the Harbor Collaboration Agreement on June 8, 2021 which resulted in a $5.7 million impairment on Harbor's long-lived asset balances, of which $5.2 million was recorded in loss attributable to noncontrolling interest.

Other expense (income)

	Years Ended December 31,		Change	
(in thousands, except for percentage)	2021	2020	$	%
Interest expense	$ 1,112	$ 9,751	$ (8,639)	(88.6 %)
Other expense (income)	$ 3,329	$ (4,428)	$ 7,757	(175.2 %)

Interest expense decreased $8.6 million due to the following: i) the change in fair value of our interest rate swap resulting in interest income during 2021 compared to interest expense in 2020; ii) the settlement of our equity participation right (EPR) liability during 2021 resulting in interest income compared to EPR interest expense in 2020; and iii) decrease in interest from a lower outstanding credit facility balance during 2021.

Other expense (income) increased $7.8 million primarily due to i) receiving $4.1 million in Provider Relief Funds in 2020 under the CARES Act; ii) an impairment of $1.4 million from our Harbor investment in 2021 and iii) an increase of $1.4 million in net losses resulting from our equity investment in CartiHeal.

Income tax expense

(in thousands, except for percentage)	Years Ended December 31, 2021	2020	Change $	Change %
Income tax (benefit) expense	$ (1,966)	$ 1,192	$ (3,158)	(264.9)%
Effective tax rate	25.8 %	7.5 %		18.3 %

We incurred an income tax benefit in 2021 primarily due to the change in structure resulting from our IPO and associated Up C partnership structure.

Noncontrolling interest

(in thousands, except for percentage)	Years Ended December 31, 2021	2020	Change $	Change %
Continuing LLC Owner	$ 4,124	$ —	$ 4,124	NM
Harbor	5,665	1,689	3,976	NM
Total	$ 9,789	$ 1,689	$ 8,100	

NM = Not meaningful

Subsequent to the IPO and Transactions, we are the sole managing member of BV LLC. We have a majority economic interest, the sole voting interest in, and control the management of BV LLC. As a result, we consolidate the financial results of BV LLC and report a non-controlling interest representing the portion owned by Smith & Nephew, Inc. (Continuing LLC Owner). Since the IPO until the Misonix Acquisition, the Continuing LLC Owner non-controlling interest was 27.8%. After the Misonix Acquisition it decreased to 21.0%.

We stopped consolidating Harbor upon the termination of the Collaboration Agreement, as we ceased being the primary beneficiary because we no longer had the power to direct Harbor's significant activities. Prior to the deconsolidation, our partial ownership and exclusive Collaboration Agreement with Harbor resulted in loss attributable to noncontrolling interest through June 8, 2021. The $4.0 million increase in loss was primarily due to the $5.7 million impairment on Harbor's long-lived asset balances of which $5.2 million is attributable to the non-controlling interest. This increase was partially offset by lower Harbor losses resulting from only one quarter in 2021 versus four quarters in 2020.

Segment Adjusted EBITDA

Adjusted EBITDA for each of our reportable segments is as follows:

(in thousands, except for percentage)	Years Ended December 31, 2021	2020	Change $	Change %
U.S.	$ 70,640	$ 69,252	$ 1,388	2.0 %
International	$ 10,119	$ 3,191	$ 6,928	NM

U.S.

Adjusted EBITDA increased $1.4 million or 2.0% primarily due to a $59.1 million increase in gross profit resulting from the increase in sales. This increase was partially offset by the increase in compensation related charges previously discussed, operating costs of acquired companies, as well as travel related expenses and public company costs.

International

Adjusted EBITDA increased $6.9 million primarily due to a $10.1 million increase in gross profit resulting from the increase in sales. This increase was partially offset by the increase in compensation related charges previously discussed as well as an increase in consulting expenses.

Liquidity and Capital Resources

Sources of liquidity

Our principal liquidity needs have historically been for acquisitions, working capital, research and development, clinical trials, and capital expenditures. We expect these needs to continue as we develop and commercialize new products and further our expansion into international markets. We believe that our existing cash and cash equivalents, borrowing capacity under our revolving credit facility and cash flow from operations will be enough to meet our anticipated cash requirements for at least the next twelve months.

We anticipate that to the extent that we require additional liquidity, we will obtain funding through the incurrence of other indebtedness, additional equity financings or a combination of these potential sources of liquidity. In addition, we may raise additional funds to finance future cash needs through receivables or royalty financings or corporate collaboration and licensing arrangements. If we raise additional funds by issuing equity securities or convertible debt, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, or making capital expenditures. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our products, future revenue streams or product candidates, or to grant licenses on terms that may not be favorable to us. The covenants under our credit agreement limit our ability to obtain additional debt financing. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any failure to raise capital in the future could have a negative impact on our financial condition and our ability to pursue our business strategies.

Initial public offering

On February 16, 2021, in connection with our IPO, we issued and sold 9,200,000 shares of our Class A common stock at a price to the public of $13.00 per share, resulting in gross proceeds to us of approximately $119.6 million, before deducting the underwriting discount, commissions and estimated offering expenses payable by us. Bioventus Inc. is a holding company and has no material assets other than the ownership of LLC Interests and has no independent means of generating revenue. Deterioration in the financial condition, earnings, or cash flow of BV LLC and its subsidiaries for any reason could limit or impair their ability to pay such distributions. In addition, the terms of our financing arrangements, including the 2019 Credit Agreement, contain covenants that may restrict BV LLC and its subsidiaries from paying such distributions, subject to certain exceptions. Further, BV LLC is generally prohibited under Delaware law from making a distribution to a member to the extent that, at the time of the distribution, after giving effect to the distribution, liabilities of BV LLC (with certain exceptions), as applicable, exceed the fair value of its assets. Subsidiaries of BV LLC are generally subject to similar legal limitations on their ability to make distributions to BV LLC. Bioventus Inc., as the managing member, causes BV LLC to make cash distributions to the owners of LLC Interests in an amount sufficient to (i) fund tax obligations in respect of allocations of taxable income from BV LLC and (ii) cover Bioventus Inc. operating expenses, including payments under the Tax Receivable Agreement (TRA).

Future cash requirements

The following table summarizes certain estimated future cash requirements under our various contractual obligations committed to as of December 31, 2021 in total and disaggregated into current and long-term obligations.

(in thousands)	Current	Long-Term	Total
Long-term debt[(a)]	$ 18,038	$ 342,712	$ 360,750
Interest payments on long-term debt[(a)]	7,989	24,568	32,557
Operating lease liabilities[(b)]	3,504	15,038	18,542
Purchase commitments[(c)]	22,486	46,686	69,172
	$ 52,017	$ 429,004	$ 481,021

(a) Refer to *Note 5. Financial Instruments* in *Part II, Item 8. Financial Statements and Supplementary Data* in this Annual Report for further information regarding long-term debt obligations.

(b) Refer to *Note 12. Commitment and contingencies* in *Part II, Item 8. Financial Statements and Supplementary Data* in this Annual Report for further information regarding operating lease liabilities.

(c) Amounts that are contractually committed to as of December 31, 2021 related to multi-year exclusive supply agreements. Generally, our purchase obligations under these supply agreements are based on forecasted requirements, subject in some cases to an annual contractual minimum.

Other cash requirements

We enter into contracts in the normal course of business with various third parties for development, collaboration and other services for operating purposes. These contracts provide for termination upon notice. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation. Certain agreements include contingent events that upon occurrence would require payment. For information regarding Commitments and Contingencies, refer to *Note 12. Commitment and contingencies* in *Part II, Item 8. Financial Statements and Supplementary Data* in this Annual Report for further information regarding other matters.

The BV LLC Agreement provides for the payment of certain distributions to the Continuing LLC Owner in amounts sufficient to cover the income taxes imposed with respect to the allocation of taxable income from BV LLC as well as obligations under the TRA. Under the TRA, we are required to make cash payments to the Continuing LLC Owner equal to 85% of the tax benefits, if any, that we actually realize (or in certain circumstances are deemed to realize), as a result of (1) increases in the tax basis of assets of BV LLC resulting from (a) any future redemptions or exchanges of LLC Interests, and (b) certain distributions (or deemed distributions) by BV LLC and (2) certain other tax benefits arising from payments under the TRA. We expect the amount of the cash payments required to be made under the TRA will be significant. The actual amount and timing of any payments under the TRA will vary depending upon a number of factors, including the timing of redemptions or exchanges by the Continuing LLC Owner, the amount of gain recognized by the Continuing LLC Owner, the amount and timing of the taxable income we generate in the future, and the federal tax rates then applicable. Any payments made by us to the Continuing LLC Owner under the TRA will generally reduce the amount of overall cash flow that might have otherwise been available to us. To the extent that we are unable to make payments under the TRA for any reason, such payments generally will be deferred and will accrue interest until paid; provided, however, that nonpayment for a specified period may constitute a material breach of a material obligation under the TRA and therefore accelerate payments due under the TRA.

We entered into a lease agreement during November 2021 to expand our current manufacturing operations in Memphis, Tennessee. The above table does not reflect the future cash requirements related to this lease. The lease term is 10 years and occupancy is expected to begin in July 2022, contingent upon certain improvements. In connection with this lease, we expect to make cash payments of $769 during the year ended December 31, 2022, and aggregate cash payments of $16,076 thereafter.

Contingent events requiring significant payments that we anticipate will occur in 2022 include the exercise of our Call Option upon FDA approval of the Agili-C device discussed above in the CartiHeal strategic transaction. We intend to finance the acquisition through additional debt. As described in *Part I, Item 1. Business*, we currently believe the required FDA approval will occur in the first half of 2022 and expect to acquire all of the shares of CartiHeal, excluding those we already own, for $314.9 million, payable at closing which is anticipated to occur in the second quarter of 2022. Upon the achievement of certain sales milestones, an additional $135.0 million could become payable after closing.

Information regarding cash flows

Cash, cash equivalents and restricted cash as of December 31, 2021 totaled $99.2 million compared to $86.8 million as of December 31, 2020. The increase in cash was primarily due to the following:

	Years Ended December 31,		Change	
(in thousands, except for percentage)	2021	2020	$	%
Net cash from operating activities - continuing operations	$ 22,991	72,199	$ (49,208)	(68.2 %)
Net cash from investing activities - continuing operations	(283,760)	(20,672)	(263,088)	NM
Net cash from financing activities	273,371	(29,569)	302,940	NM
Net cash from discontinued operations	—	(228)	228	(100.0 %)
Effect of exchange rate changes on cash	(228)	589	(817)	(138.7 %)
Net change in cash, cash equivalents and restricted cash	$ 12,374	$ 22,319	$ (9,945)	(44.6 %)

NM = Not Meaningful

Operating activities

Net cash from operating activities decreased $49.2 million during 2021, primarily due to completed acquisitions and resulting integration costs, higher employee compensation, and increased general and administrative expense as a result of becoming a public company. These decreases were partially offset by increased collections from higher sales and the economic impact of COVID-19 during 2020.

Investing activities

Cash flows used in investing activities increased $263.1 million, primarily due to the acquisitions of Misonix and Bioness as well as $3.3 million in capital expenditures. These increases were partially offset by a $3.1 million decrease in investments.

Financing activities

Cash flows provided by financing activities increased $302.9 million, primarily due to the $257.5 million in proceeds from the issuance of long-term debt, $107.8 million in net proceeds from the issuance of Class A common stock sold during our IPO and a $19.5 million decrease in net partner distributions. These increases were partially offset by a $81.3 million increase in debt payments primarily due to the $80.0 million debt prepayment in conjunction with the Misonix Acquisition and the scheduled escalation in quarterly principal payments.

Indebtedness

On December 6, 2019, we entered into the 2019 Credit Agreement and during 2021 we executed two amendments in connection with the Misonix Acquisition (as amended, the Amended 2019 Credit Agreement). The Amended 2019 Credit Agreement is comprised of our $360.8 million term loan and our $50.0 million revolving credit facility. All obligations under the Amended 2019 Credit Agreement are guaranteed by certain of our wholly owned domestic subsidiaries, are secured by substantially all our and the guarantors' assets and mature on October 29, 2026.

On October 29, 2021, in conjunction with the Misonix Acquisition, we prepaid $80.0 million on the pre-amendment term loan. On the same date, we used the $262.0 million in proceeds from an amendment to the 2019 Credit Agreement to finance the $223.1 million in Misonix Acquisition cash consideration, transaction costs of $8.0 million and fees and expenses associated with the amendment totaling $4.5 million. The remaining $26.3 million will be used for ongoing operations.

The Amended 2019 Credit Agreement contains various restrictive covenants, including a quarterly covenant not to exceed a consolidated leverage ratio of 3.50 to 1.00 (with the option to increase the leverage ratio up to 4.00 to 1.00 after a permitted acquisition) and an interest coverage ratio of 3.00 to 1.00 for the prior four consecutive quarters. The leverage and interest coverage ratios are based on Consolidated EBITDA as defined in the Amended 2019 Credit Agreement, which includes several differences from Adjusted EBITDA as calculated in this Annual Report. Consolidated EBITDA as defined in the Amended 2019 Credit Agreement permits, among other things, the exclusion of (1) certain extraordinary, unusual and/or other expenses, some of which are subject to an aggregate cap, including but not limited to severance, acquisitions, dispositions, debt refinancing/amendment and IPO-related, (2) foreign currency gains/losses recognized in the statement of operations and (3) franchise, excise and property taxes recognized in the statement of operations. The restrictive covenants include limitations on (1) the declaration or payment of certain distributions on or in respect of our equity interests, (2) restrictions on acquisitions, investments and certain other payments, (3) limitations on the incurrence of new indebtedness, (4) limitations on transfers, sales and other dispositions and (5) limitations on making changes to our business and organizational documents.

As of December 31, 2021, we were in compliance with all covenants under the Amended 2019 Credit Agreement and there was $357.7 million of outstanding borrowings under the term loan. Refer to *Note 5. Financial instruments* in *Part II, Item 8. Financial Statements and Supplementary Data* in this Annual Report for repayment obligations. We have one nominal outstanding letter of credit. Our revolving credit facility had $49.9 million in borrowing capacity as of December 31, 2021.

Recent accounting pronouncements

Refer to *Note 2. Summary of significant accounting policies* in *Part II, Item 8. Financial Statements and Supplementary Data* for further information regarding recently adopted and proposed accounting pronouncements.

Critical accounting policies and estimates

The preparation of the consolidated financial statements requires us to make assumptions, estimates and judgments that affect the reported amounts of assets and liabilities, the disclosures of contingent assets and liabilities as of the date of the consolidated financial statements, and the reported amounts of sales and expenses during the reporting periods. Certain of our more critical accounting policies require the application of significant judgment by management in selecting the appropriate assumptions for calculating financial estimates. By their nature, these judgments are subject to an inherent degree of uncertainty. On an ongoing basis, we evaluate our judgments, including those related to inventories, recoverability of long-lived assets and the fair value of our common stock. We use historical experience and other assumptions as the basis for our judgments in making these estimates. Because future events and their effects cannot be determined with precision, actual results could differ significantly from these estimates. Any changes in these estimates will be reflected in our consolidated financial statements as they occur. Refer to *Note 1. Organization and basis of presentation of financial information* in *Part II, Item 8. Financial Statements and Supplementary Data* for a further description of our significant accounting policies, however, we believe that the following accounting policies and estimates that are considered critical to our business in order to obtain a full understanding and to evaluate our reported financial results. The critical accounting policies addressed below reflect our most significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition

Sale of products

We derive revenue primarily from product sales within our (i) Pain Treatments portfolio, which includes osteoarthritic (OA) joint pain treatments, which are hyaluronic acid (HA), viscosupplementation therapies and peripheral nerve stimulation products (ii) Surgical Solutions, which includes bone graft substitutes, tissue resection, ultrasonic bone cutting and sculpting systems and other surgical products, and (iii) Restorative Therapies, which includes minimally invasive fracture treatments, rehabilitation and wound products. We sell products directly to healthcare institutions, patients, distributors and dealers. We also enter into arrangements with pharmacy and health benefit managers that provide for privately negotiated rebates, chargebacks and discounts with respect to the purchase of our products.

We recognize revenue generally at a point in time upon transfer of control of the promised product to customers in an amount that reflects the consideration we expect to receive in exchange for those products. We exclude taxes collected from customers and remitted to governmental authorities from revenues.

Revenues are recorded at the transaction price, which is determined as the contracted price net of estimates of variable consideration resulting from discounts, rebates, returns, chargebacks, contractual allowances, estimated third-party payer settlements, and certain distribution and administration fees offered in customer contracts and other indirect customer contracts relating to the sale of products. We establish reserves for the estimated variable consideration based on the amounts earned or eligible for claim on the related sales. Where appropriate, these estimates take into consideration a range of possible outcomes, which are probability-weighted for relevant factors such as our historical experiences, current contractual requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. We regularly review all reserves and update them at the end of each reporting period as needed. There were no significant adjustments arising from the change in estimates of variable consideration for the years ended December 31, 2021 and 2020.

Pain Treatments

Revenue from customers such as healthcare providers, distribution centers or specialty pharmacies is recognized at the point in time when control is transferred to the customer, typically upon shipment.

Distributor chargebacks

We have preexisting contracts with established rates with many of the distributors' customers that require the distributors to sell our product at their established rate. We offer chargebacks to distributors who supply these customers with our products. We reduce revenue at the time of sale for the estimated future chargebacks. We record chargeback reserves as a reduction of accounts receivable and base the reserves on the expected value by using probability-weighted estimates of volume of purchases, inventory holdings and historical chargebacks requested for each distributor.

Discounts and gross-to-net deductions

We offer retrospective discounts and gross-to-net deductions linked to the volume of purchases which may increase at negotiated thresholds within a contract-buying period. We reduce revenue and record the reserve as a reduction to accounts receivable for the estimated discount and rebate at the most likely amount the customer will earn, based on historical buying trends and forecasted purchases.

Surgical Solutions

The majority of our product sales related to bone graft substitutes are through consignment inventory with hospitals, where ownership remains with us until the hospital performs a surgery and consumes the consigned inventory. We recognize the revenue when the surgery has been performed. The customer does not have control of the product until the customer consumes it, as we are able to require the return or transfer of the product to a third-party. An unconditional obligation to pay for the product does not exist until the customer consumes it.

We typically recognize revenue from sales of our ultrasonic products acquired through the Misonix acquisition in accordance with shipping terms. Control is transferred to the customer when the product is shipped or received, and revenue is recognized accordingly.

Restorative Therapies

We recognize revenue from third-party payers, such as governmental agencies, insurance companies or managed care providers, when we transfer control to the patient, typically when the patient has accepted the product or upon delivery. We record this revenue at the contracted rate, net of contractual allowances and estimated third-party payer settlements at the time of sale, or an estimated price based on historical data and other available information for non-contracted payers. We record contractual allowances based on probability weighting historical data and collections.

Settlements with third-party payers for retroactive revenue adjustments due to audits, reviews or investigations are considered variable consideration and are included in the determination of the estimated transaction price using the expected outcome method. These settlements are estimated based on the terms of the payment agreement with the payer, correspondence from the payer and historical settlement activity, including an assessment to ensure that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the retroactive adjustment is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, reviews and investigations. We are not aware of any claims, disputes or unsettled matters with any payer that would materially affect revenues for which we have not been adequately provided.

We recognize revenue from patients (self-pay and insured patients with coinsurance and deductible responsibilities) based on billed amounts giving effect to any discounts and implicit price concessions. Implicit price concessions represent differences between amounts billed and the amounts we expect to collect from patients, which considers historical collection experience and current market conditions. We recognize revenue from other restorative therapies products generally at the point in time when control is transferred to the customer, either upon shipment or reaching the destination depending on the product.

Product returns

We estimate the amount of returns and reduce revenue in the period the related product revenue is recognized. We record a liability for expected returns based on probability weighted historical data.

Accounts receivable, net

Accounts receivable, net are amounts billed and currently due from customers. We record the amounts due net of allowance for credit losses. We maintain allowances for credit losses to provide for receivables we do not expect to collect. We base the allowance on an assessment of customer creditworthiness, historical payment experience, the age of outstanding receivables and other information as applicable. Collection of the consideration that we expect to receive typically occurs within 30 to 90 days of billing. We apply the practical expedient for contracts with payment terms of one year or less which does not consider the effects of the time value of money. Occasionally, we enter into payment agreements with patients that allow payment terms beyond one year. In those cases, the financing component is not deemed significant to the contract.

Contract assets

Contract assets consist of unbilled amounts resulting from estimated future royalties from an international distributor that exceeds the amount billed. Contract assets are included in prepaid and other current assets on the consolidated balance sheets.

Contract liabilities

Contract liabilities consist of customer advance payments or deposits and deferred revenue. Occasionally for certain international customers, we require payments in advance of shipping product and recognizing revenue resulting in contract liabilities. Contract liabilities are included in accrued liabilities on the consolidated balance sheets.

Shipping and handling

We classify amounts billed for shipping and handling as a component of net sales. The related shipping and handling fees and costs as well as other distribution costs are included in cost of sales. We have elected to recognize shipping and handling activities that occur after control of the related product transfers to the customer as fulfillment costs and are included in cost of sales.

Contract costs

We apply the practical expedient of recognizing the incremental costs of obtaining contracts as an expense when incurred as the amortization period of the assets that we otherwise would have recognized is one year or less. These incremental costs include our sales incentive programs for the internal sales force and third-party sales agents as the compensation is commensurate with annual sales activities. These costs are included in selling, general and administrative expense on the consolidated statements of operations and comprehensive income.

Fair value

We record certain assets and liabilities at fair value. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. A three-level fair value hierarchy that prioritizes the inputs used to measure fair value is described below. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. Assets and liabilities are categorized based on the lowest level that is significant to the valuation.

The three levels of inputs used to measure fair value are as follows:

- Level 1—Quoted prices in active markets for identical assets or liabilities;
- Level 2—Observable inputs other than quoted prices included within Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data; and
- Level 3—Unobservable inputs that are supported by little or no market data. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

Business combinations

We record identifiable assets acquired, liabilities assumed and any noncontrolling interest in an acquiree resulting from a business combination at their estimated fair values on the date of the acquisition. We generally have third-party valuations completed for intangible assets in a business combination using a discounted cash flow analysis, incorporating various assumptions. Goodwill represents the excess of the purchase price over the estimated fair value of the net assets acquired, including the amount assigned to identifiable intangible assets. The most significant estimates and assumptions inherent in a discounted cash flow analysis include the amount and timing of projected future cash flows, discount rate used to measure the risks inherent in the future cash flows, assessment of the asset's life cycle, and competitive and other trends impacting the asset, including consideration of technical, legal, regulatory, economic and other factors. Each of these factors and assumptions can significantly affect the value of the intangible asset.

Acquired in-process research and development, or IPR&D, is the fair value of projects for which the related products have not received regulatory approval and have no alternative future use and is capitalized as an indefinite-lived intangible asset. Due to inherent uncertainty related to research and development, actual results could differ materially from the assumptions used in the discounted cash flow model. Additionally, there are risks including, but not limited to, delay or failure to receive regulatory requirements to conduct clinical trials, required market clearances, or patent issuance, and that the research and development project does not result in a successful commercial product. Development costs incurred after the acquisition are expensed as incurred. Upon receipt of regulatory approval of the related technology or product, the indefinite-lived intangible asset is accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the research and development project is abandoned, the indefinite-lived asset is charged to expense.

We recognize contingent consideration liabilities resulting from business combinations at estimated fair value on the acquisition date. Contingent consideration liabilities are revalued subsequent to the acquisition date with changes in fair value recognized in earnings. Contingent payments related to acquisitions consist of development, regulatory and commercial milestone payments, and are valued using discounted cash flow techniques. Significant estimates and assumptions required for these valuations include the probability of achieving regulatory approval under specified time frames, product sales projections under various scenarios and discount rates used to calculate the present value of the estimated payments. Changes in the fair value of contingent consideration liabilities result from changes in these estimates and assumptions. Significant judgment is employed in determining the appropriateness of the estimates and assumptions as of the acquisition date and in post-acquisition periods.

Contingent consideration

The Company initially values contingent consideration related to business combinations using a probability-weighted calculation of potential payment scenarios discounted at rates reflective of the risks associated with the expected future cash flows. Key assumptions used to estimate the fair value of contingent consideration include revenue and the probability of achieving the specific targets. After the initial valuation, the Company will use its best estimate to measure contingent consideration at each subsequent reporting period. Gains and losses are recorded with selling, general and administrative expenses within the consolidated statements of operations and comprehensive income.

Impairment

We evaluate goodwill and other indefinite-lived intangible assets for impairment annually during the fourth quarter, or more frequently if events or changes in circumstances indicate that the asset might be impaired. Our reporting units are U.S. and International and we analyze each reporting unit separately in our goodwill impairment evaluation. We used independent third-party valuation specialists in 2021 and 2020 using year-to-date October data in each year to assist management in performing the annual review of goodwill for impairment. We also utilized valuation specialists in April 2020 as we believed COVID-19 represented a triggering event that might indicate impairment. The specialists assist management in the determination of fair value of reporting units based upon inputs and assumptions provided by management, which management uses for its impairment assessment. We analyze all other indefinite-lived intangible assets qualitatively to determine if it is more likely than not for an impairment to exist. If we meet the criteria, we perform a quantitative analysis to determine if an impairment exists.

Goodwill

Our goodwill impairment process includes applying a quantitative impairment analysis where the fair value of the reporting unit and compare it to its carrying value (including goodwill). We determine the fair value of U.S. and International reporting units based primarily on an income approach, which incorporates the use of a discounted free cash flow analysis. The discounted free cash flow analyses is based on significant judgments, including the current operating budgets, estimated long-term growth projections and future forecasts for each reporting unit. We discount future cash flows based on a market comparable weighted average cost of capital rate for each reporting unit. The discount rates used in the discounted free cash flow analyses reflect the risks inherent in the expected future cash flows generated by the respective intangible assets. Market risk, industry risk and a small company premium has an impact on the discount rate. The value of each reporting unit is determined on a stand-alone basis from the perspective of a market participant and represents the price we estimate we would receive in a sale of the reporting unit in an orderly transaction between market participants at the measurement date. Significant judgments inherent in this analysis include estimating the amount and timing of future cash flows and the selection of appropriate discount rates, royalty rate and long-term growth rate assumptions. Changes in these estimates and assumptions could materially affect the determination of fair value for each reporting unit and for some of the reporting units and could result in an impairment charge, which could be material to our financial position and results of operations. As of December 31, 2021, the fair value of our reporting units is significantly in excess of the carrying value. There has been no impairment of our goodwill related to our U.S. and International reporting units since our formation.

Equity-based compensation

We operate an equity-based compensation plan (2021 Plan). The 2021 Plan is designed to grant incentive awards to eligible employees and other service providers in order to attract, motivate and retain the talent for which we compete. The 2021 Plan allows for the issuance of stock options (incentive and nonqualified), restricted stock, dividend equivalents, restricted stock units (RSUs), other stock-based awards, and cash awards. (collectively, Awards). Generally, non-cash Awards granted under the 2021 Plan are equity-classified. Equity-based compensation expense is primarily included in selling, general and administrative expense with a nominal amount in research and development expense on the consolidated statement of operations and comprehensive income based upon the classification of the employee.

Equity-based compensation expense generated from the granting restricted stock units represents the fair value of the stock measured at the market price on the date of grant. Restricted stock equity-based compensation expense is recognized over the vesting period.

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, net of actual forfeitures. Assumptions used in determining stock option fair value include risk-free interest rate, expected dividend yield, expected price volatility, expected life of stock options and weighted-average fair value of stock options granted. The expected term of the options granted is estimated using the simplified method. Expected volatility is based on the historical volatility of our peers' 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.

Prior to the IPO, we operated two equity-based compensation plans, the MIP and the Phantom Plans, which had allowed our employees to share our future profit without granting any additional voting rights. Awards granted under the MIP and certain Phantom Plan awards granted in 2015 and thereafter, or the 2015 Phantom Plan Units, were liability-classified. Those Phantom Plan awards granted from inception in 2012 and until the grant of the 2015 Phantom Plan Units, or the 2012 Phantom Plan Units, were equity-classified, as they did not contain a put option or other features requiring them to be liability-classified. Equity compensation included compensation expense for all equity awards made to employees that are part of continuing operations and were based on estimated fair values as of the grant date for the 2012 Phantom Plan Units and period end fair value for the MIP units and 2015 Phantom Plan Units. We recognized expense for performance-based awards when we expected them to be earned. We recognized timed-based awards over the requisite service period, which was generally the vesting period of the award. Forfeitures were recognized as they occurred.

We used independent third-party valuation specialists in 2020 and 2019 using year-to-date October data in each year to assist management in performing the annual valuation of MIP and 2015 Phantom Plan Units. We utilized valuation specialists in April 2020 as we believed COVID-19 represented a triggering event that might indicate impairment. The specialists assist management in the determination of fair value of awards granted using the Monte Carlo option pricing model. The subjective assumptions and the application of judgment in determining the fair value of the awards represent management's best estimates. The most significant assumptions utilized in the MIP and Phantom Plans were expected volatility, time outstanding, risk-free rate and expected dividend yield. Expected volatility was based on the historical volatility of our peer group. The risk-free rate was based on U.S. Government Constant Maturity Treasury rates for a term corresponding to the amount of time the awards were expected to be outstanding. The Expected dividend yield assumption had the rate of zero as we have not previously issued dividends and did not anticipate paying dividends in the foreseeable future.

Income taxes

As a result of the IPO, Bioventus Inc. became the sole managing member of BV LLC, which is treated as a partnership for U.S. federal and most applicable state and local income tax purposes. As a partnership, BV LLC is not subject to U.S. federal and certain state and local income taxes. Any taxable income or loss generated by BV LLC is passed through to and included in the taxable income or loss of its members, including the Company following the Transactions, on a pro rata basis. Bioventus Inc. is subject to U.S. federal income taxes, in addition to state and local income taxes with respect to its allocable share of any taxable income of BV LLC following the Transactions. We are also subject to taxes in foreign jurisdictions.

The tax provision for interim periods is determined using an estimate of our annual effective tax rate, adjusted for discrete items, if any, that arise during the period. Each quarter, we update our estimate of our annual effective tax rate, and if the estimated annual effective tax rate changes, we make a cumulative adjustment in such period. The quarterly tax provision, and estimate of our annual effective tax rate, are subject to variation due to several factors, including variability in pre-tax income (or loss), the mix of jurisdictions to which such income relates, changes in how we conduct business, and tax law developments.

We maintain a valuation allowance on certain deferred tax assets that has determined are not more-likely-than-not to be realizable and assess the need for an adjustment to this valuation allowance on a quarterly basis. The assessment is based on estimates of future sources of taxable income for the jurisdictions in which we operate and the periods over which deferred tax assets will be realizable. In the event we determine we will be able to realize all or part of the net deferred tax assets in the future, all or part of the valuation allowance will be reversed in the period it is determined. The release of all or part of the valuation allowance against deferred tax assets may cause greater volatility in the effective tax rate in the periods in which it is reversed.

We recognize a tax benefit from any uncertain tax positions only if they are more likely than not to be sustained upon examination based on the technical merits of the position. The amount of the accrual for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that we believe is more likely than not to be realized upon ultimate settlement of the position. Components of the reserve, if relevant, are classified as a current or noncurrent liability in the consolidated balance sheet based on when we expect each of the items to be settled. Interest and penalties related to unrecognized tax benefits are recognized as a component of income tax expense.

Tax Receivable Agreement

We expect to obtain an increase in the share of the tax basis of the assets of BV LLC when LLC Interests are redeemed or exchanged by the Continuing LLC Owner and other qualifying transactions. This increase in tax basis may have the effect of reducing the amounts that we would otherwise pay in the future to various tax authorities. The increase in tax basis may also decrease gains (or increase losses) on future dispositions of certain capital assets to the extent tax basis is allocated to those capital assets.

On February 16, 2021, we entered into a tax receivable agreement (TRA) with the Continuing LLC Owner that provides for the payment by us to the Continuing LLC Owner of 85% of the amount of tax benefits, if any, that we actually realize as a result of (i) increases in the tax basis of assets of BV LLC resulting from any redemptions or exchanges of LLC Interests or any prior sales of interests in BV LLC and (ii) certain other tax benefits related to our making payments under the TRA.

We will maintain a full valuation allowance against deferred tax assets related to the tax attributes generated as a result of redemptions of LLC Interests or exchanges described above until it is determined that the benefits are more-likely-than-not to be realized. As of December 31, 2021, Continuing LLC Owner had not exchanged LLC Interests for shares of Class A common stock and therefore we had not recorded any liabilities under the TRA.

Long-lived assets

Property and equipment are stated at cost and are depreciated using the straight-line method over the shorter of the asset's estimated useful life, or the lease term if related to leased property, as follows in years:

Computer software and hardware	3 - 5
Demonstration and consignment inventory	5
Furniture and fixtures	3 - 7
Leasehold improvements	3 - 7
Machinery and equipment	3 - 7

We amortize finite-lived identifiable intangible assets using the straight-line method over their estimated remaining weighted average useful lives as follows in years:

	Weighted Average Useful Life
Intellectual property	17.7
Distribution rights	11.6
Customer relationships	11.6
Developed technology	9.5

We capitalize costs incurred from third-party vendors for software design, configuration, coding and testing and amortizes these costs on a straight-line basis over the estimated useful life of the product, not to exceed three years. We do not capitalize costs that are precluded from capitalization in authoritative guidance, such as preliminary project phase costs, planning, oversight, process re-engineering costs, training costs or data conversion costs.

The carrying values of property, equipment and finite lived intangible assets are reviewed for recoverability if the facts and circumstances suggest that a potential impairment may have occurred. If this review indicates that carrying values may not be recoverable, we will perform an assessment to determine if an impairment charge is required to reduce carrying values to estimated fair value. There were no events, facts or circumstances for the years ended December 31, 2021 and 2020 that resulted in any impairment charges to our property, equipment or finite lived intangible assets.

JOBS Act

We qualify as an "emerging growth company" pursuant to the provisions of the JOBS Act. For as long as we are an "emerging growth company," we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, reduced disclosure obligations relating to the presentation of financial statements in the "Management's discussion and analysis of financial condition and results of operations" section and exemptions from the requirements of holding advisory "say-on-pay" votes on executive compensation and shareholder advisory votes on golden parachute compensation. We have availed ourselves of the reduced reporting obligations and executive compensation disclosure in this Annual Report and expect to continue to avail ourselves of the reduced reporting obligations available to emerging growth companies in future filings.

In addition, an emerging growth company can delay its adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we are choosing to "opt out" of such extended transition period, and as a result, we plan to comply with any new or revised accounting standards on the relevant dates on which non-emerging growth companies must adopt such standards. Section 107 of the JOBS Act provides that our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable.

We will continue to qualify as an emerging growth company until the earliest of:

- The last day of our fiscal year following the fifth anniversary of the date of our IPO;
- The last day of our fiscal year in which have annual gross revenues of $1.07 billion or more;
- The date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt;
- The date on which we are deemed to be a "large accelerated filer", which will occur at such time as we (1) have an aggregate worldwide market value of common equity securities held by non-affiliates of $700 million or more as of the last business day of our most recently completed second quarter, (2) have been required to file annual and quarterly reports under the Exchange Act for a period of at least 12 months, (3) have filed at least one annual report pursuant to the Exchange Act, and (4) are not eligible to use the requirements for smaller reporting companies as defined in Rule 12b-2 under the Exchange Act (annual revenue less than $100 million and either no public float or a public float of less than $700 million).

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Quantitative and qualitative disclosures about market risk

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates and foreign exchange rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes. We use derivative instruments to manage exposures to interest rates and foreign currencies. Derivatives are recorded on the balance sheet at fair value at each balance sheet date. We have elected the fair value method of accounting and do not designate whether the derivative instrument is an effective hedge of an asset, liability or firm commitment. Changes in the fair values of derivative instruments are recognized in the consolidated statements of operations and comprehensive income in the period incurred.

Interest rate risk

Our cash and cash equivalents balance as of December 31, 2021 consisted of demand deposits and institutional money market funds held in U.S. and foreign banks. Cash equivalents consist of highly liquid investment securities with original maturities on the date of purchase of three months or less and can be exchanged for a known amount of cash. We are exposed to the market risk related to fluctuations in interest rates and market prices for our cash equivalents. We are also exposed to interest rate risk in connection with borrowings under our credit agreement, which bear interest at a floating rate based on one-month LIBOR plus an applicable borrowing margin. As of December 31, 2021, a 1.0% increase in interest rate would result in $14.9 million increase in total interest payable over the remaining life of the credit agreement in the event we were to draw down the entire capacity of our revolving credit facility. For variable rate debt, interest rate changes generally do not affect the fair value of the debt instrument, but impact future earnings and cash flows, assuming other factors are constant. In the ordinary course of business, we may enter into contractual arrangements to reduce our exposure to interest rate risks.

We have an interest rate swap agreement to limit our exposure to changes in the variable interest rate on our term loan. The derivative instrument was not designated as a hedge.

Foreign exchange risk management

We operate in countries other than the U.S. and are exposed to foreign currency risks. We bill most direct sales outside of the U.S. in local currencies. We expect that the percentage of our sales denominated in foreign currencies will increase in the foreseeable future as we continue to expand into international markets. When sales or expenses are not denominated in U.S. dollars, a fluctuation in exchange rates could affect our net income. We believe that the risk of a significant impact on our operating income from foreign currency fluctuations is minimal. Although we do not currently have any foreign currency hedges, we have used foreign exchange forward contracts in the past to protect against the impact of foreign currency fluctuations and may use forward contracts, derivatives or other hedges for foreign exchange risk management purposes in the future.

Effects of inflation

We do not believe that inflation has had a material effect on our results of operations during the periods presented herein.

Item 8. Financial Statements and Supplementary Data

Index to Consolidated Financial Statements

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
Bioventus Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Bioventus Inc. (a Delaware corporation) and subsidiaries (the "Company") as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive (loss) income, changes in stockholders' and members' equity, and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

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 Public Company Accounting Oversight Board (United States) ("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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2019.

Raleigh, North Carolina
March 11, 2022

Bioventus Inc.

Consolidated Statements of Operations and Comprehensive Income
Years Ended December 31, 2021, 2020 and 2019
(Amounts in thousands, except share amounts)

	2021	2020	2019
Net sales	$ 430,898	$ 321,161	$ 340,141
Cost of sales (including depreciation and amortization of $26,471, $21,169 and $22,399 respectively)	128,192	87,642	90,935
Gross profit	302,706	233,519	249,206
Selling, general and administrative expense	254,253	193,078	198,475
Research and development expense	19,039	11,202	11,055
Change in fair value of contingent consideration	829	—	—
Restructuring costs	2,487	563	575
Depreciation and amortization	8,363	7,439	7,908
Impairment of variable interest entity assets	5,674	—	—
Operating income	12,061	21,237	31,193
Interest expense	1,112	9,751	21,579
Other expense (income)	3,329	(4,428)	(75)
Other expense	4,441	5,323	21,504
Income from continuing operations before income taxes	7,620	15,914	9,689
Income tax (benefit) expense	(1,966)	1,192	1,576
Net income from continuing operations	9,586	14,722	8,113
Loss from discontinued operations, net of tax	—	—	1,815
Net income	9,586	14,722	6,298
Loss attributable to noncontrolling interest	9,789	1,689	553
Net income attributable to Bioventus Inc.	$ 19,375	$ 16,411	$ 6,851
Net income	$ 9,586	$ 14,722	$ 6,298
Other comprehensive income (loss), net of tax			
Change in prior service cost and unrecognized gain (loss) for defined benefit plan adjustment	60	(54)	(78)
Change in foreign currency translation adjustments	(1,318)	2,126	(322)
Comprehensive income	8,328	16,794	5,898
Comprehensive loss attributable to noncontrolling interest	9,789	1,689	553
Comprehensive income attributable to Bioventus Inc.	$ 18,117	$ 18,483	$ 6,451
Loss per share of Class A common stock, basic and diluted[(1)]:	$ (0.15)		
Weighted-average shares of Class A common stock outstanding, basic and diluted[(1)]:	45,472,483		

[(1)] Per share information for the year ended December 31, 2021 represents loss per share of Class A common stock and weighted-average shares of Class A common stock outstanding from February 16, 2021 through December 31, 2021, the period following Bioventus Inc.'s initial public offering and related transactions described in *Note 1. Organization* and *Note 9. Earnings per share* within the *Notes to the Consolidated Financial Statements.*

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

Bioventus Inc.

Consolidated Balance Sheets as of December 31, 2021 and 2020
(Amounts in thousands, except share amounts)

	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	$ 43,933	$ 86,839
Restricted cash	5,280	—
Accounts receivable, net	124,963	88,283
Inventory	61,688	29,120
Prepaid and other current assets	27,239	7,552
Total current assets	263,103	211,794
Restricted cash, less current portion	50,000	—
Property and equipment, net	22,985	6,879
Goodwill	147,623	49,800
Intangible assets, net	695,193	191,650
Operating lease assets	17,186	14,961
Deferred tax assets	481	—
Investment and other assets	29,291	19,382
Total assets	$ 1,225,862	$ 494,466
Liabilities and Stockholders' and Members' Equity		
Current liabilities:		
Accounts payable	$ 16,915	$ 4,422
Accrued liabilities	131,473	88,187
Accrued equity-based compensation	10,875	11,054
Current portion of long-term debt	18,038	15,000
Other current liabilities	3,558	3,926
Total current liabilities	180,859	122,589
Long-term debt, less current portion	339,644	173,378
Accrued equity-based compensation, less current portion	—	29,249
Deferred income taxes	133,518	3,362
Contingent consideration	16,329	—
Other long-term liabilities	21,723	21,728
Total liabilities	692,073	350,306
Commitments and contingencies (Note 12)		
Stockholders' and Members' Equity:		
Members' equity	—	144,160
Preferred stock, $0.001 par value, 10,000,000 shares authorized, 0 shares issued		
Class A common stock, $0.001 par value 250,000,000 shares authorized, 59,548,504 shares issued and outstanding	59	—
Class B common stock, $0.001 par value, 50,000,000 shares authorized, 15,786,737 shares issued and outstanding	16	—
Additional paid-in capital	465,272	—
Accumulated deficit	(6,602)	—
Accumulated other comprehensive income	179	—
Total stockholders' equity attributable to Bioventus Inc. and members' equity	458,924	144,160
Noncontrolling interest	74,865	—
Total stockholders' and members' equity	533,789	144,160
Total liabilities and stockholders' and members' equity	$ 1,225,862	$ 494,466

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

Bioventus Inc.

Consolidated Statements of Changes in Stockholders' and Members' Equity
Years Ended December 31, 2021, 2020 and 2019
(Amounts in thousands, except share amounts)

	Members' Equity	Class A Common Stock		Class B Common Stock		Additional Paid-In -Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Non-controlling Interest	Total Stockholders' and Members' Equity
		Shares	Amount	Shares	Amount					
Balance at December 31, 2018	$ 145,267									
Equity-based compensation	(6)									
Distribution to members	(8,730)									
Acquisition of noncontrolling interest	3,188									
Net income	6,298									
Other comprehensive loss	(400)									
Balance at December 31, 2019	$ 145,617									
Equity-based compensation	26									
Distribution to members	(19,250)									
Debt conversion	973									
Net income	14,722									
Other comprehensive income	2,072									
Balance at December 31, 2020	$ 144,160	—	$ —	—	$ —	$ —	$ —	$ —	$ —	$ 144,160
Prior to Organizational Transactions:										
Refund from members	123	—	—	—	—	—	—	—	—	123
Equity-based compensation	(39)	—	—	—	—	—	—	—	—	(39)
Net income	25,977	—	—	—	—	—	—	—	—	25,977
Other comprehensive loss	(1,507)	—	—	—	—	—	—	—	—	(1,507)
Effect of Organizational Transactions	(168,714)	31,838,589	32	15,786,737	16	41,813	—	—	79,119	(47,734)
Subsequent to Organizational Transactions:										
Initial public offering, net of offering costs	—	9,200,000	9	—	—	106,441	—	—	—	106,450
Issuance of Class A common stock for equity plans	—	169,125	—	—	—	1,617	—	—	—	1,617
Issuance of Class A common stock for acquisitions, net of registration fees	—	18,340,790	18	—	—	272,706	—	—	—	272,724
Distribution to Continuing LLC Owner	—	—	—	—	—	—	—	—	(3,306)	(3,306)
Net loss	—	—	—	—	—	—	—	(6,602)	(9,789)	(16,391)
Deconsolidation of variable interest entity	—	—	—	—	—	—	—	—	3,746	3,746
Equity based compensation	—	—	—	—	—	15,059	—	—	4,825	19,884
Replacement equity awards in connection with acquisitions	—	—	—	—	—	27,636	—	—	—	27,636
Acquisition of noncontrolling interest	—	—	—	—	—	—	—	—	200	200
Other comprehensive income	—	—	—	—	—	—	179	—	70	249
Balance at December 31, 2021	$ —	59,548,504	$ 59	15,786,737	$ 16	$ 465,272	$ 179	$ (6,602)	$ 74,865	$ 533,789

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

Bioventus Inc.

Consolidated Statements of Cash Flows
Years Ended December 31, 2021, 2020 and 2019
(Amounts in thousands)

	2021	2020	2019
Operating activities:			
Net income	$ 9,586	$ 14,722	$ 6,298
Net loss from discontinued operations	—	—	1,815
Net income from continuing operations	9,586	14,722	8,113
Adjustments to reconcile net income to net cash provided by operating activities from continuing operations:			
Depreciation and amortization	34,875	28,643	30,316
Payment of contingent consideration in excess of amount established in purchase accounting	—	—	(945)
Provision for expected credit losses	485	1,215	2,242
Equity-based compensation from 2021 Stock Incentive Plan	19,844	—	—
Profits interest plan, liability-classified and other equity awards compensation	(24,356)	10,103	10,844
Change in fair value of contingent consideration	829	—	—
Change in fair value of interest rate swap	(2,730)	1,599	—
Change in fair value of Equity Participation Rights unit	(2,774)	644	565
Impairments related to variable interest entity	7,043	—	—
Loss on debt retirement and modification	2,162	—	3,352
Deferred income taxes	(9,756)	(511)	(348)
Other, net	1,060	476	1,978
Changes in operating assets and liabilities:			
Accounts receivable	(20,052)	(3,941)	(14,909)
Inventories	3,183	(528)	(1,427)
Accounts payable and accrued expenses	18,211	20,510	6,646
Other assets and liabilities	(14,619)	(733)	(3,882)
Net cash from operating activities - continuing operations	22,991	72,199	42,545
Net cash from operating activities - discontinued operations	—	(400)	(1,832)
Net cash from operating activities	22,991	71,799	40,713
Investing activities:			
Acquisitions, net of cash acquired	(262,870)	—	430
Investments and acquisition of distribution rights	(13,520)	(16,579)	(6,000)
Purchase of property and equipment	(7,370)	(4,093)	(2,342)
Net cash from investing activities - continuing operations	(283,760)	(20,672)	(7,912)
Net cash from investing activities - discontinued operations	—	172	—
Net cash from investing activities	(283,760)	(20,500)	(7,912)
Financing activities:			
Proceeds from issuance of Class A common stock sold in initial public offering, net of underwriting discounts and offering costs	107,777	—	—
Proceeds from issuance of Class A and B common stock	1,633	—	—
Registration fees for the Class A common stock to purchase Misonix	(1,838)	—	—
Borrowing on revolver	20,000	49,000	—
Payment on revolver	(20,000)	(49,000)	—
Proceeds from the issuance of long-term debt, net of issuance costs	257,453	—	198,134
Payments on long-term debt	(91,250)	(10,000)	(199,500)
Distributions to members	(367)	(19,886)	(9,137)
Other, net	(37)	317	(448)
Net cash from financing activities	273,371	(29,569)	(10,951)
Effect of exchange rate changes on cash	(228)	589	(104)
Net change in cash, cash equivalents and restricted cash	12,374	22,319	21,746
Cash, cash equivalents and restricted cash at the beginning of the period	86,839	64,520	42,774
Cash, cash equivalents and restricted cash at the end of the period	$ 99,213	$ 86,839	$ 64,520
Supplemental disclosure of noncash investing and financing activities			
Accrued liabilities for distribution rights	$ —	$ 1,000	$ —
Accrued member distributions	$ 3,181	$ 31	$ 499
Debt conversion	$ —	$ 973	$ —
Accounts payable for purchase of property, plant and equipment	$ 695	$ 336	$ 34

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

Bioventus Inc.

Notes to the consolidated financial statements
(Amounts in thousands, except unit and share amounts)

1. Organization

The Company

Bioventus Inc. (together with its subsidiaries, the Company) was formed as a Delaware corporation for the purpose of facilitating an initial public offering (IPO) and other related transactions in order to carry on the business of Bioventus LLC and its subsidiaries (BV LLC). Bioventus Inc. functions as a holding company with no direct operations, material assets or liabilities other than the equity interest in BV LLC. BV LLC, is a limited liability company formed under the laws of the state of Delaware on November 23, 2011 and operates as a partnership. BV LLC commenced operations in May 2012. The Company is focused on developing and commercializing clinically differentiated, cost efficient and minimally invasive treatments that engage and enhance the body's natural healing processes. The Company is headquartered in Durham, North Carolina and has approximately 1,200 employees.

Initial Public Offering

On February 16, 2021, the Company closed an initial public offering (IPO) of 9,200,000 shares of Class A common stock at a public offering price of $13.00 per share, which includes 1,200,000 shares issued pursuant to the underwriters' over-allotment option. The Company received $111,228 in proceeds, net of underwriting discounts and commissions of $8,372, which was used to purchase newly-issued membership interests from BV LLC at a price per interest equal to the IPO price of $13.00. The Company is the sole managing member of, has a majority economic interest in, has the sole voting interest in, and controls the management of BV LLC. As a result, the Company consolidates the financial results of BV LLC and reports a non-controlling interest for the interest not held by the Company.

IPO Transactions

In connection with the IPO, the Company completed the following transactions (Transactions).

- Amended and restated the limited liability company agreement of BV LLC (BV LLC Agreement), to, among other things, (i) provide for a new single class of common membership interests in BV LLC (LLC Interests), (ii) exchange all of the existing membership interests in BV LLC (Original BV LLC Owners) for new LLC Interests and (iii) appoint Bioventus Inc. as the sole managing member of BV LLC. Refer to *Note 7. Stockholders' and members' equity* for further information.
- Amended and restated the Bioventus Inc. certificate of incorporation to, among other things, (i) provide for an increase in the authorized shares of Class A common stock; (ii) provide for Class B common stock with voting rights but no economic interest, which shares were issued to the Original BV LLC Owners on a one-for-one basis with the number of LLC Interests they owned; and (iii) provide for undesignated preferred stock. Refer to *Note 7. Stockholders' and members' equity* for further information.
- Acquired, by merger, ten entities that were Original BV LLC Owners (Former LLC Owners), for which the Company issued 31,838,589 shares of Class A common stock as merger consideration (IPO Mergers). The only assets held by the Former LLC Owners were 31,838,589 LLC Interests and a corresponding number of shares of Class B common stock. Upon consummation of the IPO Mergers, the 31,838,589 shares of Class B common stock were canceled, and the Company recognized the 31,838,589 LLC Interests at carrying value, as the IPO Mergers are considered to be a recapitalization transaction.

The financial statements for periods prior to the IPO and Transactions have been adjusted to combine the previously separate entities for presentation purposes. Prior to the Transactions, Bioventus Inc. had no operations.

Interim periods

The Company reports quarterly interim periods on a 13-week basis within a standard calendar year. Each annual reporting period begins on January 1 and ends on December 31. Each quarter ends on the Saturday closest to calendar quarter-end, with the exception of the fourth quarter, which ends on December 31. The 13-week quarterly periods for fiscal year 2021 ended on April 3, July 3 and October 2. Comparable periods for 2020 ended on March 28, June 27 and September 26. The fourth and first quarters may vary in length depending on the calendar year.

Principles of consolidation

The consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP). The consolidated financial statements include the Company, its subsidiaries and investments in which the Company has control. Amounts pertaining to the non-controlling ownership interests held by third parties in the operating results and financial position of the Company's controlled subsidiaries are reported as non-controlling interests. All intercompany balances and transactions have been eliminated in consolidation.

Reclassifications

Certain prior period amounts have been reclassified to conform to the current period presentation. These changes had no effect on previously reported total revenues, net income, other comprehensive income, members' equity or cash flows. Unless otherwise noted, all financial information in the consolidated financial statement footnotes reflect the Company's results from continuing operations.

Segment reporting

The Company identifies a business as an operating segment if: (i) it engages in business activities from which it may earn revenues and incur expenses; (ii) its operating results are regularly reviewed by the Chief Operating Decision Maker (CODM), to make decisions about resources to be allocated to the segment and assess its performance; and (iii) it has available discrete financial information. The Company's CODM is its Chief Executive Officer. The CODM reviews financial information at the operating segment level to allocate resources and to assess the operating results and financial performance for each operating segment.

The Company's two reportable segments are U.S. and International. U.S. and International products are primarily sold to physicians spanning the orthopedic continuum, including sports medicine, total joint reconstruction, hand and upper extremities, foot and ankle, podiatric surgery, trauma, spine and neurosurgery, as well as directly to their patients. Refer to *Note 13. Revenue recognition* and *Note 14. Segments* for further information regarding the Company's business segments.

Use of estimates

The preparation of financial statements in accordance with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities, at the date of the financial statements, as well as the reported amounts of revenues and expenses during the period. On an ongoing basis, management evaluates these estimates, including those related to contractual allowances and sales incentives, allowance for credit losses, inventory reserves, goodwill and intangible assets impairment, valuation of assets and liabilities assumed in acquisitions, useful lives of long lived assets, noncontrolling interest, fair value measurements, litigation and contingent liabilities, income taxes, and equity-based compensation. Management bases its estimates on historical experience, future expectations and other relevant assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates.

COVID-19 pandemic impact

In 2020, the COVID-19 pandemic spread around the world including the United States. New variants of the virus have emerged, some of which have shown to be more contagious. The COVID-19 pandemic has had widespread, rapidly evolving and unpredictable impacts on global society, economies, financial markets and business practices. Federal and state governments implemented measures in an effort to prevent or minimize the spread of the virus, and ongoing effects of the pandemic, including social distancing, travel restrictions, border closures, limitations on public gatherings, mandatory closure or reduced capacity of businesses, work from home, supply chain logistical changes and other measures, which caused global business disruptions and significant volatility in U.S. and international debt and equity markets. The Company's business, results of operations and financial condition have been and may continue to be, materially impacted by fluctuations in patient visits and elective procedures and any future temporary cessations of elective procedures and could be further impacted by delays in payments from customers, supply chain interruptions, extended "shelter-in-place" orders or advisories, facility closures or other reasons related to the pandemic. Furthermore, the long-term impact of COVID-19 on the Company's business will depend on many factors, including, but not limited to, the duration and severity of the pandemic, new and ongoing measures taken in response to the pandemic, the availability, adoption and effectiveness of vaccines and treatments, the impact on economic activity from the pandemic and actions taken in response and the resulting impact it has on the Company's partners, patients and communities in which the Company operates, all of which continue to be uncertain. As of the date of issuance of these consolidated financial statements, the extent to which COVID-19 could materially impact the Company's financial conditions, liquidity or results of operations is uncertain.

To the extent COVID-19 disruptions continue to adversely impact the Company's business, results of operations and financial condition, it may also have the effect of heightening risks relating to the Company's ability to successfully commercialize newly developed or acquired products or therapies, consolidation in the healthcare industry, intensified pricing pressure as a result of changes in the purchasing behavior of hospitals and maintenance of the Company's numerous contractual relationships.

On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act (CARES Act) was signed into law, which was aimed at providing emergency assistance and health care for individuals, families, and businesses affected by the COVID-19 pandemic and generally supporting the U.S. economy. The CARES Act, among other things, included provisions relating to refundable payroll tax credits, deferment of employer social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, and modifications to the net interest deduction limitations. The CARES Act allowed the Company to defer employer social security payroll tax payments from May 2020 through December 31, 2020 totaling $1,889. The Company repaid $1,440 in December 2021, including payments on deferred payroll tax balances acquired in business combinations. The deferred balance is $1,440 as of December 31, 2021, which is recorded in other current liabilities on the consolidated balance sheets and is due on December 31, 2022.

As a result of the CARES Act and at the direction of the U.S. Department of Health and Human Services (HHS), the Company received $4,101 in Provider Relief Fund Payments in 2020. The Company determined it complied with the conditions to be able to keep and use the funds to reimburse for health care related expenses and lost revenue attributable to the public health emergency resulting from COVID-19. The payments were recorded as other income on the consolidated statement of operations and comprehensive income for the year ended December 31, 2020.

2. Summary of significant accounting policies

Recent accounting pronouncements

The Company has elected to comply with non-accelerated public company filer effective dates of adoption. Therefore, the required effective dates for adopting new or revised accounting standards as described below are generally earlier than when emerging growth companies are required to adopt.

Accounting Pronouncements Recently Adopted

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update 2019-12, *Income Taxes* (ASU 2019-12), which amended the accounting for income taxes. ASU 2019-12 eliminates certain exceptions to the guidance for income taxes related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences as well as simplifying aspects of the accounting for franchise taxes and enacted changes in tax laws or rates and clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The Company adopted ASU 2019-12 on January 1, 2021 and it did not have a material impact on its consolidated financial statements.

In November 2021, the FASB issued Accounting Standards Update 2021-10, Government Assistance (ASU 2021-10), which requires disclosures that increase the transparency of transactions involving government grants, including the types of transactions, the accounting for those transactions and the effect of those transactions on an entity's financial statements. The Company early adopted the provisions of ASU 2021-10 on December 31, 2021, as the Company received Provider Relief Fund Payments during 2020. Refer to *Note 1. Organization* for further details.

Variable Interest Entity

The Company reviews each investment and collaboration agreement to determine if it has a variable interest in the entity. In assessing whether the Company has a variable interest in the entity as a whole, the Company considers and makes judgments regarding the purpose and design of entity, the value of the licensed assets to the entity, the value of the entity's total assets and the significant activities of the entity. If the Company has a variable interest in the entity as a whole, the Company assesses whether or not the Company is a primary beneficiary of that variable interest entity (VIE), based on a number of factors, including: (i) which party has the power to direct the activities that most significantly affect the VIE's economic performance, (ii) the parties' contractual rights and responsibilities pursuant to the collaboration agreement, and (iii) which party has the obligation to absorb losses of or the right to receive benefits from the VIE that could be significant to the VIE. If the Company determines that it is the primary beneficiary of a VIE at the onset of the collaboration, the collaboration is treated as a business combination and the Company consolidates the financial statement of the VIE into the Company's consolidated financial statements. On a quarterly basis, the Company evaluates whether it continues to be the primary beneficiary of the consolidated VIE. If the Company determines that it is no longer the primary beneficiary of a consolidated VIE, it deconsolidates the VIE in the period the determination is made.

Assets and liabilities recorded as a result of consolidating financial results of the VIE into the Company's consolidated balance sheet do not represent additional assets that could be used to satisfy claims against the Company's general assets or liabilities for which creditors have recourse to the Company's general assets.

Noncontrolling Interest

The Company records noncontrolling interest on its consolidated balance sheet related to the economic interest in BV LLC held by the only continuing BV LLC owner as well as consolidated VIEs. The Company records loss attributable to noncontrolling interest on its consolidated statements of operations, which reflects the net loss for the reporting period, adjusted for changes in the noncontrolling interest holders claim to net assets, including contingent milestone and royalty payments, which are evaluated each reporting period.

Deconsolidation and discontinued operations

Upon the occurrence of certain events and on a regular basis, the Company evaluates whether it no longer has a controlling interest in its subsidiaries, including consolidated VIEs. If the Company determines it no longer has a controlling interest, the subsidiary is deconsolidated. The Company records a gain or loss on deconsolidation based on the difference on the deconsolidation date between (i) the aggregate of (a) the fair value of any consideration received, (b) the fair value of any retained noncontrolling investment in the former subsidiary and (c) the carrying amount of any noncontrolling interest in the subsidiary being deconsolidated, less (ii) the carrying amount of the former subsidiary's assets and liabilities.

The Company assesses whether a deconsolidation is required to be presented as discontinued operations in its consolidated financial statements on the deconsolidation date. This assessment is based on if the deconsolidation represents a strategic shift that has or will have a major effect on the Company's operations or financial results. If the Company determines that a deconsolidation requires presentation as a discontinued operation on the deconsolidation date, it will present the former subsidiary as a discontinued operation for all periods presented.

Effect of foreign currency

The assets and liabilities of foreign subsidiaries whose functional currency is the local currency are translated into U.S. dollars at rates of exchange in effect at the close of their month end. Equity accounts are translated at their historical rates. Revenues and expenses are translated at the exchange rate on the transaction date. Translation gains and losses are accumulated within accumulated other comprehensive income as a separate component of equity.

Foreign currency transaction gains and losses are included in other expense on the consolidated statements of operations and comprehensive income. There were losses of $132 and gains of $117 for the years ended December 31, 2021 and 2020, respectively, and nominal losses for the year ended December 31, 2019.

Comprehensive income

Comprehensive income consists of two components: net income and other comprehensive income, which refers to gains and losses that are recorded under U.S. GAAP as an element of stockholders' equity and are excluded from net income. The Company's other comprehensive income consists of a defined benefit plan adjustment and foreign currency translation adjustments from those subsidiaries not using the U.S. dollar as their functional currency.

Cash, cash equivalents and restricted cash

Cash equivalents consist of highly liquid investments with an original maturity of three months or less at date of purchase. The Company's cash is primarily held in financial institutions in the United States and the Netherlands. The Company maintains cash balances in the United States in excess of the federally insured limits. Restricted cash is cash the Company holds for specific reasons and is not available for immediate business use.

Derivatives

The Company uses derivative instruments to manage exposures to interest rates. Derivatives are recorded on the balance sheet at fair value at each balance sheet date and the Company does not designate whether the derivative instrument is an effective hedge. Changes in the fair values of derivative instruments are recognized in the consolidated statements of operations and comprehensive income. The Company has entered, and may in the future enter, into derivative contracts related to its debt. Refer to *Note 5. Financial instruments* for further details regarding the Company's derivatives.

Fair value

The Company records certain assets and liabilities at fair value. Refer to *Note 6. Fair value measurements* for details regarding assets and liabilities measured at fair value. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. A three-level fair value hierarchy that prioritizes the inputs used to measure fair value is described below. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. Assets and liabilities are categorized based on the lowest level that is significant to the valuation.

The three levels of inputs used to measure fair value are as follows:

- Level 1—Quoted prices in active markets for identical assets or liabilities;
- Level 2—Observable inputs other than quoted prices included within Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data; and
- Level 3—Unobservable inputs that are supported by little or no market data. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

Revenue recognition

Sale of Products

The Company derives revenue primarily from product sales in its (i) Pain Treatments portfolio, which includes osteoarthritic (OA) joint pain treatments, which are hyaluronic acid (HA), viscosupplementation therapies and peripheral nerve stimulation products (ii) Surgical Solutions, which includes bone graft substitutes, tissue resection, ultrasonic bone cutting and sculpting systems and other surgical products, and (iii) Restorative Therapies, which includes minimally invasive fracture treatments, rehabilitation and wound products. The Company sells product directly to healthcare institutions, patients, distributors and dealers. The Company also enters arrangements with pharmacy and health benefit managers that provide for privately negotiated rebates, chargebacks and discounts with respect to the purchase of the Company's products.

The Company recognizes revenue generally at a point in time upon transfer of control of the promised product to customers in an amount that reflects the consideration it expects to receive in exchange for those products. The Company excludes taxes collected from customers and remitted to governmental authorities from revenues.

Revenues are recorded at the transaction price, which is determined as the contracted price net of estimates of variable consideration resulting from discounts, rebates, returns, chargebacks, contractual allowances, estimated third-party payer settlements, and certain distribution and administration fees offered in customer contracts and other indirect customer contracts relating to the sale of products. The Company establishes reserves for the estimated variable consideration based on the amounts earned or eligible for claim on the related sales. Where appropriate, these estimates take into consideration a range of possible outcomes, which are probability-weighted for relevant factors such as the Company's historical experience, current contractual requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. The Company regularly reviews all reserves and updates them at the end of each reporting period as needed. There were no significant adjustments arising from the change in estimates of variable consideration for the years ended December 31, 2021, 2020 and 2019.

Pain Treatments

Revenue from customers, such as healthcare providers, distribution centers or specialty pharmacies is recognized at the point in time when control is transferred to the customer, typically upon shipment.

Distributor chargebacks

The Company has preexisting contracts with established rates with many of the distributors' customers that require the distributors to sell product at their established rate. The Company offers chargebacks to distributors who supply these customers with products. The Company reduces revenue at the time of sale for the estimated future chargebacks. The Company records chargeback reserves as a reduction of accounts receivable and base the reserves on the expected value by using probability-weighted estimates of volume of purchases, inventory holdings and historical chargebacks requested for each distributor.

Discounts and gross-to-net deductions

The Company offers retrospective discounts and gross-to-net deductions linked to the volume of purchases which may increase at negotiated thresholds within a contract-buying period. The Company reduces revenue and records the reserve as a reduction to accounts receivable for the estimated discount and rebate at the expected amount the customer will earn, based on historical buying trends and forecasted purchases.

Surgical Solutions

Most of the Company's product sales related to bone graft substitutes are through consignment inventory with hospitals, where ownership remains with the Company until the hospital or ambulatory surgical center (ASC) performs a surgery and consumes the consigned inventory. The Company recognizes revenue when the surgery has been performed. Control of the product is not transferred until the customer consumes it, as the Company is able to require the return or transfer of the product to a third-party prior to the products use. An unconditional obligation to pay for the product does not exist until the customer uses it.

The Company typically recognizes revenue from sales of our ultrasonic products acquired through the Misonix acquisition in accordance with shipping terms. Control is transferred to the customer when the product is shipped or received, and revenue is recognized accordingly.

Restorative Therapies

The Company recognizes revenue from third-party payers, such as governmental agencies, insurance companies or managed care providers, when the Company transfers control to the patient, typically when the patient has accepted the product or upon delivery. The Company records this revenue at the contracted rate, net of contractual allowances and estimated third-party payer settlements at the time of sale, or an estimated price based on historical data and other available information for non-contracted payers. The Company estimates the contractual allowances using the portfolio approach and based on probability weighting historical data and collections history within those portfolios. The portfolios determined using the portfolio approach consist of the following customer groups: government payers, commercial payers, and patients.

Settlements with third-party payers for retroactive revenue adjustments due to audits, reviews or investigations are considered variable consideration and are included in the determination of the estimated transaction price using the expected amount method. These settlements are estimated based on the terms of the payment agreement with the payer, correspondence from the payer and historical settlement activity, including an assessment to ensure that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the retroactive adjustment is subsequently resolved. Estimated settlements are adjusted in future periods as adjustments become known (that is, new information becomes available), or as years are settled or are no longer subject to such audits, reviews and investigations. The Company is not aware of any claims, disputes or unsettled matters with any payer that would materially affect revenues for which the Company has not adequately provided for or disclosed in the accompanying consolidated financial statements. Refer to *Note 12. Commitments and contingencies* for further information.

The Company recognizes revenue from patients (self-pay and insured patients with coinsurance and deductible responsibilities) based on billed amounts giving effect to any discounts and implicit price concessions. Implicit price concessions represent differences between amounts billed and the amounts the Company expects to collect from patients, which considers historical collection experience and current market conditions. The Company recognizes revenue from other restorative therapies products generally at the point in time when control is transferred to the customer, either upon shipment or reaching the destination, depending on the product.

Product returns

The Company estimates the amount of returns and reduces revenue in the period the related product revenue is recognized. The Company records a liability for expected returns based on probability-weighted historical data.

Accounts receivable, net

Accounts receivable, net are amounts billed and currently due from customers. The Company records the amounts due net of allowance for credit losses. The Company maintains an estimated allowance for credit losses to provide for receivables the Company does not expect to collect. The Company bases the allowance on an assessment of customer creditworthiness, historical payment experience, the age of outstanding receivables and other information as applicable. Collection of the consideration that the Company expects to receive typically occurs within 30 to 90 days of billing. The Company applies the practical expedient for contracts with payment terms of one year or less which does not consider the effects of the time value of money. Occasionally, the Company enters into payment agreements with patients that allow payment terms beyond one year. In those cases, the financing component is not deemed significant to the contract.

Contract assets

Contract assets consist of unbilled amounts resulting from estimated future royalties from an international distributor that exceeds the amount billed. Contract assets totaling $82 and $81 as of December 31, 2021 and 2020, respectively, are included in prepaid and other current assets on the consolidated balance sheets.

Contract liabilities

Contract liabilities consist of customer advance payments or deposits and deferred revenue. Occasionally for certain international customers, the Company requires payments in advance of shipping product and recognizing revenue resulting in contract liabilities. Contract liabilities were $2,399 and nominal as of December 31, 2021 and 2020, respectively, are included in accrued liabilities on the consolidated balance sheets.

Shipping and handling

The Company classifies amounts billed for shipping and handling as a component of net sales. The related shipping and handling fees and costs as well as other distribution costs are included in cost of sales. The Company has elected to recognize shipping and handling activities that occur after control of the related product transfers to the customer as fulfillment costs and are included in cost of sales.

Contract costs

The Company applies the practical expedient of recognizing the incremental costs of obtaining contracts as an expense when incurred as the amortization period of the assets that the Company otherwise would have recognized is one year or less. These incremental costs include the Company's sales incentive programs for the internal sales force and third-party sales agents as the compensation is commensurate with annual sales activities. These costs are included in selling, general and administrative expense on the consolidated statements of operations and comprehensive income.

Inventory

The Company values its inventory at the lower of cost or net realizable value and adjusts for the value of inventory that is estimated to be excess, obsolete or otherwise unmarketable. Cost is determined using the first-in, first-out (FIFO) method. Elements of cost in inventory include raw materials, direct labor, manufacturing overhead and inbound freight. The Company records allowances for excess and obsolete inventory based on historical and estimated future demand and market conditions. Inventory items used for demonstration purposes, rentals and consigned generators are classified as property and equipment.

Business combinations

Accounting for acquisitions requires the Company to recognize separately from goodwill assets acquired and the liabilities assumed at their acquisition date fair values. Goodwill as of the acquisition date is measured as the excess of consideration transferred over the net of the acquisition date fair values of the assets acquired and the liabilities assumed. While best estimates and assumptions are used to accurately value assets acquired and liabilities assumed at the acquisition date, as well as contingent consideration where applicable, estimates are inherently uncertain and subject to refinement. During the measurement period, which may be up to one year from the acquisition date, the Company may record adjustments to the assets acquired and liabilities assumed with a corresponding offset to goodwill. Upon the conclusion of the measurement period or final determination of the values of assets acquired or liabilities assumed, whichever comes first, any subsequent adjustments are recorded within the consolidated statements of operations and comprehensive income. Subsequent changes in the estimated fair value of contingent consideration are recognized in earnings in the period of change.

Long-lived assets

The carrying values of property, equipment, intangible assets as well as other long-lived and indefinite lived assets are reviewed for recoverability if the facts and circumstances suggest that a potential impairment may have occurred. If this review indicates that carrying values may not be recoverable, the Company will perform an assessment to determine if an impairment charge is required to reduce carrying values to estimated fair value. If quoted market prices are not available, the Company estimates fair value using an undiscounted value of estimated future cash flows. Upon retirement or sale of property and equipment, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts, and any resulting gain or loss is included in income from operations. During the year ended December 31, 2021, the Company recognized an impairment of $5,674 on long lived assets related to a VIE of which $5,176 is attributable to the non-controlling interests, refer to *Note 4. Acquisitions and investments* for further information. Except for the impairment related to the VIE, there were no other events, facts or circumstances for the years ended December 31, 2021, 2020 and 2019 that resulted in any impairment charges to the Company's property, equipment, intangible or other long-lived assets.

Property and equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense are recognized using the straight-line method over the estimated useful life of each asset, or the shorter of the lease term or useful life if related to leasehold improvements. Depreciation of generators used with certain surgical solutions are consigned to customers and depreciation is charged to selling expenses. The useful lives in years are as follows:

Computer software and hardware	3 - 5
Demonstration and consignment inventory	5
Furniture and fixtures	3 - 7
Leasehold improvements	3 - 7
Machinery and equipment	3 - 7

Intangible assets

Finite-lived intangible assets were initially recorded at fair value upon acquisition and are amortized using the straight-line method over their estimated useful lives in years are as follows:

	Weighted Average Useful Life
Intellectual property	17.7
Distribution rights	11.6
Customer relationships	11.6
Developed technology	9.5

Goodwill

Goodwill is not amortized but is evaluated for impairment annually or more frequently if events or changes in circumstances indicate that goodwill might be impaired. The Company reviews goodwill for impairment by applying a quantitative impairment analysis where the fair value of the reporting unit is compared with the carrying value, including goodwill. The Company determines the fair value of each reporting unit based on an income approach. The value of each reporting unit is determined on a stand-alone basis from the perspective of a market participant and represents the price estimated to be received in a sale of the reporting unit in an orderly transaction between market participants at the measurement date. The Company performs its annual goodwill impairment test on October 31. If the fair value of the reporting unit is less than its carrying value, the Company will recognize the difference as an impairment loss, which is limited to the amount of goodwill allocated to the reporting units. There were no goodwill impairment charges for the years ended December 31, 2021, 2020 and 2019.

Software development costs

The Company capitalizes internal and external costs incurred to develop internal-use software during the application development stage for software design, configuration, coding and testing upon placing the asset in service and then amortizes these costs on a straight-line basis over the estimated useful life of the product, not to exceed three years. The Company does not capitalize costs that are precluded from capitalization in authoritative guidance, such as preliminary project phase costs, training costs or data conversion costs. Capitalized software costs totaled $20,706 and $17,653 as of December 31, 2021 and 2020 and the related accumulated amortization totaled $15,491 and $13,264, respectively. Amortization expense was $2,227, $1,184 and $1,138 for the years ended December 31, 2021, 2020 and 2019, respectively.

Acquired in-process research and development

The fair value of in-process research and development (IPR&D) assets acquired in a business combination are capitalized and accounted for as indefinite-lived intangible assets and are not amortized until development is completed and the product is available for sale. Once the product is available for sale, the asset is transferred to developed technology and amortized over its estimated useful life. Impairment tests for IPR&D assets occur at least annually in December, or more frequently if events or changes in circumstances indicate that the asset might be impaired. If the fair value of the intangible assets is less than the carrying amount, an impairment loss is recognized for the difference.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting, filing and other fees related to registration statements are capitalized. The deferred offering costs are offset against proceeds from a successful registration or expensed if unsuccessful. Deferred offering costs capitalized during the year ended December 31, 2020 totaled $2,187. There were no deferred costs during the year ended December 31, 2021.

Equity Method Investments

Investments in which the Company can exercise significance influence, but does not control, are recorded under the equity method of accounting and are included in investments and other assets on the consolidated balance sheets. The Company's share of net earnings or losses is included in other expense (income) within the consolidated statements of operations and comprehensive income on a quarter lag. The Company evaluates investments for impairment whenever events or changes in circumstances indicate that the carrying amounts of such investments may be impaired. Impairment losses are recorded within earnings within the current period.

Concentration of risk

The Company provides credit, in the normal course of business, to its customers. The Company does not require collateral or other securities to support customer receivables. Credit losses are provided for through allowances and have historically been materially within management's estimates.

Certain suppliers provide the Company with product that results in a significant percentage of total sales for the years ended December 31, as follows:

	2021	2020	2019
Supplier A	27 %	26 %	20 %
Supplier B	15 %	17 %	19 %
Supplier C	8 %	10 %	15 %

Accounts payable to these significant suppliers at December 31, were as follows:

	2021	2020
Supplier A	$ 4,928	$ 2,983
Supplier B	$ 633	$ 471
Supplier C	$ 1,476	$ 1,000

Certain products provide the Company with a significant percentage of total sales for the years ended December 31, as follows:

	2021	2020	2019
Product A	27 %	26 %	20 %
Product B	20 %	27 %	30 %
Product C	15 %	17 %	19 %
Product D	8 %	10 %	15 %

Restructuring costs

The Company has restructured portions of its operations and future restructuring activities are possible. Identifying and calculating the cost to exit these operations requires certain assumptions to be made, the most significant of which are anticipated future liabilities. Although estimates have been reasonably accurate in the past, significant judgment is required, and these estimates and assumptions may change as additional information becomes available and facts or circumstances change. Restructuring costs are recorded at estimated fair value. Key assumptions in determining the restructuring costs include negotiated terms and payments to terminate contractual obligations.

Equity-based compensation

The Company measures compensation cost for all share-based payments at fair value and recognizes this cost as compensation expense over the vesting period. The Company uses the Black-Scholes method to value options and the market price on the date of grant to value restricted stock. The Company utilizes the straight-line amortization method to recognize the expense associated with the awards with graded vesting terms. Compensation expense is included in selling, general and administrative expense and Research and development expense on the consolidated statement of operations and comprehensive income based upon the classification of the employees who were granted the awards.

Advertising costs

Advertising costs include costs incurred to promote the Company's business and are expensed as incurred and recorded as selling, general and administrative expense within the consolidated statement of operations and comprehensive income. Advertising costs were $3,873, $2,769 and $2,351 for the years ended December 31, 2021, 2020 and 2019, respectively.

Research and development expense

Research and development expense consist primarily of employee compensation and related expenses as well as contract research organization services. Internal research and development costs are expensed as incurred. Research and development costs incurred by third parties are expensed as the contracted work is performed.

Collaborative agreements

The Company periodically enters into strategic alliance agreements with counterparties to produce products and/or provide services to customers. Alliances created by such agreements are not legal entities, have no employees, no assets and have no true operations. These arrangements create contractual rights and the Company accounts for these alliances as a collaborative arrangement by reporting costs incurred from transactions within research and development expense within the consolidated statements of operations.

Contingencies

The Company records a liability in the consolidated financial statements on an undiscounted basis for loss contingencies when a loss is known or considered probable and the amount may be reasonably estimated. If the reasonable estimate of known or probable loss is a range, and no amount within the range is a better estimate than any other, the minimum amount of the range is accrued. If a loss is reasonably possible but not known or probable, and may be reasonably estimated, the estimated loss or range of loss is disclosed. Legal fees expected to be incurred in connection with a loss contingency are not included in the estimated loss contingency. The Company accrues for any legal costs as they are incurred.

Income taxes

The Company accounts for income taxes using the asset and liability method, under which deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and income tax basis of assets and liabilities, and for operating losses and credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the years in which those items are expected to be realized. Tax law and rate changes are recorded in the period such changes are enacted. The Company establishes a valuation allowance when it is more likely than not that certain deferred tax assets will not be realized in the foreseeable future.

The Company recognizes a tax benefit from any uncertain tax positions only if they are more likely than not to be sustained upon examination based on the technical merits of the position. The amount of the accrual for which an exposure exists is measured as the largest amount of benefit determined on a cumulative probability basis that the Company believes is more likely than not to be realized upon ultimate settlement of the position. Components of the reserve, if relevant, are classified as a current or noncurrent liability in the consolidated balance sheet based on when the Company expects each of the items to be settled. Interest and penalties related to unrecognized tax benefits are recognized as a component of income tax expense.

Earnings per share

Basic earnings per share is calculated using net income or loss attributable to Bioventus, Inc. Class A common stock holders, divided by the weighted-average Class A common stock outstanding. Diluted earnings per share is calculated using net income attributable to Bioventus, Inc. Class A common stock holders, divided by the weighted average Class A common stock outstanding adjusted for the effect of granted stock awards determined to be dilutive under the treasury stock method.

3. Balance sheet information

Cash, cash equivalents and restricted cash

A summary of cash, cash equivalents and restricted cash as of December 31:

	2021	2020
Cash and cash equivalents	$ 43,933	$ 86,839
Restricted cash		
Current	5,280	—
Noncurrent	50,000	—
	$ 99,213	$ 86,839

Current restricted cash consists of an escrow deposit with a financial institution for the purpose of paying a Paycheck Protection Program (PPP) loan acquired as part of a business combination and noncurrent restricted cash consists of an escrow deposit with a financial institution for a potential future acquisition. Refer to *Note 4. Acquisitions and investments* for further information.

Accounts receivable, net

Accounts receivable, net are amounts billed and currently due from customers. The Company records the amounts due net of allowance for credit losses. Collection of the consideration that the Company expects to receive typically occurs within 30 to 90 days of billing. The Company applies the practical expedient for contracts with payment terms of one year or less which does not consider the effects of the time value of money. Occasionally, the Company enters into payment agreements with patients that allow payment terms beyond one year. In those cases, the financing component is not deemed significant to the contract.

Accounts receivable, net of allowances, consisted of the following as of December 31:

	2021	2020
Accounts receivable	$ 128,365	$ 92,273
Less: Allowance for credit losses	(3,402)	(3,990)
	$ 124,963	$ 88,283

Due to the short-term nature of its receivables, the estimate of expected credit losses is based on aging of the account receivable balances. The allowance is adjusted on a specific identification basis for certain accounts as well as pooling of accounts with similar characteristics. The Company has a diverse customer base with no single customer representing ten percent of sales or accounts receivable. Historically, the Company's reserves have been adequate to cover credit losses. The Company considered the current and expected future economic and market conditions surrounding the COVID-19 pandemic and determined that the estimate of credit losses was not significantly impacted.

Changes in credit losses were as follows for the years ended December 31:

	2021	2020
Beginning balance	$ (3,990)	$ (4,146)
Provision for expected credit losses	(485)	(1,215)
Write-offs	1,246	1,787
Recoveries	(173)	(416)
Ending balance	$ (3,402)	$ (3,990)

Inventory

Inventory consisted of the following as of December 31:

	2021	2020
Raw materials and supplies	$ 12,213	$ 3,665
Finished goods	50,805	26,323
Gross	63,018	29,988
Excess and obsolete reserves	(1,330)	(868)
	$ 61,688	$ 29,120

Changes in excess and obsolete reserves for inventory were as follows for the years ended December 31:

	2021	2020
Beginning balance	$ (868)	$ (532)
Provision for losses	(1,835)	(904)
Write-offs	1,373	568
Ending balance	$ (1,330)	$ (868)

Prepaid and other current assets

Prepaid and other current assets consisted of the following as of December 31:

	2021	2020
Prepaid taxes	$ 12,236	$ 145
Prepaid and other current assets	15,003	7,407
	$ 27,239	$ 7,552

Property and equipment, net

Property and equipment consisted of the following as of December 31:

	2021	2020
Computer equipment and software	$ 24,412	$ 20,547
Demonstration and consignment inventory	10,453	—
Leasehold improvements	3,131	3,126
Furniture and fixtures	1,964	1,474
Machinery and equipment	2,722	1,234
Assets not yet placed in service	3,403	819
	46,085	27,200
Less accumulated depreciation	(23,100)	(20,321)
	$ 22,985	$ 6,879

Depreciation expense was $3,204, $2,106 and $2,579 for the years ended December 31, 2021, 2020 and 2019, respectively.

Goodwill and intangible assets, net

There were no changes to goodwill during the year ended December 31, 2020. Changes in the carrying amounts of goodwill by reportable segment during the year ended December 31, 2021 are as follows:

	U.S.	International	Consolidated
Balance at December 31, 2020	$ 41,040	$ 8,760	$ 49,800
Acquisitions	97,823	—	97,823
Balance at December 31, 2021	$ 138,863	$ 8,760	$ 147,623

Additions during the year ended December 31, 2021 resulted from the acquisitions of Misonix, Inc. and Bioness Inc. Refer to *Note 4. Acquisitions and investments* for further information.

Intangible assets consisted of the following as of December 31:

	2021	2020
Intellectual property	$ 789,195	$ 263,422
Distribution rights	60,700	60,700
Customer relationships	67,450	57,700
IPR&D	5,500	1,445
Developed technology and other	13,999	13,999
Total carrying amount	936,844	397,266
Less accumulated amortization:		
Intellectual property	(140,767)	(117,281)
Distribution rights	(39,379)	(34,461)
Customer relationships	(56,312)	(51,247)
Developed technology and other	(5,031)	(3,786)
Total accumulated amortization	(241,489)	(206,775)
Intangible assets, net before currency translation	695,355	190,491
Currency translation	(162)	1,159
	$ 695,193	$ 191,650

There were $545,000 of intangible additions during the year ended December 31, 2021 as a result of acquisitions. Refer to *Note 4. Acquisitions and investments* for further information.

Amortization expense related to intangible assets was $35,480, $27,565 and $26,252 for the years ended December 31, 2021, 2020 and 2019 of which $12,179, $7,455 and $6,416 are included in ending inventory at December 31, 2021, 2020 and 2019, respectively. Estimated amortization expense for the years ended December 31, 2022 through 2026 is expected to be $55,626, $53,919, $52,850, $50,022 and $46,864, respectively.

Accrued liabilities

Accrued liabilities consisted of the following as of December 31:

	2021	2020
Gross-to-net deductions	$ 67,945	$ 43,656
Bonus and commission	23,342	15,188
Compensation and benefits	10,665	5,875
Income and other taxes	8,139	2,434
Other liabilities	21,382	21,034
	$ 131,473	$ 88,187

4. Acquisitions and investments

Acquisitions

Misonix, Inc.

On October 29, 2021, in order to broaden its portfolio, the Company acquired 100% of the capital stock of Misonix, Inc. (Misonix) in a cash-and-stock transaction (the Misonix Acquisition). Misonix manufactures minimally invasive surgical ultrasonic medical devices used for precise bone sculpting, removal of soft and hard tumors and tissue debridement, primarily in the areas of neurosurgery, orthopedic surgery, plastic surgery, wound care and maxillo-facial surgery. Misonix also exclusively distributes skin allografts and wound care products used to support healing of wounds. The fair value of the consideration for the Misonix Acquisition is comprised of the following:

	Common Shares	Price per Share[(a)]	Amount
Cash			$ 182,988
Bioventus Class A shares	18,340,790	$ 14.97	274,562
Value of Misonix options settled in Bioventus options			27,636
Merger consideration			485,186
Other cash consideration			40,130
Total Misonix consideration			$ 525,316

(a) Closing price of the Company's Class A common stock as of October 28, 2021.

The Company accounted for the Misonix Acquisition using the acquisition method of accounting whereby the total purchase price was preliminarily allocated to tangible and intangible assets acquired and liabilities assumed based on respective fair values. The following table summarizes the preliminary fair values of the assets acquired and liabilities assumed at the acquisition date:

Fair value of consideration	$ 525,316
Assets acquired and liabilities assumed:	
Cash and cash equivalents	7,126
Accounts receivable	13,301
Inventory	24,720
Prepaid and other current assets	419
Property and equipment	10,571
Intangible assets	486,500
Operating lease assets	1,049
Other assets	77
Accounts payable and accrued liabilities	(16,888)
Other current liabilities	(589)
Deferred income taxes	(94,012)
Other liabilities	(1,351)
Net assets acquired	430,923
Resulting goodwill	$ 94,393

As of December 31, 2021, the purchase price allocation for the Misonix Acquisition was preliminary and subject to completion. Adjustments to the current fair value estimates in the above table may occur as the process conducted for various valuations and assessments is finalized, including tax liabilities and other working capital accounts. Nearly 100% of the goodwill represents the estimated future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. The factors contributing to the recognition of goodwill are based on several strategic and synergistic benefits that are expected to be realized from the Misonix Acquisition. The goodwill is not tax deductible and was allocated to the U.S. reporting unit for purposes of the evaluation for any future goodwill impairment.

The following table summarizes the preliminary fair values of identifiable intangible assets and their useful lives:

	Useful Life	Fair Value
Intellectual property	15 - 20 years	$ 477,000
Customer relationships	12 years	9,500
		$ 486,500

The preliminary fair value of the Misonix intellectual property was determined using a variation of the income approach or the multi-period excess earnings method, with projected earnings discounted at a rate of 12.0%. The preliminary fair value of the customer relationship asset was determined using the income approach or the profit-split method, with projected cash flow discounted at a rate of 12.0%. The determination of the useful lives was based upon consideration of market participant assumptions and transaction specific factors.

The results of operations of the business have been included in the accompanying consolidated financial statements since the October 29, 2021 acquisition date. The Company's consolidated statements of operations reflect net sales and net loss attributable to Misonix of $15,463 and $3,889, respectively, for the year ended December 31, 2021. The Company incurred $7,992 in Misonix Acquisition costs during the year ended December 31, 2021, which are included in selling, general and administrative expense within the consolidated statement of operations and comprehensive income.

Bioness, Inc.

On March 30, 2021, in order to broaden its portfolio and increase its global footprint, the Company acquired 100% of the capital stock of Bioness, Inc. (Bioness Acquisition). Bioness, Inc. (Bioness) is a global leader in neuromodulation and advanced rehabilitation medical devices through its innovative peripheral nerve stimulation therapy and premium advanced rehabilitation solutions. The Company had previously made a $1,500 convertible debt investment in Bioness on January 4, 2021 as part of an exclusive negotiation to purchase Bioness, which was subsequently repaid in conjunction with the acquisition. The fair value of the consideration for Bioness Acquisition is comprised of the following:

Cash	$ 48,933
Contingent consideration	15,500
Total Bioness consideration	$ 64,433

Contingent consideration is comprised of future earn-out payments contingent upon the achievement of certain research and development projects as well as sales milestones related to Bioness products. The Bioness Acquisition Agreement includes maximum earn-out payments of $65,000 as follows:

- $15,000 for obtaining FDA approval for U.S. commercial distribution of a certain product for certain indications on or before June 30, 2022;
- $20,000 for meeting net sales targets for certain implantable products over a three year period ending on June 30, 2025 at the latest;
- Up to $10,000 for meeting net sales milestones for certain implantable products over a three year period ending on June 30, 2025 at the latest; and
- $20,000 for maintaining Centers for Medicare & Medicaid Services coverage and reimbursement for certain products at specified levels as of December 31, 2024.

In December 2021, it became clear that the $15,000 FDA approval milestone would not be met, therefore, was assigned no value and was recorded as a measurement period adjustment. As of December 31, 2021, the maximum contingent earn-out payment decreased to $50,000 as a result.

The Company accounted for the Bioness Acquisition using the acquisition method of accounting whereby the total purchase price was preliminarily allocated to tangible and intangible assets acquired and liabilities assumed based on respective fair values. The following table summarizes the final fair values of the assets acquired and liabilities assumed at the acquisition date:

Fair value of consideration	$	64,433
Assets acquired and liabilities assumed:		
Cash and cash equivalents		2,143
Accounts receivable		4,124
Inventory		7,257
Prepaid and other current assets		1,947
Property and equipment		673
Intangible assets		58,500
Operating lease assets		3,616
Other assets		131
Accounts payable and accrued liabilities		(11,405)
Other current liabilities		(1,020)
Other liabilities		(4,868)
Net assets acquired		61,098
Resulting goodwill	$	3,335

As of December 31, 2021, the purchase price allocation for the Bioness Acquisition was completed. Nearly 100% of the goodwill represents the estimated future economic benefits arising from other assets acquired that could not be individually identified and separately recognized. The factors contributing to the recognition of goodwill are based on several strategic and synergistic benefits that are expected to be realized from the Bioness Acquisition. The goodwill is tax deductible and was allocated to the U.S. reporting unit for purposes of the evaluation for any future goodwill impairment.

The following table summarizes the fair values of identifiable intangible assets and their useful lives:

	Useful Life		Fair Value
Intellectual property	10 years	$	52,750
IPR&D	N/A		5,500
Customer relationships	2 years		250
		$	58,500

The fair value of the Bioness intellectual property, IPR&D and the customer relationship asset was determined using the income approach through an excess earnings analysis, with projected earnings discounted at a rate of 23.1% for intellectual property and IPR&D and 16.0% for the customer relationship asset. The determination of the useful lives was based upon consideration of market participant assumptions and transaction specific factors.

The results of operations of the business have been included in the accompanying consolidated financial statements since the March 30, 2021 acquisition date. The Company's consolidated statements of operations reflect net sales and net loss attributable to Bioness of $33,980 and $5,652, respectively, for the year ended December 31, 2021. The Company incurred $7,982 in acquisition costs relating to the Bioness Acquisition during the year ended December 31, 2021, which is included in selling general and administrative expense within the consolidated statement of operations and comprehensive income.

Pro forma financial information

The results of operations for Misonix and Bioness have been included in the accompanying consolidated financial statements since their respective acquisition dates of October 29, 2021 and March 30, 2021, respectively. Revenue, earnings and earnings per share including the Bioness and Misonix operations as if the companies were acquired at January 1, 2020 are as follows for the years ended December 31:

	2021		2020
	(unaudited)		(unaudited)
Net sales	$	504,619	$ 429,080
Net loss attributable to Bioventus Inc.	$	(24,178)	$ (45,297)

The historical consolidated financial information of the Company, Misonix and Bioness have been adjusted in the pro forma information to give effect to pro forma events that are (1) directly attributable to the both the Misonix and Bioness acquisitions, (2) factually supportable and (3) expected to have a continuing impact on the combined results. The unaudited pro forma results include adjustments to reflect the inventory step-up amortization, the incremental intangible asset amortization to be incurred based on the valuations of the assets acquired, transaction costs that would have been incurred in the prior period, vesting of equity-based compensation that was accelerated due to the Misonix Acquisition, adjustments to financing costs to reflect the new capital structure as well as the income tax effect and the noncontrolling interest impact of these adjustments. These pro forma amounts are not necessarily indicative of the results that would have been obtained if the acquisition had occurred prior to the beginning of the period presented or that may occur in the future, and does not reflect future synergies, integration costs, or other such costs or savings.

Investments

VIE

The Company and Harbor Medtech Inc. (Harbor) entered into an exclusive Collaboration Agreement in 2019 for purposes of developing a product for orthopedic uses to be commercialized by the Company and supplied by Harbor. The Company's fully diluted partial ownership of 8.8% of Harbor's Series C Preferred Stock and exclusive Collaboration Agreement created a variable interest in Harbor. The Company terminated the Collaboration Agreement in June 2021.

Harbor had been consolidated in the Company's consolidated financial statements from the third quarter of 2019 through June 2021 when the Company ceased being the primary beneficiary because it no longer had the power to direct Harbor's significant activities. The Company determined that the termination was a triggering event requiring an impairment assessment of Harbor's long lived assets. The assessment resulted in an impairment of $5,674, representing Harbor's long-lived asset balance, which was recorded within impairment of variable interest entity assets for the year ended December 31, 2021 in the consolidated statements of operations and comprehensive income, of which $5,176 is attributable to the non-controlling interest. The Company assessed the fair value of the remaining investment balance in Harbor which resulted in a $1,369 impairment recorded within other expense for the year ended December 31, 2021 in the consolidated statements of operations and comprehensive income bringing the investment balance to zero. The Company continues to have license rights to certain technology obtained from Harbor and is continuing product development initiated under the Collaboration Agreement.

Harbor assets that could only be used to settle Harbor obligations and Harbor liabilities for which creditors did not have recourse to the general credit of the Company were as follows at December 31, 2020:

Cash and cash equivalents	$	803
Property and equipment, net		173
Intangible assets, net		5,635
Operating lease assets		178
Other assets		74
	$	6,863
Accounts payable and accrued liabilities	$	366
Other current liabilities		2,004
Other long-term liabilities		659
	$	3,029

Equity Method

On January 30, 2018, the Company purchased 337,397 shares of Series F Convertible Preferred Stock of CartiHeal (2009) Ltd. (CartiHeal), a privately held entity, for $2,500. On January 22, 2020, the Company made an additional $152 investment in CartiHeal, through a Simple Agreement for Future Equity (SAFE). On July 15, 2020, CartiHeal completed the future equity financing and the Company received 12,825 in Series G-1 Preferred Shares resulting in the SAFE being terminated. In addition, on July 15, 2020, the Company entered into an Option and Equity Purchase Agreement with CartiHeal (Option Agreement). Under the terms of the agreement, the Company purchased 1,014,267 shares of CartiHeal Series G Preferred Shares for $15,000. The CartiHeal investment totaled $16,579, including capitalized transaction costs of $1,427, and the Company's equity ownership in CartiHeal increased to 10.03% of its fully diluted shares. The investment does not have a readily determinable fair value and is included within investments and other assets on the consolidated balance sheets. Beginning in July 2020, the Company was able to exercise significant influence over CartiHeal but did not have control and as a result the investment was recognized as an equity method investment. Net losses from CartiHeal for the years ended December 31, 2021 and 2020 totaled $1,868 and $467, respectively, which are included in other expense (income) on the consolidated statement of operations and comprehensive income. The CartiHeal investment carrying value was $16,771 and $18,689 as of December 31, 2021 and 2020, respectively.

In August 2021, CartiHeal achieved pivotal clinical trial success, as defined in the Option Agreement, for a CartiHeal product, which provides the Company with an exclusive option to acquire 100% of CartiHeal's shares (Call Option), and provides CartiHeal with a put option that would require the Company to purchase 100% of CartiHeal's shares under certain conditions (Put Option). In order to preserve the Company's Call Option, in accordance with the Option Agreement and upon approval of the BOD, the Company deposited $50,000 into escrow in August 2021 for the potential acquisition of CartiHeal, which is included in restricted cash on the consolidated balance sheet. Consideration for the acquisition of all of the remaining shares of CartiHeal, excluding those the Company already owns, pursuant to the Call Option or Put Option would be $314,895, inclusive of the existing deposit, all of which would be payable at closing, with an additional $134,955 payable upon achievement of certain sales milestones related to Agili-C. Such closing would be subject to customary closing conditions.

The Call Option may be exercised at any time up to and within 45 days following notice of the U.S. Food and Drug Administration (FDA) approval for a CartiHeal product currently in development. In addition, upon the same FDA approval, CartiHeal may exercise the Put Option within 45 days, which requires the Company to complete the acquisition of the remaining equity in CartiHeal.

During the fourth quarter of 2021, CartiHeal submitted the final clinical module of a Modular Premarket Approval Application (PMA) seeking FDA approval. In order to support the completion of the PMA, if needed, the Company will purchase an additional 338,089 of CartiHeal Series G Preferred Shares for $5,000.

Other

On August 23, 2021, the Company purchased 13,896,609 shares of Trice Medical, Inc.'s (Trice) Series D Preferred Stock for $10,000, representing a 8.4% ownership interest of its fully diluted shares. Trice is a privately held company that develops and commercializes minimally invasive technologies for sports medicine and orthopedic surgical procedures and it does not have a readily determinable fair value. The investment in Trice is recorded at cost, less any impairment, plus or minus any changes resulting from observable price changes in orderly transactions for an identical or similar investment of the same issuer.

5. Financial instruments

Debt

On December 6, 2019, the Company entered into a $250,000 credit and guaranty agreement with Wells Fargo Bank National Association (Wells), as well as a syndicate of other banks (Lenders) which was comprised of a $200,000 term loan (Original Term Loan) and a $50,000 revolving facility (the Revolver). During 2021, in connection with the Misonix Acquisition, the Company amended the 2019 Credit Agreement (as amended, the Amended 2019 Credit Agreement). The Company prepaid $80,000 on the Original Term Loan in conjunction with the Misonix Acquisition on October 29, 2021. The Amended 2019 Credit Agreement, subsequent to the prepayment, is comprised of a $360,750 term loan (Term Loan) and the Revolver. All obligations under the Amended 2019 Credit Agreement are guaranteed by the Company and certain wholly owned subsidiaries where substantially all the assets of the Company collateralize the obligations. The Term Loan and Revolver mature on October 29, 2026 (Maturity).

Term loan

As of December 31, 2021, $357,682 was outstanding on the Term Loan, net of original issue discount of $1,381 and deferred financing costs of $1,687. Scheduled quarterly principal payments are as follows with the final payment of $225,469 at Maturity:

2022	$	4,509
2023 and 2024	$	6,764
2025 and 2026	$	9,019

The Company may voluntarily prepay the Term Loan without premium or penalty upon prior notice. The Company may be required to make additional principal payments on the Term Loan dependent upon certain events as defined in the Amended 2019 Credit Agreement. These additional prepayments will be applied to the scheduled installments of principal in direct order of maturity of first the Base Rate (BR) portions of the Term Loan and then the Eurodollar portions.

The estimated fair value of the Term Loan as of December 31, 2021 is $360,046. The fair value was determined using a discounted cash flow model based on current market interest rates available to the Company. These inputs are corroborated by observable market data for similar obligations and are classified as Level 2 instruments within the fair value hierarchy.

Revolver

The Revolver is a five-year revolving credit facility of $50,000 which includes revolving and swingline loans as well as letters of credit (LOC) and, inclusive of all, cannot exceed $50,000 at any one time. LOCs are available in an amount not to exceed $7,500. Revolving loans are due at the earlier of termination or Maturity. Swingline loans are available as BR interest rate option loans only and must be outstanding for at least five days. Swingline loans are due the fifteenth or last day of a calendar month or Maturity whichever is earlier. As of December 31, 2021, the Company had one nominal LOC outstanding leaving approximately $49,917 available.

Interest

The Term Loan and Revolver permits the Company to elect either Eurodollar or BR interest rate options for the entire amount or certain portions of the loans and have interest rates equal to a formula driven base interest rate plus a margin, tied to a leverage ratio. The leverage ratio is the ratio of debt to consolidated EBITDA as defined in the Amended 2019 Credit Agreement (Bank EBITDA), for four consecutive quarters at the end of each period.

BR portions of the Term Loan have interest due the last day of each calendar quarter-end. Eurodollar portions of the Term Loan have one, two, three or six-month interest reset periods and interest is due on the last day of each three-month period or the last day of the loan term if less than three months. In advance of the last day of the current Eurodollar Loan, the Company may select a new loan type so long as it does not extend beyond Maturity. The outstanding Term Loan has been a Eurodollar Loan since inception and is an auto-renewing one-month loan for setting an interest rate. In addition, the Term Loan has an interest due date concurrent with any scheduled principal repayment or prepayment.

Interest is calculated based on a 360-day year except for BR loans where the base interest is the Wells Prime Rate, in which case it is calculated based on a calendar-day year. The base interest rate for all BR loans is equal to the highest of (a) the Wells Prime Rate, (b) the greater of the Federal Funds Effective Rate or Overnight Bank Funding Rate plus 1/2% and (c) the Eurodollar Rate for a USD deposit with a maturity of one month plus 1.0%. The base interest rate for all Eurodollar Loans is equal to the rate determined for such day in accordance with the following formula with the Term Loan having a floor of 0%:

$$\frac{\text{LIBOR}}{1\text{—Eurocurrency Reserve Requirements}}$$

Pricing grids are used to determine the loan margins based on the type of loan and the leverage ratio. As of December 31, 2021, the Term Loan interest rate including a margin of 2.00% was 2.10%. The loan margin is adjusted after the quarterly financial statements are delivered to the lenders in accordance with the pricing grid below:

Leverage ratio	Eurodollar	BR
> 2.50 to 1.00	2.00 %	1.00 %
> 1.50 to 1.00 and < 2.50 to 1.00	1.75 %	0.75 %
> 0.75 to 1.00 and < 1.50 to 1.00	1.50 %	0.50 %
< 0.75 to 1.00	1.25 %	0.25 %

The Revolver includes a commitment fee at 0.30% of the average daily amount of the available revolving commitment, assuming any swingline loans outstanding are zero. There were no swingline loans outstanding as of December 31, 2021. The fee is payable quarterly in arrears on the last day of the calendar quarters and at Maturity. The commitment fee rate is adjusted after the quarterly financial statements are delivered to lenders based on the pricing grid below:

Leverage ratio	Commitment fee rate
> 2.50 to 1.00	0.30 %
> 1.50 to 1.00 and < 2.50 to 1.00	0.25 %
> 0.75 to 1.00 and < 1.50 to 1.00	0.20 %
< 0.75 to 1.00	0.15 %

Fees are charged on all outstanding LOCs at an annual rate equal to the margin in effect on Eurodollar revolving loans. A funding fee of 0.125% per year on the undrawn and unexpired amount of each LOC is payable as well. The fees are payable quarterly in arrears on the last day of the calendar quarters.

As of December 31, 2021, the Company's effective weighted average interest rate on all outstanding debt, including the commitment fee and interest rate swap, was 2.29%. Cash paid for interest totaled $5,837, $7,486 and $15,450 for the years ended December 31, 2021, 2020 and 2019, respectively.

Other

The Amended 2019 Credit Agreement contains customary affirmative and negative covenants, including those related to financial reporting and notification, restrictions on the declaration or payment of dividends or certain other distributions, restrictions on acquisitions, investments and certain other payments, limitations on the incurrence of new indebtedness, limitations on transfers, sales and other dispositions of Company assets, as well as limitations on making changes to the Company's business and organizational documents. Financial covenant requirements include a maximum debt leverage ratio as well as an interest coverage ratio not less than 3.00 to 1.00 as defined in the Amended 2019 Credit Agreement. As of December 31, 2021, the Company was in compliance with the financial covenants in the Amended 2019 Credit Agreement.

Each Lender may provide an additional Term or Revolving Loan by executing and delivering notice specifying the terms, if doing so would not cause certain undesired events to occur as defined or extend repayment beyond Maturity. The aggregate amount of all additional borrowings may not exceed the greater of $100,000 and the trailing four quarters Bank EBITDA without the consent of the Lenders holding more than 50% of the total outstanding debt under the Amended 2019 Credit Agreement.

Financing costs

During October 2021 and December 2019 the Company amended its credit agreements and as a result paid financing costs totaling $3,318 and $2,117 of which $1,897 and $269 were recorded directly to selling, general and administrative expense for the years ended December 31, 2021 and 2019, respectively. The remaining $1,421 and $1,848 were capitalized to the consolidated balance sheets. Due to the change in the participating lenders, an additional $269 and $2,985 in deferred costs were written off and recorded in interest expense for the years ended December 31, 2021 and 2019, respectively. The loss on the debt retirement and modification for the years ended December 31, 2021 and 2019 totaled $2,162 and $3,252, respectively.

Capitalized deferred fees resulting from the amendments totaled $3,174 and $893 for the Term Loan and Revolver, respectively. These deferred fees are being amortized to interest expense on a straight-line basis over the term of the Amended 2019 Credit Agreement, which approximates the effective interest method. The Company recorded $588, $543 and $711 in interest expense associated with deferred costs for the years ended December 31, 2021, 2020 and 2019, respectively.

Contractual maturities of long-term debt as of December 31, 2021 were as follows:

2022	$ 18,038
2023	27,056
2024	27,056
2025	36,075
2026 and thereafter	252,525
Deferred financing costs	(1,687)
Original issue discount	(1,381)
Total long-term debt	357,682
Less current portion	(18,038)
Total	$ 339,644

The Company enters into interest rate swap agreements to limit its exposure to changes in the variable interest rate on its long-term debt. On March 26, 2020, the Company entered an interest rate swap agreement with one of its Lenders, which expires in December 2024. The interest rate swap was not designated as a hedge. The Company has no other active derivatives and the swap is carried at fair value on the balance sheet. Refer to *Note 6. Fair value measurements*. There were no outstanding derivatives as of December 31, 2019. Interest income of $2,730 and expense of $1,599 was recorded within the consolidated statements of operations and comprehensive income related to the change in fair value of the swap for the years ended December 31, 2021 and 2020, respectively.

The notional value of the swap totaled $100,000 or 27.7%, of the Term Loan outstanding principal at December 31, 2021. The swap locked in the variable portion of the interest rate on the $100,000 notional at 0.64%.

6. Fair value measurements

There were no assets or liabilities valued at fair value using Level 1 inputs as of December 31, 2021 and 2020. The following table provides information for liabilities measured at fair value on a recurring basis using Level 2 and Level 3 inputs:

	December 31, 2021			December 31, 2020		
	Total	Level 2	Level 3	Total	Level 2	Level 3
Assets:						
Interest rate swap	$ 1,128	$ 1,128	$ —	$ —	$ —	$ —
Liabilities:						
Interest rate swap	$ —	$ —	$ —	$ 1,602	$ 1,602	$ —
Contingent consideration	16,329	—	16,329	—	—	—
Management incentive plan and liability-classified awards	—	—	—	40,303	—	40,303
Equity Participation Right	—	—	—	6,101	—	6,101
Total liabilities	$ 16,329	$ —	$ 16,329	$ 48,006	$ 1,602	$ 46,404

Interest rate swap

The Company values interest rate swaps using discounted cash flows. Forward curves and volatility levels are used to estimate future cash flows that are not certain. These are determined using observable market inputs when available and based on estimates when not available. The fair value of the swap was recorded in the Company's consolidated balance sheets within other current assets as of December 31, 2021 and accrued liabilities as of December 31, 2020. Changes in fair value are recognized as interest expense within the consolidated statements of operations and comprehensive income.

Contingent consideration

The Company initially values contingent consideration related to business combinations using a probability-weighted calculation of potential payment scenarios discounted at rates reflective of the risks associated with the expected future cash flows for certain milestones. For other milestones, the Company used a variation of the income approach where revenue was simulated in a risk-neutral framework using Geometric Brownian Motion, a stock price behavior model.

Key assumptions used to estimate the fair value of contingent consideration include projected financial information market data and the probability and timing of achieving the specific targets as discussed in *Note 4. Acquisitions and investments*. After the initial valuation, the Company generally uses its best estimate to measure contingent consideration at each subsequent reporting period using the following unobservable Level 3 inputs:

	Valuation Technique	Unobservable inputs	Range
Bioness contingent consideration	Discounted cash flow	Payment discount rate	6.4% - 6.8%
		Payment period	2024 - 2025

Significant changes in these assumptions could result in a significantly higher or lower fair value. The contingent consideration reported in the above table resulted from the March 30, 2021 Bioness acquisition, which is adjusted quarterly based upon the passage of time or the anticipated success or failure of achieving certain milestones. Refer to *Note 4. Acquisitions and investments* for further details. Changes in contingent consideration related to the Bioness acquisition totaled $829 for the year ended December 31, 2021, were recorded as the change in fair value of contingent consideration within the consolidated statements of operations and comprehensive income.

Management incentive plan (MIP) and liability-classified awards

BV LLC had operated two equity-based compensation plans, the management incentive plan (MIP) and the BV LLC Phantom Profits Interest Plan (Phantom Plan and, together with the MIP, the Plans), which were terminated on February 11, 2021 in connection with the Company's IPO. Awards granted under the MIP Plan and the Phantom Units primarily granted in 2015 and thereafter (2015 Phantom Units) were liability-classified and the Phantom Units granted under the initial 2012 Phantom Profits Interest Plan (2012 Phantom Units) were equity-classified. Prior to the IPO and during the year ended December 31, 2021, the Company settled the remaining 183,078 units with the sole MIP awardee for $10,802. No awards under the Plans were granted post-IPO. Phantom Plan awardees whose BV LLC employment terminated prior to the IPO were entitled to receive cash of $10,875, which is included in accrued equity-based compensation on the consolidated balance sheets and $10,413 was paid in March 2022. Awardees that were active BV LLC employees at the IPO were entitled to receive an aggregate of 798,422 shares of Class A common stock. In February 2022, awardees received 538,203 Class A common stock, of which 260,219 shares were withheld to satisfy employee payroll taxes.

The following table provides a reconciliation of the beginning and ending balances for the MIP and liability-classified awards at fair value using significant unobservable inputs or Level 3:

Balance at December 31, 2019	$ 40,802
Initial estimate (vesting)	4,734
Forfeitures	(1,298)
Change in fair value	6,641
Payments	(10,576)
Balance at December 31, 2020	40,303
Change in fair value	(25,185)
Initial estimate (vesting)	829
Payments	(11,281)
Phantom plan conversion to Class A common stock	(4,666)
Balance at December 31, 2021	$ —

Equity Participation Right (EPR) Unit

Prior to the IPO, the only member of BV LLC that remained a member following the Transactions (Continuing LLC Owner) owned the only EPR Unit. The EPR Unit's only entitlement was 0.55% of available distributions arising from a distribution event such as the IPO. The EPR Unit was redeemed in exchange for $3,327 in connection with the IPO in February 2021, at which time the EPR ceased to exist and all entitlements ended. The revaluation for the EPR liability is recognized in interest expense on the consolidated statements of operations and comprehensive income.

The following table provides a reconciliation of the beginning and ending balances for the EPR Unit at fair value using significant unobservable inputs Level 3:

Balance at December 31, 2019	$	5,457
Change in fair value		644
Balance at December 31, 2020		6,101
Change in fair value		(2,774)
Payment		(3,327)
Balance at December 31, 2021	$	—

7. Stockholders' and members' equity

Amendment and restatement of certificate of incorporation

On February 16, 2021 the Company amended and restated its certificate of incorporation to, among other things, provide for (i) the authorization of 250,000,000 shares of Class A common stock with a par value of $0.001 per share; (ii) authorization of 50,000,000 shares of Class B common stock with a par value of $0.001 per share; (iii) the authorization of 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company's Board of Directors (BOD) in one or more series; and (iv) the establishment of a classified BOD, divided into three classes, each of whose members will serve for staggered three-year terms.

Holders of Class A and Class B common stock are entitled to one vote per share and, except as otherwise required, will vote together as a single class on all matters on which stockholders generally are entitled to vote. Holders of Class B common stock are not entitled to receive dividends and will not be entitled to receive any distributions upon the liquidation, dissolution or winding up of the Company. Shares of Class B common stock may only be issued to the extent necessary to maintain the one-to-one ratio between the number of LLC Interests and the number of shares of Class B common stock held by the Continuing LLC Owner. Shares of Class B common stock are transferable only together with an equal number of LLC Interests. Shares of Class B common stock will be canceled on a one-for-one basis upon the redemption or exchange of any outstanding LLC Interests.

The Company must, at all times, maintain a one-to-one ratio between the number of outstanding shares of Class A common stock and the number of LLC Interests owned by the Company.

Initial public offering

As described in *Note 1. Organization*, on February 16, 2021, the Company closed an IPO of 9,200,000 shares of Class A common stock at a public offering price of $13.00 per share, which includes 1,200,000 shares issued pursuant to the underwriters' over-allotment option. The Company received $111,228 in proceeds, net of underwriting discounts and commissions which was used to purchase newly-issued membership interests from BV LLC at a price per interest equal to the IPO price of $13.00.

In connection with the IPO, the Company issued 15,786,737 shares of Class B common stock to the Original BV LLC Owners.

BV LLC recapitalization

As described in *Note 1. Organization*, on February 16, 2021, the Company amended and restated the BV LLC Agreement to, among other things, (i) provide for the new LLC Interests, (ii) exchange all of the then-existing membership interests of the Original BV LLC Owners for new LLC Interests and (iii) appoint Bioventus Inc. as the sole managing member of BV LLC.

The BV LLC Agreement also provides that holders of LLC Interests may, from time to time, require the Company to redeem all or a portion of their LLC Interests for newly-issued shares of Class A common stock on a one-for-one basis. The Company may elect to settle any such redemption in shares of Class A common stock or in cash. In the event of cash settlement, the Company would issue new shares of Class A common stock and use the proceeds from the sale of these newly-issued shares of Class A common.

The amendment also requires that the Company, at all times, maintain (i) a one-to-one ratio between the number of outstanding shares of Class A common stock and the number of LLC Interests owned by Bioventus Inc. and (ii) a one-to-one ratio between the number of shares of Class B common stock owned by the Continuing LLC Owner and the number of LLC Interests owned by the Continuing LLC Owner.

IPO Merger

As described in *Note 1. Organization*, the Company acquired, by merger, the Former LLC Owners, for which the Company issued 31,838,589 shares of Class A common stock as merger consideration. In connection with the IPO Merger, the Company canceled 15,786,737 shares of Class B common stock and the Company received 15,786,737 of LLC Interests.

Issuance of common stock

The Company issued 18,340,790 of $0.001 par value Class A common stock to certain Misonix shareholders at $14.97 per share in order to partially fund the Misonix Merger. As a result, the Company recorded $18 in common stock and $272,706 in additional paid-in capital, net of registration fees totaling $1,838, within the consolidated balance sheets during the year ended December 31, 2021. Refer to *Note 4. Acquisitions and investments* for further discussion concerning the Misonix Merger.

Noncontrolling interest

In connection with any redemption, the Company will receive a corresponding number of LLC Interests, increasing the ownership interest in BV LLC. Future redemptions of LLC Interests will result in a change in ownership and reduce the amount recorded as noncontrolling interest and increase additional paid-in capital. There were no redemptions during the year ended December 31, 2021. The following table summarizes the ownership interest in BV LLC as of December 31, 2021 and immediately following the Transactions on February 16, 2021 (number of units in thousands).

	December 31, 2021		February 16, 2021	
	LLC Interests	Ownership %	LLC Interests	Ownership %
Number of LLC Interests owned				
Bioventus Inc.	59,548	79.0 %	41,038	72.2 %
Continuing LLC Owner	15,787	21.0 %	15,787	27.8 %
Total	75,335	100.0 %	56,825	100.0 %

The Company’s ownership percentage remained constant at 72.2% from February 16, 2021 through the closing of the Misonix Acquisition on October 29, 2021. Immediately following the Misonix Acquisition, the Company’s ownership percentage increased to 79.0%.

Dividend restrictions

Bioventus Inc. is a holding company with no direct operations. As a result, the ability to pay cash dividends on the Company’s common stock, if any, is dependent upon cash dividends, distributions or other transfers from BV LLC. The amounts available to the Company to pay cash dividends are subject to certain covenants and restrictions set forth in Amended 2019 Credit Agreement. Refer to *Note 5. Financial instruments* for further discussion concerning the covenant restrictions.

Related party BV LLC member distributions

The Company made cash distributions of $19,886 and $9,137 to the BV LLC members, or tax authorities on their behalf, in an amount equal to approximately 40% of the members’ estimated taxable income for the years ended December 31, 2020 and 2019, respectively. Prior to the IPO, for the period from January 1, 2021 through February 15, 2021 their were no distributions. At December 31, 2020, there were distributions payable to tax authorities on the BV LLC members behalf totaling $541 and nominal tax distributions payable to the BV LLC members.

During 2021, after the IPO, the Company made cash distributions of $367 to tax authorities on Continuing LLC Owner behalf, in an amount equal to their estimated 2021 tax liability. At December 31, 2021, there were $3,181 in distributions payable to the Continuing LLC Owner.

8. Equity-based compensation

Terminated plans

Prior to the IPO, BV LLC operated two equity-based compensation plans that were terminated on February 11, 2021 in conjunction with the IPO. Prior to the Plans termination, during the year ended December 31, 2021, (i) the Company granted 90,000 Phantom Plan units; (ii) there were no MIP awards granted; (iii) 900 Phantom Plan units were forfeited and (iv) other Phantom Units were redeemed for $479. Compensation expense related to the Phantom Plan totaled $829 for the year ended December 31, 2021, which excludes a $25,185 decrease in fair market value of accrued equity-based compensation. The decrease was due to adjustments to reflect the difference between the expected pricing from the pending IPO and the actual offering price which was primarily recorded in selling, general and administrative expense with $1,777 recorded in research and development expense within the consolidated statement of operations and comprehensive income for the year ended December 31, 2021. The Plans compensation expense totaled $10,103 and $10,844 for the years ended December 31, 2020 and 2019, respectively.

2021 Plan

The Company operates an equity-based compensation plan (2021 Plan). The 2021 Plan is designed to grant incentive awards to eligible employees and other service providers in order to attract, motivate and retain the talent for which the Company competes. The 2021 Plan allows for the issuance of stock options (incentive and nonqualified), restricted stock, dividend equivalents, restricted stock units (RSUs), other stock-based awards, and cash awards. (collectively, Awards). Generally, non-cash Awards granted under the 2021 Plan are equity-classified. Certain Awards provide for accelerated vesting if there is a change in control as defined in the 2021 Plan. As of December 31, 2021, 7,592,476 shares of Class A common stock were authorized to be awarded and 1,597,215 shares remained available for future awards. The number of shares available for issuance will be increased annually on January 1 of each calendar year beginning in 2022 through 2031, equal to the lesser of (i) 4.5% of the shares of Class A common stock outstanding on the final day of the immediately preceding calendar year and (ii) a smaller number of shares as determined by the Company's BOD.

Equity-based compensation expense of $19,504 was recognized for the year ended December 31, 2021, for Awards granted under the 2021 Plan. The expense is primarily included in selling, general and administrative expense with a nominal amount in research and development expense on the consolidated statement of operations and comprehensive income based upon the classification of the employee. There was no income tax benefit related to this expense for the year ended December 31, 2021.

Restricted Stock Units

During the year ended December 31, 2021, the Company granted employees and non-employee directors time-based RSUs which vest at various dates through December 6, 2025. The compensation expense, which represents the fair value of the stock measured at the market price on the date of grant, is recognized over the vesting period, which is typically between 1 and 4 years.

No RSUs vested during the year ended December 31, 2021. Unamortized compensation expense related to the RSUs totaled $5,116 at December 31, 2021, and is expected to be recognized over a weighted average period of approximately 1.16 years. A summary of the RSU award activity for the year ended December 31, 2021 is as follows (number of units in thousands):

	Number of units	Weighted-average grant-date fair value per unit
Unvested at December 31, 2020	—	$ —
Granted	1,032	$ 14.41
Forfeited or canceled	(8)	$ 13.86
Unvested at December 31, 2021	1,024	$ 14.41

Stock Options

During the year ended December 31, 2021, the Company granted employees time-based stock options which vest over 2 to 4 years. In addition, in conjunction with the Misonix Acquisition, the Company issued fully vested stock options as part of the Misonix Acquisition consideration. Refer to *Note 4. Acquisitions and investments* for further information regarding the Misonix Acquisition. Options expire 10 years from the grant date. The fair value of stock options is estimated on the date of grant using the Black-Scholes valuation model, with such value recognized as expense over the service period, which is typically 2 to 4 years, net of actual forfeitures. The expected term of the options granted is generally estimated using the simplified method. Expected volatility is based on the historical volatility of the Company's peers' common stock due the limited trading history of the Company's Class A 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.

A summary of the Company's assumptions used in determining the fair value of the stock options granted during the year ended December 31, 2021 is shown in the following table.

Risk-free rate	0.59% - 1.32%
Expected dividends	— %
Expected volatility	33.0% - 36.0%
Expected term (in years)	4.17- 6.25

A summary of stock option activity is as follows for the year ended December 31, 2021 (number of shares in thousands):

	Shares	Weighted-average exercise price	Weighted average remaining contractual term	Aggregate intrinsic value
Outstanding at December 31, 2020	—	$ —		
Granted	8,442	$ 11.12		
Exercised	(74)	$ 6.00		
Forfeited or canceled	(4)	$ 13.00		
Outstanding at December 31, 2021	8,364	$ 11.16	8.32 years	$ 28,315
Exercisable and vested at December 31, 2021	3,393	$ 8.17	7.06 years	$ 21,461

The weighted-average grant-date fair value of options granted during the year ended December 31, 2021was $5.88. The total intrinsic value of options exercised during the year ended December 31, 2021 was $541 for which the Company received a $446 payment. The aggregate intrinsic value 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 $14.49, the closing price of the Company's stock on December 31, 2021. Unamortized compensation expense related to the options amounted to $11,961 at December 31, 2021, and is expected to be recognized over a weighted average period of approximately 2.88 years.

Employee Stock Purchase Plan

In February 2021, in connection with the IPO, the Company began operating the 2021 Employee Stock Purchase Plan (ESPP). The ESPP provides for the issuance of shares of the Company's common stock to eligible employees of the Company and its subsidiaries that elect to participate in the plan and purchase shares of common stock through payroll deductions (including executive officers).

During each enrollment period, eligible employees may designate between 1% and 15% 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). The purchase price of the shares under the ESPP is equal to 85% of the fair market value on the first day of the offering period or, if lower, on the last day of the offering period.

As of December 31, 2021, the aggregate number of shares available for issuance under the ESPP was 447,525. A total of 94,795 shares were issued and $340 of expense was recognized under the ESPP during the year ended December 31, 2021.

Defined contribution plans

The Company has various defined contribution plans which are offered in Canada, Germany, the Netherlands, United Kingdom and Israel. These plans are required by local laws or regulations in some cases. Contributions are primarily discretionary, except in some countries where contributions are contractually required. These plans cover substantially all eligible employees in the countries where the plans are offered either voluntarily or statutorily.

In the U.S., the Company provides a 401(k) defined contribution plan (U.S. Plan) that covers substantially all U.S. employees that meet minimum age requirements. Beginning in April 2021, the Company matches 100% of the employees' contribution up to 4% of the employees' wages and 50% on the next 2%. Prior to this change, the Company matched 50% of the employees' contribution up to 6% of the employees' wages. The U.S. Plan also provides for an additional 1 to 3% at the Company's discretion.

For the years ended December 31, 2021, 2020 and 2019, Company contributions totaled $4,477, $3,379 and $5,401, respectively, for all global plans. The expense is included in cost of sales, selling, general and administrative expense and research and development expense on the consolidated statement of operations and comprehensive income based upon the classification of the employee.

9. Earnings per share

The following table sets forth the computation of basic and diluted loss per share of Class A common stock for the period following the Transactions (amounts in thousands, except share and per share data):

	February 16, 2021 through December 31, 2021
Numerator:	
Net loss	$ (16,391)
Net loss attributable to noncontrolling interests	9,789
Net loss attributable to Bioventus Inc. Class A common stockholders	$ (6,602)
Denominator:	
Weighted-average shares of Class A common stock outstanding - basic and diluted	45,472,483
Net loss per share of Class A common stock, basic and diluted	$ (0.15)

Shares of Class B common stock do not share in the losses of the Company and are therefore not participating securities. As such, separate presentation of basic and diluted losses per share of Class B common stock under the two-class method has not been presented.

The following number of weighted-average potentially dilutive shares as of December 31, 2021 were excluded from the calculation of diluted loss per share because the effect of including such potentially dilutive shares would have been antidilutive upon conversion:

LLC Interests held by Continuing LLC Owner[(a)]	15,786,737
Stock options	5,373,442
RSUs	966,673
Unvested shares of Class A common stock	30,056
Total	22,156,908

[(a)] Class A Shares reserved for future issuance upon redemption or exchange of LLC Interests by Continuing LLC Owner.

10. Restructuring

Restructuring costs are not allocated to the Company's reportable segments as they are not part of the segment performance measures regularly reviewed by management. These charges are included in restructuring expenses in the consolidated statement of operations and comprehensive income.

In the third and fourth quarters of 2021, the Company adopted restructuring plans for the Bioness Acquisition to reduce headcount, reorganize management structure and consolidate certain facilities. The Company expects total charges related to this restructuring plan to be $2,900 and expects the plan will be completed in the first quarter of 2022.

In the fourth quarter of 2020, the Company adopted a restructuring plan to improve the performance of International operations, principally through headcount reduction and closing offices in certain countries as the Company shifted to an indirect distribution model in these countries. The plan was completed in 2020 and all costs were incurred in 2020.

The Company recorded total pre-tax charges for all plans of $2,487, $563 and $575 primarily related to severance and other charges for the years ended December 31, 2021, 2020 and 2019, respectively. The Company's restructuring charges and payments for all plans comprised of the following:

	Employee severance and temporary labor costs	Other charges	Total
Balance at December 31, 2019	$ —	$ —	$ —
Expenses incurred	408	155	563
Payments made	(242)	(74)	(316)
Balance at December 31, 2020	166	81	247
Expenses incurred	2,351	136	2,487
Payments made	(1,117)	(81)	(1,198)
Balance at December 31, 2021	$ 1,400	$ 136	$ 1,536

11. Income taxes

As a result of the Transactions, Bioventus Inc. became the sole managing member of BV LLC, which is treated as a partnership for income tax purposes. As a partnership, BV LLC is not subject to U.S. federal and certain state and local income taxes. Any taxable income or loss generated by BV LLC is passed through to and included in the taxable income or loss of its members, including the Company following the Transactions, on a pro rata basis. Prior to the Transactions, income from other domestic subsidiaries included BV LLC and thereafter is included in income from domestic taxable subsidiaries. The components of income from continuing operations before taxes for the years ended December 31 are as follows:

	2021	2020	2019
United States	$ 9,511	$ 15,527	$ 6,722
International	(1,891)	387	2,967
Income from continuing operations before income taxes	$ 7,620	$ 15,914	$ 9,689

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

	2021	2020	2019
Current:			
United States federal	$ 5,675	$ 782	$ 932
United States state and local	1,750	214	177
International	367	707	815
Total current	7,792	1,703	1,924
Deferred:			
United States federal	(9,015)	(508)	(345)
United States state and local	(533)	(3)	(3)
International	(210)	—	—
Total deferred	(9,758)	(511)	(348)
Total income tax (benefit) expense	$ (1,966)	$ 1,192	$ 1,576

Cash paid for income taxes totaled $7,456, $1,541 and $1,577 for the years ended December 31, 2021, 2020 and 2019, respectively. The Company's investment in foreign subsidiaries continues to be indefinite in nature; however, the Company may periodically repatriate a portion of these earnings to the extent that it does not incur significant additional tax liability.

The differences between the effective income tax rate and the federal statutory income tax rates for the years ended December 31 are as follows:

	2021	2020	2019
U.S. statutory federal corporate income tax rate	21.0 %	21.0 %	21.0 %
Noncontrolling interest	(18.6)	—	—
LLC flow-through structure	(70.4)	(20.1)	(8.8)
Non-deductible expenses	43.8	—	—
State and local income taxes, net of federal benefit	11.8	1.5	2.4
Change in valuation allowance	7.0	—	—
Research and other tax credits	(4.5)	—	—
Organizational Transactions	(8.6)	—	—
Uncertain tax positions	(9.0)	—	—
Foreign rate differential	(0.9)	1.2	1.7
Other	2.6	3.9	—
Effective income tax rate	(25.8 %)	7.5 %	16.3 %

For the year ended December 31, 2021, after the Transactions, the Company's effective tax rate differed from statutory rates primarily due to the non-deductible expenses, state and local taxes as well as the change in valuation allowances. These increases were partially offset by the noncontrolling interest, uncertain tax positions and the impact of the Transactions. Prior to the Transactions, the Company's effective tax rate differed from statutory rates primarily due to Bioventus LLC's pass-through structure for U.S. income tax purposes while being treated as taxable in certain states and various foreign jurisdictions as well as for certain subsidiaries. In addition, certain states assess income taxes on pass-through structures.

Deferred tax assets and liabilities are determined based on the difference between financial statement and tax bases using enacted tax rates in effect for the year in which the differences are expected to reverse. The components of the deferred taxes were as follows:

	2021	2020
Deferred tax assets:		
Net operating losses and tax credit carryforwards	$ 16,303	$ 3,874
Transaction costs	969	—
Accrued liabilities	862	—
Fixed assets	644	—
Other	925	696
Gross deferred tax assets	19,703	4,570
Valuation allowance	(2,320)	(2,993)
Total deferred tax assets	17,383	1,577
Deferred tax liability:		
Misonix Acquisition	106,732	—
Organizational Transactions	38,805	—
Acquired intangible	4,157	4,939
Operating lease assets	726	—
	150,420	4,939
Net deferred tax liability	$ 133,037	$ 3,362

The valuation allowance is primarily attributable to net operating losses (NOLs). The Company considered many factors when assessing the likelihood of future realization of these deferred tax assets, including expectations of future taxable income or loss, the carryforward periods available to the Company for tax reporting purposes, and other relevant factors. The net change in the valuation allowance was $673. The valuation allowance at December 31, 2021 principally relates to recognizing a full valuation allowance against foreign NOLs resulting from 2021 acquisitions. The December 31, 2020 valuation allowance was related to Harbor NOL carryforwards and upon deconsolidation was written off along with the corresponding asset. It is reasonably possible that the valuation allowance will decrease in 2022 related to expiration of NOLs.

The Company has federal and foreign NOL carryforwards of $70,275 and research and other tax credits of $983 as a result of the acquisitions. These carryforwards are subject to limitation under the provisions of Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Internal Revenue Code and will begin to expire in 2031. Section 382 states that if an "ownership change" occurs with respect to a corporation with net operating and other loss carryforwards, such carryforwards will be available to offset taxable income in each taxable year after the ownership change only up to the Section 382 Limitation for each year. The Company has state NOL carryforwards of approximately $15,942 as a result of the Misonix Acquisition, which begins to expire in 2024.

The Company evaluated its tax positions and has an unrecognized tax benefit of $4,517 as of December 31, 2021. There was no unrecognized tax benefit as of December 31, 2020. The Company had $1,837 accrued for payment of interest and penalties as of December 31, 2021. The entire amount of unrecognized tax benefits, including interest, would favorably impact the Company's effective tax rate if recognized. The Company believes it is reasonably possible that, in the next 12 months, the amount of unrecognized tax benefits, exclusive of interest and penalties, related to the resolution of federal, state and foreign matters could be increased by $2,800 as statutes expire. Minimal other tax related interest and penalties were incurred for the years ended December 31, 2021, 2020 and 2019. The Company is subject to audit by various taxing jurisdictions for the years 2018 through 2021.

A reconciliation of the gross unrecognized tax benefits (excluding interest and penalties) for the years ended December 31, 2021 follows:

	2021
Beginning of the period	$ —
Additions for current year tax positions	5,431
Expiration of statutes	(914)
End of the period	$ 4,517

Tax Receivable Agreement

The Company expects to obtain an increase in the share of the tax basis of the assets of BV LLC when LLC Interests are redeemed or exchanged by the Continuing LLC Owner and other qualifying transactions. This increase in tax basis may have the effect of reducing the amounts that the Company would otherwise pay in the future to various tax authorities. The increase in tax basis may also decrease gains (or increase losses) on future dispositions of certain capital assets to the extent tax basis is allocated to those capital assets.

On February 16, 2021, the Company entered into a tax receivable agreement (TRA) with the Continuing LLC Owner that provides for the payment by the Company to the Continuing LLC Owner of 85% of the amount of tax benefits, if any, that the Company actually realizes as a result of (i) increases in the tax basis of assets of BV LLC resulting from any redemptions or exchanges of LLC Interests or any prior sales of interests in BV LLC and (ii) certain other tax benefits related to payments under the TRA.

The Company will maintain a full valuation allowance against deferred tax assets related to the tax attributes generated as a result of redemptions of LLC Interests or exchanges described above until it is determined that the benefits are more-likely-than-not to be realized. As of December 31, 2021, the Continuing LLC Owner had not exchanged LLC Interests for shares of Class A common stock and therefore the Company had not recorded any liabilities under the TRA.

12. Commitments and contingencies

Leases

The Company determines if an arrangement is a lease at inception. The Company leases its office facilities as well as other property, vehicles and equipment under operating leases. The Company also leases certain office equipment under nominal finance leases. Lease assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Lease assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company's incremental borrowing rate is used as a discount rate, based on the information available at the commencement date, in determining the present value of lease payments. Lease assets also include the impact of any prepayments made and are reduced by impact of any lease incentives.

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

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

The remaining lease terms range from 1 month to 6.75 years. The components of lease cost were as follows for the years ended December 31:

	2021	2020
Operating lease cost	$ 3,478	$ 2,610
Short-term lease cost[(a)]	668	388
Total lease cost	$ 4,146	$ 2,998

(a) Includes variable lease cost and sublease income, which are immaterial.

Supplemental cash flow information were as follows for the years ended December 31:

	2021	2020
Cash paid for amounts included in the measurement of operating lease liabilities	$ 3,616	$ 2,567
Right-of-use assets obtained in exchange for operating lease obligations	$ 4,665	$ 1,497

Supplemental balance sheet and other information were as follows for the years ended December 31:

	2021	2020
Operating lease assets	$ 17,186	$ 14,961
Operating lease liabilities- current	$ 3,504	$ 1,960
Operating lease liabilities- noncurrent	15,038	14,108
Total operating lease liabilities	$ 18,542	$ 16,068
Weighted average remaining operating lease term in years	5.6	7.2
Weighted average discount rate for operating leases	4.7 %	5.0 %

Maturities of operating lease liabilities as of December 31, 2021 were as follows:

2022	$ 4,253
2023	3,637
2024	3,590
2025	3,282
2026	2,654
Thereafter	3,735
Total future lease payments[(a)]	21,151
Less imputed interest	(2,609)
Present value of future lease payments	$ 18,542

(a) The above table does not reflect the future maturities of a lease entered into during November 2021 in which the Company agreed to lease a facility to expand its manufacturing operations and relocate from its current leased facilities in Memphis, Tennessee. The lease term is 10 years and occupancy is expected to begin in July 2022, contingent upon certain improvements. Expected payments of the Memphis lease are as follows for the next five years beginning in July 2022 and thereafter: $769, $1,554, $1,585, $1,617, $1,649 and $9,671.

Product recall

In December 2020, the Company voluntarily recalled its ultrasound gel, an accessory to one of the Restorative Therapies product. The Company has incurred $2,061 in total costs associated with this recall. Reserves of $126 and $1,684 were recorded within accrued liabilities on the consolidated balance sheets at December 31, 2021 and 2020, respectively.

Governmental and legal contingencies

In the normal course of business, the Company periodically becomes involved in various claims and lawsuits, and governmental proceedings and investigations that are incidental to the business. The Company accrues a liability when a loss is considered probable and the amount can be reasonably estimated. When a material loss contingency is reasonably possible but not probable, the Company does not record a liability, but instead discloses the nature and amount of the claim, and an estimate of the possible loss or range of loss, if such an estimate can be made. Legal fees are expensed as incurred. With respect to governmental proceedings and investigations, like other companies in the industry, the Company is subject to extensive regulation by national, state and local governmental agencies in the U.S. and in other jurisdictions in which the Company and its affiliates operate. As a result, interaction with governmental agencies is ongoing. The Company's standard practice is to cooperate with regulators and investigators in responding to inquiries.

Other than the settled OIG matter, the Company is presently unable to predict the duration, scope, or result of the following matters. As such, the Company is presently unable to develop a reasonable estimate of a possible loss or range of losses, if any, related to these matters. While the Company intends to defend these matters vigorously, the outcome of such litigation or any other litigation is necessarily uncertain, are not within the Company's complete control and may not be known for extended periods of time. In the opinion of management, the outcome of any existing claims and legal or regulatory proceedings, other than the specific matters described below, if decided adversely, is not expected to have a material adverse effect on the Company's business, financial condition, results of operations, or cash flows.

OIG matter

During 2018, the Company identified non-compliance with certain U.S. federal statutes and requirements governing the Medicare program in 2018. Upon voluntary self-disclosure to the Office of Inspector General of the U.S. Department of Health and Human Services (OIG), the Company entered into a formal settlement agreement on February 22, 2021, which included releases from further liability and penalties that are customary in self-disclosures of this type. Total settlement charges were $3,600, of which $2,400 had previously been paid. The remaining $1,200 net settlement amount due under the agreement was recorded in accrued liabilities within the consolidated balance sheets as of December 31, 2020 and paid on February 23, 2021.

Misonix stockholder

On September 15, 2021, a purported stockholder of Misonix filed an action in the United States District Court for the Eastern District of New York, captioned Stein v. Misonix, Inc., et al., Case No. 2:21-cv-05127 (E.D.N.Y.) (the Stein Complaint). The Stein Complaint names Misonix and members of its board of directors as defendants. On September 16, 2021, a purported stockholder of Misonix filed an action in the United States District Court for the Southern District of New York, captioned Ciccotelli v. Misonix, Inc. et al., Case No. 1:21-cv-07773 (S.D.N.Y.) (the Ciccotelli Complaint) against Misonix, members of its board of directors, the Company, and its subsidiaries, Merger Sub I and Merger Sub II, as defendants. Plaintiff voluntarily dismissed the Ciccotelli Complaint on November 10, 2021. On October 12, 2021, another purported stockholder of Misonix filed an action in the United States District Court for the Eastern District of New York, captioned Rubin v. Misonix, Inc. et al., Case No. 1:21-cv-05672 (S.D.N.Y.) (the Rubin Complaint) and on October 15, 2021, another purported stockholder of Misonix filed an action in the United States District Court for the Southern District of New York, captioned Taylor v. Misonix, Inc. et al., Case No. 1:21-cv-08513 (S.D.N.Y.) (the Taylor Complaint). The Rubin Complaint and the Taylor Complaint name Misonix and members of its board of directors as defendants.

Each of the complaints asserts claims under Section 14(a) and Section 20(a) of the Exchange Act and SEC Rule 14a-9, challenging the adequacy of disclosures in the proxy statement/prospectus filed with the SEC on September 8, 2021 or the Definitive Proxy Statement filed with the SEC on September 24, 2021, regarding Misonix and/or Bioventus' projections and J.P. Morgan's financial analysis. The complaints seek, among other relief, (i) injunctive relief preventing the parties from proceeding with the merger, (ii) rescission in the event that the merger is consummated, and (iii) an award of costs, including attorneys' and experts' fees.

Misonix former distributor

On March 23, 2017, Misonix's former distributor in China, Cicel (Beijing) Science & Technology Co., Ltd., filed a lawsuit against Misonix and certain of its officers and directors in the United States District Court for the Eastern District of New York. The complaint alleged that Misonix improperly terminated its contract with the former distributor. The complaint sought various remedies, including compensatory and punitive damages, specific performance and preliminary and post judgment injunctive relief, and asserted various causes of action, including breach of contract, unfair competition, tortious interference with contract, fraudulent inducement, and conversion. On October 7, 2017, the court granted Misonix's motion to dismiss each of the tort claims asserted against Misonix, and also granted the individual defendants' motion to dismiss all claims asserted against them. On January 23, 2020, the Court granted Cicel's motion to amend its complaint, to include claims for alleged defamation and theft of trade secrets in addition to the breach of contract claim. Discovery in the matter ended on August 5, 2021. On January 20, 2022, the Court granted Misonix's summary judgment motion on Cicel's breach of contract and defamation claims. The Company believes that it has various legal and factual defenses to the remaining trade secret claim and intend to defend the action vigorously. There is no trial date currently set.

Bioness shareholder

Prior to closing the Bioness Acquisition, Bioness had been named as a defendant in a lawsuit, for which the Company is indemnified under the indemnification provisions contained in the Bioness Merger Agreement. The case relates to an action brought in February 2021 in the Delaware State Court of Chancery by a former minority shareholder and director of Bioness, seeking a temporary restraining order contesting the acquisition of Bioness. While the complaint to block the Bioness acquisition was dismissed by the court, a separate action was brought against the Company under the indemnification provisions of the Bioness Certificate of Incorporation to recover attorney fees and other expenses totaling approximately $2,000 incurred by the director and shareholder in connection with the dismissed case.

On August 19, 2021, the court issued a ruling granting, in part, plaintiff's motion for summary judgment, awarding plaintiff attorney's fees and related expenses incurred in connection with performance of the plaintiff's directorial duties, and denying fees and expenses incurred in a non-director capacity. In its ruling, the Court's order also directed the parties to agree upon a process that will govern the payment of and challenges to plaintiff's payment requests and required Bioness to pay 50% of the demanded amount into escrow if more than 50% of the total invoiced amount was in dispute. Pursuant to the court's order, to date, Bioness has paid approximately $1,000 into escrow. The Company awaits the court's final ruling on the appropriateness of these fees.

Other matters

On November 10, 2021, the Company entered into an asset purchase agreement for an HA product and made an upfront payment of $853. An additional maximum of $853 is due upon the transfer of certain seller customer data. If the Company is able to obtain a Medical Device Regulation Certification for the product, $1,707 will be paid to the seller within five days. The Company is required to pay royalties through 2026 of 5.0% on the first $569 in sales and 2.5% thereafter.

On August 23, 2019, the Company was assigned a third-party license on a product currently in development and the Company is subject to a 3% royalty on certain commercial sales, or a nominal minimum amount per quarter, beginning in 2023.

On May 29, 2019, the Company and the Musculoskeletal Transplant Foundation, Inc. d/b/a MTF Biologics (MTF), entered into a collaboration and development agreement to develop one or more products for orthopedic application to be commercialized by the Company and supplied by MTF (the Development Agreement). The first phase has been completed. Additional fees for the subsequent phases will be determined as the development work progresses. The Development Agreement continues until the date when the parties execute a supply agreement for the commercial products.

On December 9, 2016, the Company entered into an amended and restated license agreement for the exclusive U.S. distribution and commercialization rights of a single injection OA product with the supplier of the Company's single injection OA product for the non-U.S. market. The agreement requires the Company to meet annual minimum purchase requirements and pay royalties on net sales. Royalties related to this agreement totaled $13,300, $10,021 and $7,622 during the years ended December 31, 2021, 2020 and 2019, respectively. These royalties are included in cost of sales on the consolidated statement of operations and comprehensive income.

As part of a supply agreement entered on February 9, 2016 for the Company's three injection OA product, the Company is subject to annual minimum purchase requirements for 10 years. After the initial 10 years, the agreement will automatically renew for additional consecutive 5 year terms unless terminated by the Company or the seller in accordance with the agreement.

As part of a supply agreement for the Company's five injection OA product, that was amended and restated on December 22, 2020, the Company is subject to annual minimum purchase requirements for 8 years.

The Company has an exclusive license agreement for bioactive bone graft putty. The Company is required to pay a royalty on all commercial sales revenue from the licensed products with a minimum annual royalty payment through 2023, the date the agreement will expire, upon the expiration of the patent held by the licensor. These royalties are included in cost of sales on the consolidated statement of operations and comprehensive income.

From time to time, the Company causes letters of credit (LOCs) to be issued to provide credit support for guarantees, contractual commitments and insurance policies. The fair values of the LOCs reflect the amount of the underlying obligation and are subject to fees payable to the issuers, competitively determined in the marketplace. As of December 31, 2021 and 2020, the Company had one LOC outstanding for a nominal amount.

The Company currently maintains insurance for risks associated with the operation of its business, provision of professional services and ownership of property. These policies provide coverage for a variety of potential losses, including loss or damage to property, bodily injury, general commercial liability, professional errors and omissions and medical malpractice. The Company is self-insured for health insurance covering most of its employees located in the United States. The Company maintains stop-loss insurance on a “claims made” basis for expenses in excess of $200 per member per year.

13. Revenue recognition

The Company attributes net sales to external customers to the U.S. and to all foreign countries based on the legal entity from which the sale originated. The following table presents net sales by segment disaggregated by geographic markets and major products (Vertical) as follows for the years ended December 31:

	2021	2020	2019
Primary geographic markets:			
U.S.	$ 387,553	$ 293,697	$ 305,072
International	43,345	27,464	35,069
Total net sales	$ 430,898	$ 321,161	$ 340,141
Vertical:			
Pain Treatments	$ 221,607	$ 171,178	$ 182,082
Restorative Therapies	121,572	88,624	103,504
Surgical Solutions	87,719	61,359	54,555
Total net sales	$ 430,898	$ 321,161	$ 340,141

14. Segments

Segment information by asset is not disclosed as it is not reviewed by the CODM or used to allocate resources or to assess the operating results and financial performance. The Company believes EBITDA, adjusted for additional non-operational factors disclosed in the table below, or Adjusted EBITDA, is a key measure for internal reporting. Segment adjusted EBITDA is the segment profitability metric reported to the Company’s CODM for purposes of decisions about allocation of resources to, and assessing performance of, each reporting segment. Adjusted EBITDA is not defined in the same manner by all companies and may not be comparable to other similarly titled measures of other companies unless the definition is the same.

The following table presents segment adjusted EBITDA reconciled to income before income taxes for the years ended December 31:

	2021	2020	2019
Segment adjusted EBITDA			
U.S.	$ 70,640	$ 69,252	$ 71,673
International	10,119	3,191	7,515
Interest expense	(1,112)	(9,751)	(21,579)
Depreciation and amortization	(34,875)	(28,643)	(30,316)
Acquisition and related costs	(21,978)	—	—
Restructuring and succession charges	(3,717)	(6,172)	(575)
Impairments related to variable interest entity	(7,043)	—	—
Equity compensation	4,512	(10,103)	(10,844)
COVID-19 benefits, net	—	4,123	—
Equity loss in unconsolidated investments	(1,868)	(467)	—
Foreign currency impact	(132)	117	(8)
Other items	(6,926)	(5,633)	(6,177)
Income from continuing operations before income taxes	$ 7,620	$ 15,914	$ 9,689

15. Discontinued operations

In March 2019, substantially all operations of the bone morphogenetic protein research and development program ceased, including project close documentation, contract termination, vacating the facility and ultimately the termination of the employees. As a result, the criteria for discontinued operations was met. For the year ended December 31, 2019, loss from discontinued operations, net of nominal tax, totaled $1,815 and was substantially all research and development expense.

16. Subsequent events

On March 3, 2022, the Company drew down $15,000 on its Revolver.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosures.

None.

Item 9A. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2021.

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.

In connection with the preparation and filing of this Annual Report, the Company's management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2021, based on the framework set forth in "Internal Control—Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Our assessment of, and conclusion on, the effectiveness of internal control over financial reporting did not include Misonix and Bioness, both acquired by the Company in 2021 and included in our 2021 consolidated financial statements. Misonix and Bioness are now wholly-owned subsidiaries of the Company and comprised approximately 51.2% and 6.4%, respectively, of total assets, and approximately 3.6% and 7.9%, respectively, of total net sales, of the Company's related consolidated financial statement amounts as of and for the year ended December 31, 2021. Based on its evaluation, the Company's management concluded that, as of December 31, 2021, the Company's internal control over financial reporting is effective.

Attestation Report of Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report on our internal control over financial reporting of our registered public accounting firm because we are a non-accelerated filer and an emerging growth company.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter of 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Not Applicable

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The following table sets forth the name, age and position(s) of each of our directors and executive officers as of March 4, 2022:

Name	Age	Position(s)
Executive Officers		
Kenneth M. Reali	56	Chief Executive Officer and Director
Gregory O. Anglum	51	Senior Vice President and Chief Financial Officer
John E. Nosenzo	64	Chief Commercial Officer
Anthony D'Adamio	61	Senior Vice President and General Counsel
Katrina Church	60	Senior Vice President and Chief Compliance Officer
Alessandra Pavesio	55	Senior Vice President and Chief Science Officer
Non-Employee Directors		
William A. Hawkins[4]	68	Director, Chairperson
Patrick J. Beyer[1]	55	Director
Philip G. Cowdy[3]	54	Director
Mary Kay Ladone[1][2]	55	Director
Michelle McMurry-Heath[3][4]	51	Director
Guido J. Neels[2]	73	Director
Guy P. Nohra[2][3]	61	Director
Martin P. Sutter[3]	66	Director
Susan M. Stalnecker[1][4]	69	Director
Stavros G. Vizirgianakis	50	Director

(1) Member of the audit and risk committee

(2) Member of the compensation committee

(3) Member of the nominating and corporate governance committee

(4) Member of the compliance, ethics and culture committee

Kenneth M. Reali has served as our Chief Executive Officer since April 2020 and as a member of our board of directors (Board) since September 2020. Mr. Reali previously served as President and Chief Executive Officer of Clinical Innovations, LLC, a medical device company focused on advancing woman's healthcare, from June 2015 until its successful sale on February 12, 2020. In this role, Mr. Reali led the company through two successful acquisitions by a private equity firm in October 2017 and later to a leading diagnostic and therapeutic medical technology company in February 2020. Prior to joining Clinical Innovations, LLC, Mr. Reali also served as the President and CEO of Baxano Surgical, Inc., a medical device company, from January 2010 until February 2015, leading its turn-around out of bankruptcy. Mr. Reali also held positions of increasing responsibility at several medical device companies, including Biomet, Inc. (now known as Zimmer Biomet) and Stryker Corporation. Mr. Reali also served as Senior Vice President and General Manager within the Biologics and Clinical Therapies business of Smith & Nephew plc from May 2005 to January 2010, a division which was later spun out to become Bioventus LLC (BV LLC). Mr. Reali has served as a member of the board of managers of BV LLC since April 2020. Mr. Reali also currently serves as a member of the board of directors, the Advanced Medical Technology Association, or AdvaMed, an American medical device trade association, and DYSIS Medical Ltd., a medical device company focused on the noninvasive, in-vivo detection of cancerous and pre-cancerous lesions. Mr. Reali also serves on the ethics and health care compliance committee of AdvaMed. Mr. Reali also served from 2015 to December 2021 as a member of the board of directors of Ossio, Ltd. an orthopedic device company, where he was a member of the compensation committee. Mr. Reali holds a Bachelor of Science in Business Administration from Valparaiso University. We believe Mr. Reali is qualified to serve on our Board because of his vast skills and experience in the medical device industry, his role as our Chief Executive Officer and his extensive knowledge of the Company.

Gregory O. Anglum has served as our Senior Vice President and Chief Financial Officer since May 2017. Previously, Mr. Anglum served as our Chief Accounting Officer from April 2016 to May 2017. Prior to joining us, Mr. Anglum served as Chief Financial Officer of Overture Networks, Inc. (now known as ADVA Optical Networking SE), a leading global provider of networking and telecommunications equipment from September 2015 to April 2016. From December 2014 to September 2015, Mr. Anglum was Chief Financial Officer at StrikeIron, Inc., a Data-as-a-Service software company. From August 2004 to July 2014, Mr. Anglum was an audit partner at Grant Thornton LLP, or GT, where he also served as leader of the Raleigh office from August 2009 through July 2014 and was a member of the firm-wide leadership team for the technology industry group. Mr. Anglum holds a Master of Business Administration with a concentration in Accounting from Vanderbilt University's Owen Graduate School of Management and a Bachelors of Arts in Economics from Vanderbilt University and is a Certified Public Accountant.

John E. Nosenzo has served as our Chief Commercial Officer since February 2017. Prior to joining us, Mr. Nosenzo served as Senior Vice President, Global Customer Operations at Beckman Coulter Diagnostics, a global leader in clinical diagnostics, from September 2011 to February 2017. From May 2010 to September 2011, Mr. Nosenzo was Senior Vice President, Customer Relations Management for Siemens Healthcare (now known as Siemens Healthineers AG), a clinical diagnostic services and therapeutic systems company, where he developed and implemented sales plans for their multi-billion dollar healthcare imaging and healthcare IT commercial organizations. Mr. Nosenzo's earlier career also includes senior positions at Quest Diagnostics and Bayer Healthcare LLC's Diagnostics Division (now known as Siemens Healthcare Diagnostics). Mr. Nosenzo currently serves as a member of the board of directors of Spectral Medical Inc. Mr. Nosenzo holds a Master of Business Administration in marketing and management from Adelphi University and received his Bachelor of Science in pharmacy from St. John's University.

Anthony D'Adamio has served as our Senior Vice President and General Counsel since August 2017. Previously, Mr. D'Adamio was General Counsel and Secretary at Siemens Healthcare (now known as Siemens Healthineers AG) from January 2010 to August 2017 and served as Deputy General Counsel and Secretary of Siemens Healthcare Diagnostics from January 2007 to January 2010. Prior to that, Mr. D'Adamio was Senior Counsel within the Diagnostics Division of Bayer Healthcare LLC (now known as Siemens Healthcare Diagnostics) from January 2001 to December 2006. Mr. D'Adamio began his legal career at the law firm of Bond, Schoeneck & King before taking corporate legal positions with companies within the health insurance, pharmaceutical and biotechnology industries, including Group Health Incorporated, Quest Diagnostics and Covance Inc. Mr. D'Adamio holds a Juris Doctor, cum laude, from Howard University School of Law and a Bachelor of Arts from the State University of New York at Binghamton.

Katrina Church has served as our Chief Compliance Officer since August 2020. Prior to joining us, Ms. Church served in corporate counsel and compliance roles within the Merz Group of companies, most recently as Global Compliance Officer for Merz Pharma GmbH & Co KGaA, a privately-held pharmaceutical company, from March 2015 to August 2020. From June 1998 to December 2008, Ms. Church was Executive Vice President and General Counsel of Connetics Corporation, a specialty pharmaceutical company that was acquired by Stiefel Laboratories, Inc. in 2008. Ms. Church began her career as an attorney at Hopkins & Carley, a San Jose-based law firm. In 2020, Ms. Church was nominated for several industry awards for compliance training and received the 2020 Women in Compliance Award for "Most Impactful Compliance Training Programme of the Year" and the Brandon Hall 2020 Gold Medal for Excellence in Training. Ms. Church holds a Juris Doctor from New York University School of Law and a Bachelor of Arts in Comparative Literature, magna cum laude, from Duke University.

Alessandra Pavesio has served as our Senior Vice President and Chief Science Officer since August 2013. Previously, Ms. Pavesio managed the Boston University Coulter Translational Partnership, a foundation-sponsored research program designed to enhance clinical impact and wealth creation through the development and transfer of innovative intellectual properties from university laboratories to commercial practice, from January 2012 to July 2013. From January 2010 to December 2011, Ms. Pavesio was Vice President of Research & Development at Anika Therapeutics, Inc., an integrated orthopedic medicines company. Prior to that, Ms. Pavesio served as Director of Research and Development at Fidia Advanced Biopolymers, s.r.l. (now known as Anika Therapeutics, Inc.), from May 1991 to December 2009. Ms. Pavesio is the co-author of numerous peer reviewed publications and more than 15 patented inventions on hyaluronan based and biologics technologies. In the European Union, she has also served as chairperson of international regenerative medicine technology platforms and government advisory councils on innovation. Ms. Pavesio holds a Master's degree in Medicinal Chemistry, magna cum laude, from the University of Turin in Italy.

William A. Hawkins has served as a member of our Board since September 2020 and as Chairperson of our Board since September 2020. Mr. Hawkins is a Senior Advisor to EW Healthcare Partners, a leading private equity firm investing in life sciences. From October 2011 to July 2015, Mr. Hawkins served as President and Chief Executive Officer of Immucor, Inc., a leading provider of transfusion and transplantation diagnostic products worldwide. Prior to that, Mr. Hawkins served in positions of increasing responsibility at Medtronic, Inc., a prominent medical technology company, from January 2002 to June 2011, most recently serving as its Chief Executive Officer from November 2007 to June 2011. Mr. Hawkins served as President and Chief Executive Officer of Novoste Corporation, a global leader in the field of vascular brachytherapy, from 1988 to 2002 and has also held several senior leadership positions at American Home Products (now known as Wyeth, LLC), Johnson & Johnson, Guidant Corp. and Eli Lilly and Co. Mr. Hawkins has served as a member of the board of managers of BV LLC since January 2016. Mr. Hawkins also currently serves on the board of directors of Biogen Inc. and MiMedx Group Inc., each a public biopharmaceutical company; and Baebies, Inc., Cirtec Medical Corp., Immucor, Inc. and Virtue Labs, LLC, each a privately-held life science company. Mr. Hawkins serves on the audit committee of Biogen and the ethics and compliance committee of MiMedx. Mr. Hawkins was elected to the Duke University Board of Trustees in 2011 and currently serves as its Vice Chairman. Mr. Hawkins is also Chair of the Duke University Health System board of director and a member of the board of directors of the North Carolina Biotechnology Center and the Focused Ultrasound Foundation Society. Mr. Hawkins holds a Master of Business Administration from the University of Virginia Darden School of Business and received a Bachelor of Science in electrical and biomedical engineering from Duke University. Mr. Hawkins was selected to serve on our Board because of his experience in and knowledge of the life science industry.

Patrick J. Beyer has served as a member of our Board since October 2021. Mr. Beyer is the President of International and Global Orthopedics for ConMed Corporation, a publicly held medical technology company, a position in which he has served since October 2020. He previously served as President of ConMed International from December 2014 to October 2020. Prior to joining ConMed, Mr. Beyer served as Chief Executive Officer of ICNet, a privately held infectious control software company from 2010 to 2014 when the company was sold. Prior to this, he spent 21 years at Stryker Corporation where he led Stryker Europe from 2005 to 2009; Stryker UK, South Africa and Ireland from 2002 to 2005 and Stryker Medical from 1999 to 2002. Mr. Beyer previously served on the board of directors of Misonix, Inc. from May 2021 to October 2021, where he was a member of its audit committee. Mr. Beyer graduated from Kalamazoo College with a BA in Economics, Western Michigan University with an MBA in Finance and Harvard Business School's Advanced Management Program. Mr. Beyer was selected to serve on our Board because of his extensive healthcare and public company experience.

Philip G. Cowdy has served as a member of our Board since September 2020. Mr. Cowdy is the Chief Business Development and Corporate Affairs Officer for Smith & Nephew plc. Since joining Smith & Nephew plc in June 2008, he has also served as Executive Vice President of Business Development and Corporate Affairs, Head of Corporate Affairs and Strategic Planning, Group Director of Corporate Affairs and Director of Investor Relations. Prior to joining Smith & Nephew plc, Mr. Cowdy served as a Senior Director at Deutsche Bank for 13 years, providing corporate finance and equity capital markets advice to a variety of UK-based companies. Mr. Cowdy is currently a member of the board of managers of BV LLC, which he has served on from January 2012 to October 2017 and again from July 2018, and he has served as a member of its Audit, Compliance and Quality Committee. Mr. Cowdy received his Bachelor of Science in Natural Sciences from Durham University (UK) and is a qualified chartered accountant. Mr. Cowdy was selected to serve on our Board because of his experience in the industry, his finance experience, and his knowledge of the Company.

Mary Kay Ladone has served as a member of our Board since July 2021. Ms. Ladone served as Senior Vice President, Corporate Development, Strategy and Investor Relations, of Hill-Rom Holdings, Inc. from December 2018 to December 2021. Ms. Ladone previously served as Hill-Rom's Vice President, Investor Relations, upon joining Hill-Rom in July 2016. Ms. Ladone served as Senior Vice President, Investor Relations, of Baxalta Inc. from 2015 to 2016 before joining Hill-Rom. Prior to Baxalta Inc., Ms. Ladone served in a variety of senior finance, business development and investor relations roles for Baxter International, Inc. Ms. Ladone holds a Bachelor of Arts from the University of Notre Dame. Ms. Ladone was selected to serve on our Board due to her significant finance and investor relations experience at large healthcare companies.

Michelle McMurry-Heath, MD, PhD, was appointed as a member of our Board in December 2021 and her appointment became effective January 1, 2022. Dr. McMurry-Heath has served as President and Chief Operating Officer of the Biotechnology Innovation Organization, a membership and advocacy organization focused on improving biotech research and applying biotech innovations to major healthcare challenges, since 2020. She previously served as Vice President, External Innovation, Global Leader for Regulatory Science and Executive Director of Scientific Partnerships for JLABS@DC, a division of Johnson & Johnson ("J&J"), a manufacturer of medical devices, pharmaceuticals and consumer goods, from 2019 to 2020. Dr. McMurry-Heath joined J&J in 2014, serving as its Worldwide Vice President and Global Head, Regulatory Affairs from 2014 to 2017 and later adding responsibilities for the company's International Clinical Evidence and Strategic Operations from 2017 to 2019. Prior to that, she served as Associate Center Director for Science, Center for Devices and Radiological Health at the U.S. Food and Drug Administration from 2010 to 2014. From 2005 to 2010, Dr. McMurry-Heath was Director of the Health, Biomedical Science and Society Policy Program at the Aspen Institute. Dr. McMurry-Heath began her career as a Senior Policy Advisor for Senator Joseph Lieberman for Health, Social, and Biomedical Innovation Policy from 2001 to 2004. She later served as a Robert Wood Johnson Health and Society Scholar at the University of California, San Francisco and Berkeley from 2004 to 2005 and a Mcarthur Fellow, Global Health for the Council on Foreign Relations from 2004 to 2006. Dr. McMurry-Heath has an MD/PhD in Immunology from Duke University and received an AB in Biochemistry from Harvard University. Dr. McMurry-Heath was selected to serve on our Board due to her significant dynamic policy, regulatory, commercial health care and advocacy experience.

Guido J. Neels has served as a member of our Board since September 2020. Mr. Neels has been with Essex Woodlands since August 2006, where he is now an Operating Partner. Prior to joining Essex Woodlands, Mr. Neels served in a variety of management positions at Guidant Corporation, a developer of cardiovascular medical products. From July 2004 until retiring in November 2005, Mr. Neels served as Guidant's Chief Operating Officer, where he was responsible for the global operations of Guidant's four operating units: Cardiac Rhythm Management, Vascular Intervention, Cardiac Surgery and Endovascular Solutions. From December 2002 to July 2004, Mr. Neels served as Guidant's Group Chairman, Office of the President, responsible for worldwide sales operations, corporate communications, corporate marketing, investor relations and government relations. In January 2000, Mr. Neels was named Guidant's President, Europe, Middle East, Africa and Canada. In addition, Mr. Neels served as Guidant's Vice President, Global Marketing, Vascular Intervention, from 1996 to 2000 and as Guidant's General Manager, Germany and Central Europe, from 1994 to 1996. Mr. Neels has served as a member of the board of managers of BV LLC since May 2012. Mr. Neels also currently serves on the board of directors of Axogen, Inc. and also is a member of its compensation committee. Mr. Neels previously served on the board of directors of Endologix, Inc. from December 2010 to June 2019 and on the board of directors of Entellus Medical from November 2009 to February 2018, each of which is a public company. Mr. Neels holds a Master in Business Administration from the Stanford University Graduate School of Business and received his Business Engineering degree from the University of Leuven in Belgium. Mr. Neels was selected to serve on our Board because of his experience in the industry, familiarity with serving on the boards of public companies and his knowledge of our business.

Guy P. Nohra has served as a member of our Board since September 2020. In March 1996, Mr. Nohra co-founded Alta Partners, a life sciences venture capital firm, and he has since been involved in the funding and development of numerous medical technology and life sciences companies. Mr. Nohra was a member of the board of managers of BV LLC, which he has served on since May 2012. Mr. Nohra currently serves as a member of the boards of directors of Spiral Therapeutics, Inc., a several private life sciences company. He also previously served on the board of directors of various public companies, including ATS Medical, Inc., Cutera, Inc., AcelRx Pharmaceuticals, Inc., and ZS Pharma, as well as several private companies, including Bionure, Inc., Sanfit Therapeutics S.A., Carbylan Biosurgery, Inc., Cerenis Therapeutics, Coapt Systems, Paracor Medical, Inc. and PneumRx. Mr. Nohra holds a Master in Business Administration from the University of Chicago and received his Bachelor of Arts in History from Stanford University. Mr. Nohra was selected to serve on our Board because of his extensive experience in the life sciences industry, his investment and development experience, and his service as a director of other life sciences companies.

Martin P. Sutter has served as a member of our Board since September 2020. Mr. Sutter is one of the two founding Managing Directors of EW Healthcare Partners (previously known as Essex Woodlands), one of the oldest and largest life sciences and healthcare focused growth equity and venture capital firms, which he formed in 1985. Mr. Sutter has more than 35 years of management experience in operations, marketing, finance and venture capital. Mr. Sutter has served as a member of the board of managers of BV LLC since May 2012. Mr. Sutter also currently serves on the board of directors of Abiomed, Inc., a publicly traded medical device company, MiMedx Group, Inc., a publicly traded regenerative medicine life sciences company, and Prolacta Biosciences, Inc., a privately held life sciences company. Mr. Sutter has also previously served on the board of directors of Tissue Tech, Inc. and Suneva Medical, Inc. Mr. Sutter currently serves on the compensation and nominating and governance committees of Abiomed, Inc., MiMedx Group, Inc. and Prolacta Biosciences, Inc. Mr. Sutter holds a Master of Business Administration from the University of Houston and received his Bachelor of Science from Louisiana State University. Mr. Sutter was selected to serve on our Board because of his extensive experience in the life sciences industry, his investment experience, and his service as a director of other life sciences companies.

Susan M. Stalnecker has served as a member of our Board since September 2020. Ms. Stalnecker has been a Senior Advisor at Boston Consulting Group, a global management consulting firm, since March 2016. Ms. Stalnecker served as Vice President of E.I. duPont de Nemours and Co. (now known as DuPont de Nemours, Inc., or DuPont), a public company, a diversified science and innovations leader in the fields of healthcare, electronics and transportation, from December 1976 until she retired in 2016. During her nearly 40-year career at DuPont, Ms. Stalnecker served in several senior leadership roles including Vice President, Treasurer & M&A; Vice President, Risk Management; Vice President, Government and Consumer Markets; and Vice President, Productivity & Shared Services. Ms. Stalnecker has served as a member of the board of managers of BV LLC since November 2018. Ms. Stalnecker also currently serves on the board of directors of Leidos Holding, Inc. and Optimum Funds McQuairie, and serves on the Board of Trustees of the Duke Health System. She also serves on the audit & finance committee of Leidos Inc., the audit committee of Optimum Funds McQuairie and the compliance, audit & finance committees of the Duke Health System. Ms. Stalnecker holds a Master of Business Administration from The Wharton School of the University of Pennsylvania and received her Bachelor of Arts from Duke University. Ms. Stalnecker was selected to serve on our Board because of her extensive experience as a financial expert, her investment experience, and her service as a director of other public companies.

Stavros G. Vizirgianakis has served as a member of our Board since October 2021. Mr. Vizirgianakis is the former Chief Executive Officer of Misonix. He has a distinguished career in the medical devices field having worked for United States Surgical Corporation as director of sales for sub-Saharan Africa and later Tyco Healthcare in the capacity of General Manager South Africa. In 2006, Mr. Vizirgianakis co-founded Surgical Innovations, which has become one of the largest privately owned medical device distributors in the African region, and now part of the Johannesburg Stock Exchange listed entity Ascendis Health. In that capacity, he acted as a distributor of the company's products. Mr. Vizirgianakis was Managing Director of Ascendis Medical from January 2014 through July 2016. Mr. Vizirgiankis served as the President and Chief Executive Officer of Misonix, Inc. from September 2016 through October 2021. He also served on the board of Tenaxis Medical and is a strategic investor and advisor to numerous medical device startups and established companies in this field. Mr. Vizirgianakis has a Degree in Commerce from the University of South Africa. Mr. Vizirgianakis was selected to serve on our Board due to his familiarity with Misonix products and his experience as a leader of a public company.

Code of compliance and ethics

We have a written code of compliance and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the code is posted on our website, *www.bioventus.com*. In addition, we intend to post on our website all disclosures that are required by law or Nasdaq listing standards concerning any amendments to, or waivers from, any provision of the code. The information on our website is deemed not to be incorporated in this Annual Report or to be part of this Annual Report on Form 10-K.

The remaining information required by this item is incorporated by reference to our definitive proxy statement for our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to our definitive proxy statement for our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

Item 12. Security Ownership of Certain Beneficial Owner and Management and Related Stockholder Matters.

The information required by this item is incorporated by reference to our definitive proxy statement for our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item is incorporated by reference to our definitive proxy statement for our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

Item 14. Principal Accounting Fees and Services.

The information required by this item is incorporated by reference to our definitive proxy statement for our 2022 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2021.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) *Financial Statements.* See the table of contents under *Part II, Item 8. Financial Statements and Supplementary Data* of this Annual Report on Form 10-K above for the list of financial statements filed as part of this report.

(b) *Exhibits.* The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit no.	Description	Form	File No.	Exhibit	Filing Date	Filed / Furnished Herewith
2.1	Agreement and Plan of Merger, dated July 29, 2021, by and among Bioventus Inc., Oyster Merger Sub I, Inc., Oyster Merger Sub II, LLC and Misonix, Inc.	8-K	001-37844	2.1	7/29/2021	
2.2	Agreement and Plan of Merger, dated as of March 30, 2021, by and among Bioventus LLC, Bioness Inc., Perseus Intermediate, Inc., Perseus Merger Sub, Inc., Alfred E. Mann Living Trust and Mann Group, LLC.	8-K	001-37844	10.1	3/30/2021	
3.1	Amended and Restated Certificate of Incorporation of Bioventus Inc.	8-K	001-37844	3.1	2/17/2021	
3.2	Amended and Restated Bylaws of Bioventus Inc.	8-K	001-37844	3.2	2/17/2021	
4.1	Specimen Stock Certificate evidencing the shares of Class A common stock	S-1	333-252238	4.1	1/20/2021	
4.2	Description of Securities	10-K	001-37844	4.2	3/26/2021	
10.1	Tax Receivable Agreement, dated as of February 16, 2021, by and among Bioventus Inc., Bioventus LLC and its Members	8-K	001-37844	10.2	2/17/2021	
10.2	Registration Rights Agreement, dated February 16, 2021, by and among Bioventus Inc. and the Original LLC	8-K	001-37844	10.3	2/17/2021	
10.3	Second Amended and Restated Limited Liability Company Agreement of Bioventus LLC dated as of February 16, 2021.	8-K	001-37844	10.1	2/17/2021	
10.4	Stockholders Agreement, dated February 16, 2021, by and among Bioventus Inc., Bioventus LLC and the Principal Stockholders	8-K	001-37844	10.4	2/17/2021	
10.5†	Amended and Restated License Agreement, dated as of December 9, 2016, by and between Bioventus LLC, Q-Med AB and Nestlé Skin Health S.A.	S-1	333-252238	10.5	1/20/2021	
10.6†	Amended and Restated Supply Agreement, dated as of December 9, 2016, by and between Bioventus LLC and Q-Med AB	S-1	333-252238	10.6	1/20/2021	
10.7†	Exclusive License, Supply and Distribution Agreement, dated as of February 9, 2016, by and between IBSA Institut Biochimique SA (Switzerland) and Bioventus LLC.	S-1	333-252238	10.7	1/20/2021	

Exhibit no.	Description	Form	File No.	Exhibit	Filing Date	Filed / Furnished Herewith
10.7(a)†	Amendment No. 1 to Exclusive License, Supply and Distribution Agreement, dated as of December 31, 2018, by and between IBSA Institut Biochimique SA (Switzerland) and Bioventus LLC	S-1	333-252238	10.7(a)	1/20/2021	
10.7(b)†	Amendment No. 2 to Exclusive License, Supply and Distribution Agreement, dated as of December 31, 2020, by and between IBSA Institut Biochimique SA (Switzerland) and Bioventus LLC	S-1/A	333-252238	10.7(b)	2/4/2021	
10.10(a)	Amendment No. 1 to Credit and Guaranty Agreement, dated as of August 29, 2021, by and among Bioventus LLC, certain Guarantor Subsidiaries party thereto, Wells Fargo Bank, National Association, as administrative agent and the lenders and other financial institutions party thereto.	10-Q	001-37844	10.1	11/10/2021	
10.10(b)	Amendment No. 2 to Credit and Guaranty Agreement, dated as of October 29, 2021, by and among Bioventus LLC, Oyster Merger Sub II, LLC, Misonix, Inc., certain Guarantor Subsidiaries party thereto, Wells Fargo Bank, National Association, as administrative agent and the lenders and other financial institutions party thereto.	8-K	001-37844	10.1	10/29/2021	
10.11^	Director Offer Letter, dated as of December 11, 2015, by and between Bioventus LLC and William A. Hawkins	S-1	333-252238	10.33	1/20/2021	
10.12^	Retention Letter, dated as of April 13, 2020, by and between Bioventus LLC and John E. Nosenzo	S-1	333-252238	10.35	1/20/2021	
10.13^	Director Offer Letter, dated as of October 3, 2018, by and between Bioventus LLC and Susan M. Stalnecker.	S-1	333-252238	10.38	1/20/2021	
10.14^	Payout Agreement Letter, dated as of June 12, 2020, by and between Bioventus LLC and Anthony P. Bihl, III	S-1	333-252238	10.41	1/20/2021	
10.15^	Phantom Profits Interest Plan Award Agreement, dated as of June 25, 2020, by and between Bioventus LLC and Kenneth M. Reali	S-1	333-252238	10.42	1/20/2021	
10.16^	Option Letter, dated as of July 30, 2020, by and between Bioventus LLC and Kenneth M. Reali	S-1	333-252238	10.43	1/20/2021	
10.17^	Bioventus Inc. 2021 Employee Stock Purchase Plan	S-1/A	333-2522	10.44	2/4/2021	
10.18^	Bioventus Inc. 2021 Equity Incentive Plan	S-1/A	333-2522	10.45	2/10/2021	
10.19^	Form of Notice of Stock Option Grant and Stock Option Agreement	S-1/A	333-2522	10.47	2/10/2021	
10.20^	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Agreement	S-1/A	333-2522	10.48	2/10/2021	

Exhibit no.	Description	Form	File No.	Exhibit	Filing Date	Filed / Furnished Herewith
10.21	Assignment and Assumption Agreement, dated as of February 9, 2021, by and between Bioventus Inc. and Bioventus LLC	S-1/A	333-2522	10.50	2/10/2021	
10.22^	Bioventus Inc. Non-Employee Director Compensation Policy	S-1/A	333-2522	10.51	2/10/2021	
10.23^	Employment Agreement, dated as of February 9, 2021, by and among Bioventus Inc., Bioventus LLC and Kenneth Reali	S-1/A	333-2522	10.52	2/10/2021	
10.24^	Employment Agreement, dated as of February 9, 2021, by and among Bioventus Inc., Bioventus LLC and Gregory O. Anglum	S-1/A	333-2522	10.53	2/10/2021	
10.25^	Employment Agreement, dated as of February 9, 2021, by and among Bioventus Inc., Bioventus LLC and John E. Nosenzo	S-1/A	333-2522	10.54	2/10/2021	
10.26^	Employment Agreement, dated as of February 9, 2021, by and among Bioventus Inc., Bioventus LLC and Anthony D'Adamio	S-1/A	333-2522	10.55	2/10/2021	
10.27^	Employment Agreement, dated as of February 9, 2021, by and among Bioventus Inc., Bioventus LLC and Alessandra Pavesio	S-1/A	333-2522	10.56	2/10/2021	
10.28^	Option Forfeiture Letter, dated as of February 3, 2021, by and between Bioventus LLC and Kenneth Reali	S-1/A	333-2522	10.57	2/10/2021	
10.29^	Form of Indemnification Agreement	S-1/A	333-2522	10.46	2/4/2021	
10.30	Settlement Agreement, dated as of February 22, 2021, by and between the United States of America, acting through the United States Attorney's Office for the Middle District of North Carolina and on behalf of the Office of Inspector General of the Department of Health and Human Services, and Bioventus LLC, through their authorized representatives					*
10.31	Lease Agreement, dated November 17, 2021, between Bioventus LLC and 7101 Goodlett Farms Parkway, LLC.	8-K	001-37844	10.1	11/22/2021	
21.1	List of subsidiaries of Bioventus Inc.					*
23.1	Consent of Grant Thornton LLP (Bioventus Inc.)					*
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended					*
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended					*

Exhibit no.	Description	Form	File No.	Exhibit	Filing Date	Filed / Furnished Herewith
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
99.1	List of patents and pending patent applications directed to Bioventus Inc.'s material products					*
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					***
101.SCH	Inline XBRL Taxonomy Extension Schema Document					***
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					***
101.DEF	Inline XBRL Extension Definition Linkbase Document					***
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					***
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					***
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document contained in Exhibit 10					***

* Filed herewith

** Furnished herewith

*** Submitted electronically herewith

† Certain portions of this exhibit have been omitted pursuant to Regulation S-K, Item (601)(b)(10).

^ Indicates management contract or compensatory plan.

Item 16. Form 10-K Summary.

None

SIGNATURES

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

Bioventus Inc.

By:	/s/	Kenneth M. Reali
	Name:	Kenneth M. Reali
	Title:	Chief Executive Officer and Director (Principal Executive Officer)

March 11, 2022

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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	Date	Title
/s/ Kenneth M. Reali Kenneth M. Reali	March 11, 2022	Chief Executive Officer and Director (Principal Executive Officer)
/s/ Gregory O. Anglum Gregory O. Anglum	March 11, 2022	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
/s/ William A. Hawkins III William A. Hawkins III	March 11, 2022	Chairman
/s/ Patrick J. Beyer Patrick J. Beyer	March 11, 2022	Director
/s/ Philip G. Cowdy Philip G. Cowdy	March 11, 2022	Director
/s/ Mary Kay Ladone Mary Kay Ladone	March 11, 2022	Director
/s/ Michelle McMurry-Heath Michelle McMurry-Heath	March 11, 2022	Director
/s/ Guido J. Neels Guido J. Neels	March 11, 2022	Director
/s/ Guy P. Nohra Guy P. Nohra	March 11, 2022	Director
/s/ Susan M. Stalnecker Susan M. Stalnecker	March 11, 2022	Director
/s/ Martin P. Sutter Martin P. Sutter	March 11, 2022	Director
/s/ Stavros G. Vizirgianakis Stavros G. Vizirgianakis	March 11, 2022	Director

Exhibit 21.1

Legal Name	Jurisdiction of Incorporation
Bioventus Inc.	Delaware
Bioventus LLC	Delaware
Bioventus Holdings LLC (1)	North Carolina
Bioventus Coöperatief U.A.(2)	The Netherlands
Bioventus Canada, Ulc (3)	British Columbia
Bioventus Germany GmbH (3)	Germany
Bioventus UK, Ltd (3)	United Kingdom
CartiHeal (2009) Ltd. (4)	Israel
Misonix LLC (1)	Delaware
Misonix OpCo, LLC (5)	Delaware
Perseus Intermediate, Inc. (1)	Delaware
Bioness Inc. (6)	Delaware
Bioness Neuromodulation Ltd. (7)	Israel
Bioness Europe B.V. (8)	The Netherlands

(1) Wholly owned subsidiary of Bioventus LLC
(2) Joint partnership between Bioventus LLC and Bioventus Holdings LLC
(3) Wholly owned subsidiary of Bioventus Coöperatief U.A
(4) Minority ownership by Bioventus Coöperatief U.A
(5) Wholly owned subsidiary of Misonix LLC
(6) Wholly owned subsidiary of Perseus Intermediate, Inc.
(7) Wholly owned subsidiary of Bioness Inc.
(8) Wholly owned subsidiary of Bioness Neuromodulation Ltd.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 11, 2022, with respect to the consolidated financial statements included in the Annual Report of Bioventus Inc. on Form 10-K for the year ended December 31, 2021. We consent to the incorporation by reference of said report in the Registration Statements of Bioventus Inc. on Forms S-8 (File No. 333-260603; File No. 333-252981) and Form S-4 (File No. 333-259392).

/s/ GRANT THORNTON LLP

Raleigh, North Carolina

March 11, 2022

Exhibit 31.1

CERTIFICATIONS

I, Kenneth M. Reali, certify that:

1. I have reviewed this Annual Report on Form 10-K of Bioventus 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 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 materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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.

/s/ Kenneth M. Reali

Name: Kenneth M. Reali

Title: Chief Executive Officer and Director (Principal Executive Officer)

Date: March 11, 2022

Exhibit 31.2

CERTIFICATIONS

I, Gregory O. Anglum, certify that:

1. I have reviewed this Annual Report on Form 10-K of Bioventus 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 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 materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer 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.

/s/ Gregory O. Anglum

Name: Gregory O. Anglum

Title: Senior Vice President and Chief Financial Officer (Principal Financial Officer)

Date: March 11, 2022

Exhibit 32

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

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, in connection with the Annual Report on Form 10-K of Bioventus Inc. (the Company) for the period ended December 31, 2021, as filed with the Securities and Exchange Commission on the date hereof (the Report), each of Kenneth M. Reali, Chief Executive Officer and Director of the Company, and Gregory O. Anglum, Senior Vice President and Chief Financial Officer of the Company, hereby certifies, that, to such officer's 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 the Company.

/s/ Kenneth M. Reali

Name: Kenneth M. Reali

Title: Chief Executive Officer and Director (Principal Executive Officer)

/s/ Gregory O. Anglum

Name: Gregory O. Anglum

Title: Senior Vice President and Chief Financial Officer (Principal Financial Officer)

Date: March 11, 2022

Exhibit 99.1

List of patents issued and pending patent applications

Country	Application Number	Filing Date	Patent Number	Application Status	Expected Expiration Date	Description	Product
AU	2009324417	December 13, 2009	2009324417	Issued	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
AU	2014259553	November 14, 2014	2014259553	Issued	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
AU	2016213839	August 11, 2016	2016213839	Issued	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
CA	2746668	December 13, 2009	2746668	Issued	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
CN	200980155596.X	December 13, 2009	200980155596.X	Issued	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
CN	201410413348.3	August 20, 2014	201410413348.3	Issued	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
EP	9832666.3	December 13, 2009		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
HK	15105678.1	June 16, 2015	HK1205007	Issued	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
IN	2567/KOLNP/2011	February 4, 2016		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
KR	10-2011-7016270	July 2, 2019	10-1713346	Issued	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
US	15/016072	December 13, 2009	10383974	Issued	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
US	16/459778	February 4, 2016		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
GB	9832666.3	December 13, 2009		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
FR	9832666.3	December 13, 2009		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
DE	9832666.3	December 13, 2009		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
IT	9832666.3	December 13, 2009		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
CH	9832666.3	December 13, 2009		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
BE	9832666.3	December 13, 2009		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
ES	9832666.3	December 13, 2009		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
PT	9832666.3	December 13, 2009		Pending	December 2029	Directed to methods of making osteoinductive implants	OsteoAMP
US	09/925,193	August 9, 2001	7429248	Granted	July 2025	Directed to applying ultrasound to tissue using a modal converter having a plurality of angled sides.	Exogen
AU	2006203281	August 1, 2006	2006203281	Granted	August 2025	Directed to treating a neuropathy disease with ultrasound using a specific frequency and pulse rate for the signal	Exogen
US	11/462271	August 3, 2006	8048006	Granted	February 2029	Directed to treating a neuropathy disease with ultrasound using a specific frequency and pulse rate for the signal	Exogen
US	12/296,333	April 7, 2007	8226582	Granted	June 2028	Directed to applying ultrasound to tissue using a modal converter having an oblique angle and speed of sound similar to human tissue	Exogen
US	17/097,350	November 13, 2020		Pending	November 2040	Directed to placental tissue particulates compositions, methods of treating musculoskeletal or orthopedic conditions, methods of treating pain associated with osteoarthritis, kits and methods of making the compositions	MOTYS
PCT	PCT/US20/60393	November 13, 2020		Pending	November 2040	Directed to placental tissue particulates compositions, for use in treating musculoskeletal or orthopedic conditions, methods of treating pain associated with osteoarthritis, kits and methods of making the compositions	MOTYS
AU	2010326076	December 1, 2010	2010326076	Issued	December 2030	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
CA	2780328	December 1, 2010	2780328	Issued	December 2030	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
EP	8827776.9	August 25, 2008	2180918	Issued	August 2028	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
EP	17195472	December 1, 2010	3299061	Issued	December 2030	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter

Country	Application Number	Filing Date	Patent Number	Application Status	Expected Expiration Date	Description	Product
FR	8827776.9	August 25, 2008	2180918	Issued	August 2028	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
FR	17195472	December 1, 2010	3299061	Issued	December 2030	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
DE	8827776.9	August 25, 2008	2180918	Issued	August 2028	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
DE	60 2010 064 767.6	December 1, 2010	3299061	Issued	December 2030	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
JP	2010-522104	August 25, 2008	5425077	Issued	August 2028	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
JP	2012-542152	December 1, 2010	5667205	Issued	December 2030	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
GB	8827776.9	August 25, 2008	2180918	Issued	August 2028	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
GB	17195472	December 1, 2010	3299061	Issued	December 2030	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
US	11/867,454	October 4, 2007	8,483,820	Issued	November 2030	Directed to a system and method for percutaneous delivery of electrical stimulation to a target body tissue	StimRouter
US	12/197,849	August 25, 2008	8,467,880	Issued	November 2031	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
US	12/628,273	December 1, 2009	8,738,137	Issued	November 2028	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
US	14/630,329	February 24, 2015	9,757,554	Issued	August 2028	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
US	13/513,318	December 1, 2010	9,072,896	Issued	May 2029	Directed to a system for transmitting electrical current to a bodily tissue	StimRouter
US	11/993,393	June 28, 2006	8,332,029	Issued	April 2028	Directed to an implant, system and method using implanted passive conductors for routing electrical current	StimRouter
US	13/618,739	September 14, 2012	8,538,517	Issued	June 2026	Directed to an implant, system and method using implanted passive conductors for routing electrical current	StimRouter
US	14/027,930	September 16, 2013	8,862,225	Issued	June 2026	Directed to an implant, system and method using implanted passive conductors for routing electrical current	StimRouter
US	12/187,662	August 7, 2008	8,494,650	Issued	April 2030	Directed to insertion tools and method for an electrical stimulation implant	StimRouter
US	12/407,097	March 19, 2009	8,167,640	Issued	December 2029	Directed to flexible connector for implantable electrical stimulation lead	StimRouter
AU	2009262237	June 24, 2009	2009262237	Issued	June 2029	Directed to treatment of indications using electrical stimulation	L300
AU	2006314072	November 16, 2006	2006314072	Issued	November 2026	Directed to gait modulation system and methods	L300
AU	2011254054	November 16, 2006	2011254054	Issued	November 2026	Directed to gait modulation system and methods	L300
AU	2013260668	November 16, 2006	2013260668	Issued	November 2026	Directed to gait modulation system and methods	L300
AU	2017202373	November 16, 2006	2017202373	Issued	November 2026	Directed to gait modulation system and methods	L300
AU	2007245258	May 1, 2007	2007245258	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
AU	2013273609	May 1, 2007	2013273609	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
AU	2015201998	May 1, 2007	2015201998	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
AU	2019200793	May 1, 2007	2019200793	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
AU	2019202303	November 16, 2006	2019202303	Issued	November 2026	Directed to gait modulation system and method	L300
AU	2012277312	June 26, 2012	2012277312	Issued	June 2032	Directed to an electrode for muscle stimulation	L300
AU	2015236546	March 17, 2015	2015236546	Issued	March 2035	Directed to systems and apparatus for gait modulation and methods of use	L300
CA	2632196	November 16, 2006	2632196	Issued	November 2026	Directed to gait modulation system and method	L300
CA	2794533	November 16, 2006	2794533	Issued	November 2026	Directed to gait modulation system and method	L300
CA	2930077	November 16, 2006	2930077	Issued	November 2026	Directed to a sensor device for a gait modulation system	L300
CA	2649663	May 1, 2007	2649663	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
CA	2956427	May 1, 2007	2956427	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
CA	3033963	November 16, 2006	3033963	Issued	November 2026	Directed to gait modulation system and method	L300

Country	Application Number	Filing Date	Patent Number	Application Status	Expected Expiration Date	Description	Product
CA	2840167	June 26, 2012	2840167	Issued	June 2032	Directed to an electrode for muscle stimulation	L300
DK	6821561.5	November 16, 2006	1951365	Issued	November 2026	Directed to gait modulation system and method	L300
EP	9770922.4	June 24, 2009	2291220	Issued	June 2029	Directed to treatment of indications using electrical stimulation	L300
EP	6821561.5	November 16, 2006	1951365	Issued	November 2026	Directed to gait modulation system and method	L300
EP	7736271.3	May 1, 2007	2012669	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
EP	12197261.6	May 1, 2007	2586489	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
EP	12803925.2	June 26, 2012	2723442	Issued	June 2032	Directed to an electrode for muscle stimulation	L300
EP	17738843.6	January 11, 2017	3402404	Issued	January 2037	Directed to systems and apparatus for gait modulation and methods of use	L300
FR	6821561.5	November 16, 2006	1951365	Issued	November 2026	Directed to gait modulation system and method	L300
FR	7736271.3	May 1, 2007	2012669	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
FR	12197261.6	May 1, 2007	2586489	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
FR	9770922.4	June 24, 2009	2291220	Issued	June 2029	Directed to treatment of indications using electrical stimulation	L300
FR	12803925.2	June 26, 2012	2723442	Issued	June 2032	Directed to an electrode for muscle stimulation	L300
FR	17738843.6	January 11, 2017	3402404	Issued	January 2037	Directed systems and apparatus for gait modulation and methods of use	L300
DE	602006053800.6	November 16, 2006	1951365	Issued	November 2026	Directed to gait modulation system and method	L300
DE	7736271.3	May 1, 2007	2012669	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
DE	12197261.6	May 1, 2007	2586489	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
DE	602009061168.2	June 24, 2009	2291220	Issued	June 2029	Directed to treatment of indications using electrical stimulation	L300
DE	602012051814.6	June 26, 2012	2723442	Issued	June 2032	Directed to an electrode for muscle stimulation	L300
DE	17738843.6	January 11, 2017	3402404	Issued	January 2037	Directed to systems and apparatus for gait modulation and methods of use	L300
JP	2009-517597	May 1, 2007	5324438	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
JP	2013-149122	May 1, 2007	5739944	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
JP	2015-088947	May 1, 2007	6178359	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
JP	2016-547617	March 17, 2015	6563934	Issued	March 2035	Directed to systems and apparatus for gait modulation and methods of use	L300
SE	6821561.5	November 16, 2006	1951365	Issued	November 2026	Directed to gait modulation system and method	L300
GB	6821561.5	November 16, 2006	1951365	Issued	November 2026	Directed to gait modulation system and method	L300
GB	7736271.3	May 1, 2007	2012669	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
GB	12197261.6	May 1, 2007	2586489	Issued	May 2027	Directed to improved functional electrical stimulation systems	L300
GB	9770922.4	June 24, 2009	2291220	Issued	June 2029	Directed to treatment of indications using electrical stimulation	L300
GB	12803925.2	June 26, 2012	2723442	Issued	June 2032	Directed to an electrode for muscle stimulation	L300
GB	17738843.6	January 11, 2017	3402404	Issued	January 2037	Directed to systems and apparatus for gait modulation and methods of use	L300
US	13/000,840	June 24, 2009	9,925,374	Issued	July 2029	Directed to treatment of indications using electrical stimulation	L300
US	12/096,077	November 16, 2006	8,209,022	Issued	June 2029	Directed to gait modulation system and method	L300
US	13/532,603	June 25, 2012	8,972,017	Issued	October 2026	Directed to gait modulation system and method	L300
US	11/380,430	April 27, 2006	7,899,556	Issued	May 2029	Directed to an orthosis for a gait modulation system	L300
US	11/552,997	October 26, 2006	7,632,239	Issued	October 2026	Directed to a sensor device for gait enhancement	L300
US	12/299,043	May 1, 2007	8,788,049	Issued	June 2030	Directed to functional electrical stimulation systems	L300
US	12/631,095	December 4, 2009	8,382,688	Issued	January 2027	Directed to a sensor device for gait enhancement	L300

Country	Application Number	Filing Date	Patent Number	Application Status	Expected Expiration Date	Description	Product
US	13/036,256	February 28, 2011	8,209,036	Issued	April 2026	Directed to an orthosis for a gait modulation system	L300
US	13/532,597	June 25, 2012	8,694,110	Issued	April 2026	Directed to an orthosis for a gait modulation system	L300
US	14/245,597	April 4, 2014	10,080,885	Issued	April 2026	Directed to an orthosis for a gait modulation system	L300
US	14/333,184	July 16, 2014	9,415,205	Issued	November 2026	Directed to functional electrical stimulation systems	L300
US	14/636,628	March 3, 2015	10,076,656	Issued	October 2026	Directed to gait modulation system and method	L300
US	15/237,208	August 15, 2016	10,016,598	Issued	November 2026	Directed to functional electrical stimulation systems	L300
US	16/030,065	July 9, 2018	10,543,365	Issued	November 2026	Directed to functional electrical stimulation systems	L300
US	16/139,927	September 24, 2018	11,058,867	Issued	April 2026	Directed an orthosis for a gait modulation system	L300
US	10/222,878	August 19, 2002	7,337,007	Issued	June 2024	Directed to a surface neuroprosthetic device having a locating system	L300
US	13/169,553	June 27, 2011	8,868,217	Issued	October 2031	Directed to an electrode for muscle stimulation	L300
US	14/223,340	March 24, 2014	9,867,985	Issued	March 2034	Directed to systems and apparatus for gait modulation and methods of use	L300
US	15/872,634	January 16, 2018	10,086,196	Issued	March 2034	Directed to systems and apparatus for gait modulation and methods of use	L300
US	16/146,368	September 28, 2018	10,850,098	Issued	March 2034	Directed to systems and apparatus for gait modulation and methods of use	L300
US	16/031,721	January 11, 2017	11,077,300	Issued	January 2037	Directed to systems and apparatus for gait modulation and methods of use	L300
AU	2021211987	May 1, 2007		Pending	November 2026	Directed to improved functional electrical stimulation systems	L300
AU	2020202739	March 17, 2015		Pending	March 2035	Directed to systems and apparatus for gait modulation and methods of use	L300
AU	2017206723	January 11, 2017		Pending	January 2037	Directed to systems and apparatus for gait modulation and methods of use	L300
CA	2936989	March 17, 2015		Pending	March 2035	Directed to systems and apparatus for gait modulation and methods of use	L300
CA	3010880	January 11, 2017		Pending	January 2037	Directed to systems and apparatus for gait modulation and methods of use	L300
EP	18198317.2	June 26, 2012		Pending	June 2032	Directed to an electrode for muscle stimulation	L300
EP	15770404	March 17, 2015		Pending	March 2035	Directed to systems and apparatus for gait modulation and methods of use	L300
JP	2018-534781	January 11, 2017		Pending	January 2037	Directed to systems and apparatus for gait modulation and methods of use	L300
US	16/773,610	January 27, 2020		Pending	May 2027	Directed to functional electrical stimulation systems	L300
US	17/103,249	November 24, 2020		Pending	March 2024	Directed to systems and apparatus for gait modulation and methods of use	L300
US	17/391,504	August 2, 2021		Pending	January 2037	Directed to systems and apparatus for gait modulation and methods of use	L300
AU	2016215484	February 2, 2016	2016215484	Issued	February 2036	Directed to methods and apparatus for body weight support system	Vector
AU	2016354524	November 11, 2016	2016354524	Issued	November 2036	Directed to apparatus and methods for support track and power rail switching in a body weight support system	Vector
CA	2897620	January 17, 2014	2897620	Issued	January 2034	Directed to methods and apparatus for body weight support system	Vector
EP	16747097	February 2, 2016	3253354	Issued	February 2036	Directed to body weight support system	Vector
EP	17849531.3	September 7, 2017	3509555	Issued	September 2036	Directed to methods and apparatus for body weight support system	Vector
FR	16747097	February 2, 2016	3253354	Issued	February 2036	Directed to a body weight support system	Vector
FR	17849531.3	September 7, 2017	3509555	Issued	September 2036	Directed to methods and apparatus for body weight support system	Vector
DE	16747097	February 2, 2016	3253354	Issued	February 2036	Directed to a body weight support system	Vector
DE	17849531.3	September 7, 2017	3509555	Issued	September 2036	Directed to methods and apparatus for body weight support system	Vector
JP	2015-553851	January 17, 2014	6114838	Issued	January 2034	Directed to methods and apparatus for body weight support system	Vector
JP	2017-052240	January 17, 2014	6480968	Issued	January 2034	Directed to methods and apparatus for body weight support system	Vector
JP	2017-534701	February 2, 2016	6769966	Issued	February 2036	Directed to methods and apparatus for body weight support system	Vector
GB	16747097	February 2, 2016	3253354	Issued	February 2036	Directed to a body weight support system	Vector

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GB	17849531.3	September 7, 2017	3509555	Issued	September 2036	Directed to methods and apparatus for body weight support system	Vector
US	13/745,830	January 20, 2013	9,682,000	Issued	June 2034	Directed to methods and apparatus for body weight support system	Vector
US	14/226,021	March 26, 2014	9,855,177	Issued	June 2034	Directed to methods and apparatus for body weight support system	Vector
US	14/613,140	February 3, 2015	10,463,563	Issued	May 2034	Directed to methods and apparatus for body weight support system	Vector
US	15/471,585	March 28, 2017	9,839,569	Issued	January 2033	Directed to methods and apparatus for body weight support system	Vector
US	15/783,755	October 13, 2017	10,219,960	Issued	January 2033	Directed to methods and apparatus for body weight support system	Vector
US	16/244,839	January 10, 2019	10,537,486	Issued	January 2033	Directed to methods and apparatus for body weight support system	Vector
US	15/896,731	February 14, 2018	10,668,316	Issued	April 2038	Directed to methods and apparatus for body weight support system	Vector
US	15/349,390	November 11, 2016	10,500,123	Issued	April 2037	Directed to apparatus and methods for support track and power rail switching in a body weight support system	Vector
AU	2017322238	September 7, 2017		Pending	September 2037	Directed to methods and apparatus for body weight support system	Vector
AU	2018220931	February 14, 2018		Pending	February 2038	Directed to methods and apparatus for body weight support system	Vector
CA	2974391	February 2, 2016		Pending	February 2036	Directed to methods and apparatus for body weight support system	Vector
CA	3035450	September 7, 2017		Pending	September 2036	Directed to methods and apparatus for body weight support system	Vector
CA	3050322	February 14, 2018		Pending	February 2038	Directed to methods and apparatus for body weight support system	Vector
CA	3003057	November 11, 2016		Pending	November 2036	Directed to apparatus and methods for support track and power rail switching in a body weight support system	Vector
EP	14740676.3	January 17, 2014		Pending	January 2034	Directed to methods and apparatus for body weight support system	Vector
EP	21200795.9	September 7, 2017		Pending	September 2037	Directed to methods and apparatus for body weight support system	Vector
EP	18753980.4	February 14, 2018		Pending	February 2038	Directed to methods and apparatus for body weight support system	Vector
EP	16865093.5	November 11, 2016		Pending	November 2036	Directed to apparatus and methods for support track and power rail switching in a body weight support system	Vector
JP	2022-009324	January 17, 2014		Pending	January 2034	Directed to methods and apparatus for body weight support system	Vector
JP	2019-508223	September 7, 2017		Pending	September 2037	Directed to methods and apparatus for body weight support system	Vector
JP	2019-539192	February 14, 2018		Pending	February 2038	Directed to methods and apparatus for body weight support system	Vector
US	15/698,184	September 7, 2017		Pending	September 2037	Directed to methods and apparatus for body weight support system	Vector
US	16/599,793	October 11, 2019		Pending	January 2034	Directed to methods and apparatus for body weight support system	Vector
US	16/742,543	January 14, 2020		Pending	January 2034	Directed to methods and apparatus for body weight support system	Vector
US	17/188,714	March 1, 2021		Pending	February 2038	Directed to methods and apparatus for body weight support system	Vector
US	17/473,690	September 13, 2021		Pending	January 2034	Directed to methods and apparatus for body weight support system	Vector
US	17/473,700	September 13, 2021		Pending	January 2034	Directed to methods and apparatus for body weight support system	Vector
AU	2016215482	February 2, 2016	2016215482	Issued	February 2036	Directed to methods and apparatus for balance support systems	BITS
US	15/013,277	February 2, 2016	10,427,002	Issued	November 2037	Directed to methods and apparatus for balance support systems	BITS
CA	2974384	February 2, 2016		Pending	February 2036	Directed to methods and apparatus for balance support systems	BITS
US	16/504,623	July 8, 2019	11,065,461	Issued	July 2039	Directed to an implantable power adapter	TalisMann
AU	2020311913	July 8, 2020		Pending	July 2040	Directed to apparatus and methods for providing electric energy to a subject	TalisMann
CA	3139126	July 8, 2020		Pending	July 2040	Directed to apparatus and methods for providing electric energy to a subject	TalisMann
EP	20837675.6	July 8, 2020		Pending	July 2040	Directed to apparatus and methods for providing electric energy to a subject	TalisMann
JP	2021-566334	July 8, 2020		Pending	July 2040	Directed to apparatus and methods for providing electric energy to a subject	TalisMann
US	17/379,220	July 19, 2021		Pending	July 2039	Directed to an implantable power adapter	TalisMann

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PCT	PCT/US2020/041234	July 8, 2020		Pending	July 2040	Directed to apparatus and methods for providing electric energy to a subject	TalisMann
CA	3088074	January 10, 2019		Pending	January 2039	Directed to apparatus and methods for biofilm removal from prostheses	BoneScalpel
CN	201980018048	January 10, 2019		Pending	January 2039	Directed to apparatus and methods for biofilm removal from prostheses	BoneScalpel
JP	2020538829	January 10, 2019		Pending	January 2039	Directed to apparatus and methods for biofilm removal from prostheses	BoneScalpel
EP	19738214.6	January 10, 2019		Pending	January 2039	Directed to apparatus and methods for biofilm removal from prostheses	BoneScalpel
US	14938280	November 11, 2015	10471281	Issued	February 2038	Directed to apparatus and methods for bone stimulation to promote healing	BoneScalpel
EP	1899238	August 1, 2011	1899238	Issued	August 2026	Directed to bone-cutting blade with 1 or 2 serrated edges (design)	BoneScalpel
US	29/384867	February 4, 2011	680218	Issued	April 2027	Directed to bone-cutting blade with single serrated edge (design)	BoneScalpel
JP	201117861	February 4, 2011	1445133	Issued	April 2027	Directed to bone-cutting blade with single serrated edge (design)	BoneScalpel
US	29/422537	February 4, 2011	667117	Issued	September 2026	Directed to bone-cutting blade with two serrated edges (design)	BoneScalpel
JP	2012503	February 4, 2011	1446424	Issued	April 2027	Directed to bone-cutting blade with two serrated edges (design)	BoneScalpel
CA	2916914	June 26, 2013	2916914	Pending	June 2033	Directed to flat blade with large shallow recess(es) for coolant	BoneScalpel
US	13931003	June 28, 2013	9387005	Issued	April 2034	Directed to flat blade with large shallow recess(es) for coolant	BoneScalpel
US	29/446074	February 20, 2013	741481	Issued	October 2029	Directed to hook blade with serrations	BoneScalpel
US	2006452608	June 14, 2006	8814870	Issued	January 2031	Directed to hook-shaped ultrasonic cutting blade	BoneScalpel
EP	7809465	June 12, 2007	2032043	Issued	June 2027	Directed to hook-shaped ultrasonic cutting blade	BoneScalpel
EP	15173566	June 12, 2007	2949279	Issued	June 2027	Directed to hook-shaped ultrasonic cutting blade	BoneScalpel
US	14338009	July 22, 2014	9119658	Issued	June 2026	Directed to hook-shaped ultrasonic cutting blade	BoneScalpel
CA	2655068	June 12, 2007	2655068	Issued	June 2027	Directed to hook-shaped ultrasonic cutting blade	BoneScalpel
JP	2016523840	June 23, 2014	6450380	Issued	June 2034	Directed to irrigation outlet(s) in shank	BoneScalpel
CA	2916838	June 23, 2014	2916838	Issued	June 2034	Directed to irrigation outlet(s) in shank	BoneScalpel
US	29/414827	March 5, 2012	685087	Issued	June 2027	Directed to laparoscopic cannula with distal end offset or window	BoneScalpel
US	15204788	July 7, 2016	9788852	Issued	June 2033	Directed to large shallow recesses in flats of blade serving as reservoirs	BoneScalpel
JP	2016524182	June 26, 2014	6490065	Issued	June 2034	Directed to large shallow recesses on side of blade	BoneScalpel
CN	201480043643.2	June 26, 2014	2014800436432	Issued	June 2034	Directed to large shallow recesses on side of blade	BoneScalpel
EP	14817142	June 26, 2014	3013260	Issued	June 2034	Directed to large shallow recesses on side of blade	BoneScalpel
HK	16111842	October 13, 2016	1223532	Issued	June 2034	Directed to large shallow recesses on side of blade	BoneScalpel
US	14939668	November 12, 2015	10842587	Issued	May 2039	Directed to method for minimally invasive surgery using therapeutic ultrasound to treat spine and orthopedic diseases, injuries and deformities	BoneScalpel
CN	201480041451.8	June 25, 2014	2014800414518	Issued	June 2034	Directed to a microporous blade	BoneScalpel
HK	16111188	September 23, 2016	1223007	Issued	June 2034	Directed to a microporous blade	BoneScalpel
CA	3023055	April 24, 2017		Pending	April 2037	Directed to a probe grounded to reduce leakage	BoneScalpel
CN	201780036867.4	April 24, 2017		Pending	April 2037	Directed to a probe grounded to reduce leakage	BoneScalpel
HK	19127426	April 24, 2017		Pending	April 2037	Directed to a probe grounded to reduce leakage	BoneScalpel
JP	2018558162	April 24, 2017		Pending	April 2037	Directed to a probe grounded to reduce leakage	BoneScalpel
EP	17793008.8	April 24, 2017		Pending	April 2037	Directed to a probe grounded to reduce leakage	BoneScalpel
US	13973711	August 22, 2013	9622766	Issued	July 2035	Directed to a probe with head traversing window in deflectable sheath	BoneScalpel

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US	13927619	June 26, 2013	9320528	Issued	April 2034	Directed to an ultrasonic blade with micro-pores for coolant conduction	BoneScalpel
JP	2016523885	June 25, 2014	6727122	Issued	June 2034	Directed to an ultrasonic blade with micro-pores for coolant conduction	BoneScalpel
CA	2917015	June 25, 2014	2917015	Pending	June 2034	Directed to an ultrasonic blade with micro-pores for coolant conduction	BoneScalpel
US	15091349	April 5, 2016	10219822	Issued	November 2034	Directed to an ultrasonic blade with micro-pores for coolant conduction	BoneScalpel
US	2005196607	August 2, 2005	8343178	Issued	February 2029	Directed to an ultrasonic blunt blade method	BoneScalpel
JP	201939303	March 5, 2019	6857203	Issued	June 2034	Directed to an ultrasonic cutting blade with coolant conduction	BoneScalpel
US	2007809676	June 1, 2007	8353912	Issued	August 2030	Directed to an ultrasonic discectomy method and tool	BoneScalpel
US	13833385	March 15, 2013	10076349	Issued	March 2035	Directed to an ultrasonic drill	BoneScalpel
EP	14767324.8	March 11, 2014		Pending	March 2034	Directed to an ultrasonic drill	BoneScalpel
US	16/116255	August 29, 2018		Pending	March 2033	Directed to an ultrasonic drill	BoneScalpel
US	29/403580	October 7, 2011	700327	Issued	February 2028	Directed to an ultrasonic osteotome design	BoneScalpel
US	29/468786	October 3, 2013	715434	Issued	October 2028	Directed to an ultrasonic osteotome design	BoneScalpel
US	29/468789	October 3, 2013	715936	Issued	October 2028	Directed to an ultrasonic osteotome design	BoneScalpel
US	29/468790	October 3, 2013	715435	Issued	October 2028	Directed to an ultrasonic osteotome design	BoneScalpel
US	29/468793	October 3, 2013	715436	Issued	October 2028	Directed to an ultrasonic osteotome design	BoneScalpel
US	13268057	October 7, 2011	8894673	Issued	October 2031	Directed to an ultrasonic osteotome especially for skull and spine	BoneScalpel
CA	2851267	October 7, 2011	2851267	Issued	October 2031	Directed to an ultrasonic osteotome especially for skull and spine	BoneScalpel
JP	2014534709	October 4, 2012	6129855	Issued	October 2032	Directed to an ultrasonic osteotome especially for skull and spine	BoneScalpel
CN	201280055896	October 4, 2012	201280055896	Issued	October 2032	Directed to an ultrasonic osteotome especially for skull and spine	BoneScalpel
EP	12837901.3.0	October 4, 2012		Pending	October 2032	Directed to an ultrasonic osteotome especially for skull and spine	BoneScalpel
US	14513923	October 14, 2014	9421028	Issued	October 2031	Directed to an ultrasonic osteotome especially for skull and spine	BoneScalpel
US	13930170	June 28, 2013	9211137	Issued	March 2034	Directed to an ultrasonic probe with irrigant outlets in probe shank	BoneScalpel
EP	14816983.2	June 23, 2014		Pending	June 2034	Directed to an ultrasonic probe with irrigant outlets in probe shank	BoneScalpel
CN	201480025182.6	March 11, 2014	2014800251826	Issued	March 2034	Directed to an ultrasonic surgical drill and associated surgical method	BoneScalpel
JP	2016501240	March 11, 2014	6509802	Issued	March 2034	Directed to an ultrasonic surgical drill and associated surgical method	BoneScalpel
CA	2906512	March 14, 2014	2906512	Issued	March 2034	Directed to an ultrasonic surgical drill and associated surgical method	BoneScalpel
US	16/388512	April 18, 2019		Pending	April 2038	Directed to an ultrasonic surgical drill, assembly and associated surgical method	BoneScalpel
US	15147323	May 5, 2016	10405875	Issued	May 2037	Directed to an ultrasonic surgical instrument and method for manufacturing same	BoneScalpel
US	16/540376	August 14, 2019		Pending	May 2036	Directed to an ultrasonic surgical instrument and method for manufacturing same	BoneScalpel
US	16/540532	August 14, 2019		Pending	May 2036	Directed to an ultrasonic surgical instrument and method for manufacturing same	BoneScalpel
US	13930148	June 28, 2013	10398463	Issued	January 2036	Directed to an ultrasonic instrument and method for manufacturing same	BoneScalpel/ Sonastar
CA	2916967	June 23, 2014		Pending	June 2034	Directed to an eccentric-head ultrasonic probe with vibration damping	BoneScalpel/ Sonastar
EP	14818585.3	June 23, 2016		Pending	June 2034	Directed to an eccentric-head ultrasonic probe with vibration damping	BoneScalpel/ Sonastar
US	2003404374	April 1, 2003	7442168	Issued	October 2025	Directed to an ergonomic handpiece with vibration damping	BoneScalpel/ Sonastar
CN	201580031790.2	April 23, 2015	2015800317902	Issued	April 2035	Directed to a light source on handpiece: induction power, removable	BoneScalpel/ Sonastar
HK	1236784	April 23, 2015	1236784	Issued	April 2035	Directed to a light source on handpiece: induction power, removable	BoneScalpel/ Sonastar
CA	2947279	April 23, 2015		Pending	April 2035	Directed to a light source on handpiece: induction power, removable	BoneScalpel/ Sonastar

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US	14733260	June 8, 2015	10092741	Issued	August 2035	Directed to monitoring nerves, blood vessels during ultrasonic surgery	BoneScalpel/ Sonastar
US	16/126649	September 10, 2018		Pending	June 2035	Directed to monitoring nerves, blood vessels during ultrasonic surgery	BoneScalpel/ Sonastar
EP	15785631.1	April 23, 2015		Pending	April 2035	Directed to monitoring nerves, blood vessels during ultrasonic surgery	BoneScalpel/ Sonastar
JP	2018120871	June 26, 2018	6567738	Issued	August 2034	Directed to a probe with head traversing window in deflectable sheath	BoneScalpel/ Sonastar
CN	201480058010.9	August 6, 2014	201480058010.9	Issued	August 2034	Directed to a probe with head traversing window in deflectable sheath	BoneScalpel/ Sonastar
EP	14838072	August 6, 2014	3035875	Issued	August 2034	Directed to a probe with head traversing window in deflectable sheath	BoneScalpel/ Sonastar
EP	16808086	June 6, 2016	3322368	Issued	June 2036	Directed to a probe with meltable plastic part as end-of-life indicator	BoneScalpel/ Sonastar
JP	2017564047	June 6, 2016	6836518	Issued	June 2036	Directed to a probe with meltable plastic part as end-of-life indicator	BoneScalpel/ Sonastar
US	13931045	June 28, 2013	10182837	Issued	June 2033	Directed to a reinforced sheath connector for use with bent probes	BoneScalpel/ Sonastar
JP	2016536284	August 6, 2014	6362700	Issued	August 2034	Directed to a semi rigid sheath flexing to increase debriding depth	BoneScalpel/ Sonastar
CA	2820572	December 1, 2011		Pending	December 2031	Directed to time-reversal manufacturing of ultrasonic probes	BoneScalpel/ Sonastar
EP	11846265.4	December 1, 2011		Pending	December 2031	Directed to time-reversal manufacturing of ultrasonic probes	BoneScalpel/ Sonastar
CA	2921617	August 6, 2014	2921617	Issued	August 2034	Directed to an ultrasonic blade with micro-pores for coolant conduction	BoneScalpel/ Sonastar
EP	14847151	September 17, 2014	3049001	Issued	September 2034	Directed to an ultrasonic probe with end-of-life indicator	BoneScalpel/ Sonastar
US	2004981368	November 4, 2004	7717913	Issued	March 2028	Directed to ultrasonic probe with width- adjustable cautery applicator	BoneScalpel/ Sonastar
CA	2988741	June 6, 2016		Pending	June 2036	Directed to an ultrasonic surgery with nerve, blood monitoring	BoneScalpel/ Sonastar
CN	201680045155.4	June 6, 2016		Pending	June 2036	Directed to an ultrasonic surgery with nerve, blood monitoring	BoneScalpel/ Sonastar
HK	18112126	September 20, 2018		Pending	June 2036	Directed to an ultrasonic surgery with nerve, blood monitoring	BoneScalpel/ Sonastar
US	15873607	January 17, 2018	10675052	Issued	August 2036	Directed to debrider with cup-shaped head with serrated rim	BoneScalpel/ Sonastar
EP	16821973.1	July 7, 2016		Pending	July 2036	Directed to debrider with cup-shaped head with serrated rim	BoneScalpel/ Sonastar
US	14038463	September 26, 2013	10117666	Issued	July 2036	Directed to ultrasonic instrument and method using same	BoneScalpel/ Sonastar
CA	2992055	July 7, 2016		Pending	July 2036	Directed to probe with meltable plastic component	BoneScalpel/ Sonastar
US	14/795667	July 9, 2015		Pending	July 2035	Directed to probe with meltable plastic part as end-of-life indicator	BoneScalpel/ Sonastar
CN	201480060740.2	September 17, 2014	201480060740	Issued	September 2034	Directed to ultrasonic probe with end-of-life indicator	BoneScalpel/ Sonastar
US	13307691	November 30, 2011	10470788	Issued	November 2031	Directed to ultrasonic instrument, associated method of use and related manufacturing method	BoneScalpel/ Sonastar
US	14264705	April 29, 2014	10398465	Issued	April 2034	Directed to ultrasonic surgical instrument assembly, related accessory, and associated surgical method	BoneScalpel/ Sonastar
US	13558947	July 26, 2012	8659208	Issued	June 2028	Directed to digital waveform generator	neXus
US	13930253	June 28, 2013	9070856	Issued	August 2028	Directed to digital waveform generator	neXus
US	2007805940	May 25, 2007	8109925	Issued	November 2030	Directed to ultrasonic breast fibroid treatment	Sonastar
US	15664663	July 31, 2017	10543012	Issued	March 2038	Directed to reduction in electrical interference	Sonastar
CA	3032805	July 31, 2017		Pending	July 2037	Directed to reduction in electrical interference	Sonastar
CN	201780047901.8	July 31, 2017		Pending	July 2037	Directed to reduction in electrical interference	Sonastar
HK	19130085.4	July 31, 2017		Pending	July 2037	Directed to reduction in electrical interference	Sonastar
JP	2019505395	July 31, 2017		Pending	July 2037	Directed to reduction in electrical interference	Sonastar
EP	17837470.8	July 31, 2017		Pending	July 2037	Directed to reduction in electrical interference	Sonastar
US	14933784	November 5, 2015	10299809	Issued	April 2037	Directed to method for reducing biofilm formation	SonicOne
US	16126737	September 10, 2018	10973537	Issued	December 2036	Directed to method for reducing biofilm formation	SonicOne
US	16/269229	February 6, 2019		Pending	November 2034	Directed to method for reducing biofilm formation	SonicOne

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CA	3054427	March 5, 2018		Pending	March 2038	Directed to biofilm removal from prostheses	SonicOne
CN	201880028668.3	March 5, 2018		Pending	March 2038	Directed to biofilm removal from prostheses	SonicOne
HK	62020007120.2	March 5, 2018		Pending	March 2038	Directed to biofilm removal from prostheses	SonicOne
JP	2019548698	March 5, 2018		Pending	March 2038	Directed to biofilm removal from prostheses	SonicOne
EP	18763856.4	March 5, 2018		Pending	March 2038	Directed to biofilm removal from prostheses	SonicOne
CA	2992121	July 7, 2016		Pending	July 2036	Directed to ultrasonic wound treatment apparatus	SonicOne
CN	201680041420	July 7, 2016		Pending	July 2036	Directed to ultrasonic wound treatment apparatus	SonicOne
HK	18109516	July 23, 2018		Pending	July 2038	Directed to ultrasonic wound treatment apparatus	SonicOne
US	14797660	July 13, 2015	9872697	Issued	August 2036	Directed to ultrasonic wound treatment apparatus and associated method	SonicOne
US	14939552	November 12, 2015	10092308	Issued	October 2036	Directed to method for reducing biofilm formation	SonicOne
US	17/228901	April 13, 2021		Pending	November 2034	Directed to method for reducing biofilm formation	SonicOne
US	15450818	March 6, 2017	10470789	Issued	July 2037	Directed to method for reducing or removing biofilm	SonicOne
US	2006582746	October 18, 2006	9693792	Issued	December 2034	Directed to ultrasonic treatment method and apparatus with active pain suppression	SonicOne
CA	3032078	July 13, 2017		Pending	July 2037	Directed to removal of biofilm from prostheses and tools	SonicOne
CN	201780046208	July 13, 2017		Pending	July 2037	Directed to removal of biofilm from prostheses and tools	SonicOne
HK	19129580	July 13, 2017		Pending	July 2037	Directed to removal of biofilm from prostheses and tools	SonicOne
EP	17834961	July 13, 2017		Pending	July 2037	Directed to removal of biofilm from prostheses and tools	SonicOne
US	15221271	July 27, 2016	10463381	Issued	September 2037	Directed to ultrasonic surgical probe, assembly, and related method	SonicOne
US	29/404754	October 25, 2011	699839	Issued	February 2028	Directed to surgical shield	SonicOne
US	2007986424	November 21, 2007	9636187	Issued	March 2028	Directed to surgical shield	SonicOne
US	2006511853	August 29, 2006	8025672	Issued	December 2026	Directed to ultrasonic debridement probe with healing mode	SonicOne
CA	2661917	August 17, 2007	2661917	Issued	August 2027	Directed to ultrasonic debridement probe with healing mode	SonicOne
EP	7837032	August 17, 2007	2059179	Issued	August 2027	Directed to ultrasonic debridement probe with healing mode	SonicOne
EP	8705586	January 11, 2008	2234556	Issued	January 2028	Directed to ultrasonic debridement probe with scalloped head	SonicOne
CA	2711770	January 11, 2008	2711770	Issued	January 2028	Directed to ultrasonic debridement probe with scalloped head	SonicOne
US	2006511856	August 29, 2006	8430897	Issued	March 2028	Directed to ultrasonic debridement probe with scalloped head	SonicOne
CA	2602485	February 23, 2006	2602485	Issued	February 2026	Directed to ultrasonic debridement probe	SonicOne
US	200587451	March 23, 2005	7931611	Issued	October 2027	Directed to ultrasonic debridement probe	SonicOne
US	14172566	February 4, 2014	9949751	Issued	February 2034	Directed to ultrasonic debridement probe head with rake-like teeth	SonicOne
CN	201580017003	January 22, 2015	201580017003	Issued	January 2035	Directed to ultrasonic debridement probe head with rake-like teeth	SonicOne
HK	17105187	May 22, 2017	1231352	Issued	January 2035	Directed to ultrasonic debridement probe head with rake-like teeth	SonicOne
EP	15746296	January 22, 2015	3102126	Issued	January 2035	Directed to ultrasonic debridement probe head with rake-like teeth	SonicOne
JP	2016550183	January 22, 2015	6787784	Issued	January 2035	Directed to ultrasonic debridement probe head with rake-like teeth	SonicOne
US	15936785	March 27, 2018	10980564	Issued	June 2036	Directed to ultrasonic debridement probe head with rake-like teeth	SonicOne
CA	2938109	January 22, 2015		Pending	January 2035	Directed to ultrasonic debridement probe head with rake-like teeth	SonicOne
JP	2019504026	July 13, 2017		Pending	July 2037	Directed to ultrasonic surgical probe and assembly	SonicOne
US	16/573703	September 17, 2019		Pending	July 2036	Directed to ultrasonic surgical probe, assembly, and related method	SonicOne
US	17/098906	November 16, 2020		Pending	January 2038	Directed to ultrasonic surgical system for osseous transection	SonicOne

Country	Application Number	Filing Date	Patent Number	Application Status	Expected Expiration Date	Description	Product
EP	1903303	August 11, 2011	1903303	Issued	August 2026	Directed to ultrasonic wound treatment probe	SonicOne
EP	1736091	July 26, 2010	1736091	Issued	July 2025	Directed to ultrasonic wound treatment probe	SonicOne
US	29/372636	December 16, 2010	644326	Issued	August 2025	Directed to ultrasonic wound treatment probe	SonicOne
EP	16824918	July 7, 2016		Pending	July 2036	Directed to ultrasonic wound treatment apparatus and associated method	SonicOne
CA	3097746	April 18, 2019		Pending	April 2039	Directed to ultrasonic surgical drill, assembly and associated surgical method	Ultrasonic Waveform
CN	201980040119	April 18, 2019		Pending	April 2039	Directed to ultrasonic surgical drill, assembly and associated surgical method	Ultrasonic Waveform
JP	2020557971	April 18, 2019		Pending	April 2039	Directed to ultrasonic surgical drill, assembly and associated surgical method	Ultrasonic Waveform
EP	19788288	April 18, 2019		Pending	April 2039	Directed to ultrasonic surgical drill, assembly and associated surgical method	Ultrasonic Waveform