

**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, 2024

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37844

BIOVENTUS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

81-0980861

(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:

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

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 ☐

Non-accelerated filer ☐

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. ☐

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

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

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

As of June 29, 2024, 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 \$176.6 million.

As of February 27, 2025, there were 66,156,868 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 2025 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, 2024.

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TRADEMARKS, TRADE NAMES AND SERVICE MARKS

This Annual Report on Form 10-K (“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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (“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 concerning our future financial results and liquidity; the impact of our recently divested Advanced Rehabilitation Business on our financial condition and operations; our business strategy, position and operations; and expected sales trends, opportunities, market position and growth. 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*, which are summarized in the list below. 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.

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 Amended 2019 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 on an accelerated basis;
- the dilution of our Class A common stockholders upon the exchange of the outstanding common membership interests in BV LLC could adversely affect the market price of our Class A common stock and the resale of such shares could cause the market price of our Class A common stock to fall;
- if we fail to properly manage growth or scale our business processes, systems, or data management, our business could suffer;
- our ability to maintain our competitive position depends on our ability to attract, retain and motivate our senior management team and other highly qualified personnel necessary to execute our strategic plans;
- we are highly dependent on a limited number of products for revenue generation and profitability;
- we may face issues with respect to the supply of our products or their components due to product quality and regulatory compliance issues, including increased costs, disruptions of supply, shortages, contamination or mislabeling;
- we might require additional capital to fund our current financial obligations and support business growth;
- failure to establish and maintain effective financial controls could adversely affect our business and stock price;
- we maintain our cash at financial institutions, often in balances that exceed federally insured limits;
- we have been subject to securities class action litigation and currently have pending derivative shareholder lawsuits and may be subject to similar or other litigation in the future, which will require significant management time and attention, result in significant legal expenses and may result in unfavorable outcomes;
- our long-term growth may be limited by our inability to develop, acquire and commercialize new products, line extensions or expanded indications;
- 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;
- 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;
- 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 business may be adversely affected if consolidation in the healthcare industry leads to demand for price concessions or if one or more Group Purchasing Organizations (“GPO”), third-party payers or other similar entities exclude us from being a supplier;
- we may be unable to complete proposed acquisitions or to successfully integrate proposed or recent acquisitions in a cost-effective and non-disruptive manner;
- we may not realize the anticipated strategic or financial benefits from our business divestitures;
- pricing pressure from our competitors or hospitals may affect our ability to sell our products at prices necessary to support our current business strategies;
- 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;
- governments outside the United States may not provide coverage or reimbursement of our products;
- our future growth depends on physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness 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 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;
- we may not be able to strengthen our brand and the brands associated with our products;
- 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;
- 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 rely on a limited number of third-party manufacturers to manufacture certain of our products;
- actual, attempted, or perceived breaches of security, unauthorized access to or disclosure of information, cyberattacks, or other incidents could result in a material loss of business, substantial legal liability or significant harm to our reputation;
- our business subjects us to economic, political (including international tariffs), regulatory, currency, and other risks associated with international sales and operations;
- our products and operations, as well as our third-party manufacturers, 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 and could lead to significant civil or criminal penalties and other liability;
- 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;
- 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;
- 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 becomes available and is subject to audit and verification procedures that could result in material changes in the final data;
- 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 and/or sanctions by regulatory bodies;
- 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;
- our products may be subject to product recalls;
- 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;
- healthcare regulatory reform may affect our ability to sell our products profitably;
- 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 operations involve the use of hazardous and toxic materials, and we must comply with environmental, health and safety laws and regulations;
- if our facilities or those of our suppliers are damaged or become inoperable, we will be unable to continue to research, develop and manufacture our products;
- 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; and
- 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.

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 helping patients recover and live life to the fullest by relieving pain and addressing musculoskeletal challenges through a diverse portfolio of high-quality, innovative, and clinically-proven solutions. We manage our business through two reporting segments, U.S. and International, which accounted for 88% and 12%, respectively, of our total net sales during the fiscal year ended December 31, 2024.

Our portfolio of products is comprised of five patient-focused areas, grouped into three businesses based on clinical use: (i) Pain Treatments, (ii) Surgical Solutions and (iii) Restorative Therapies.

- Pain Treatments, comprised of:
 - **Knee Osteoarthritis (“KOA”) area:** Our product portfolio includes a range of intra-articular, hyaluronic acid (“HA”) injections that help relieve patient discomfort and improve quality of life.
 - **Peripheral Nerve Stimulation (“PNS”) area:** We are focused on developing a full portfolio of peripheral nerve stimulation products with solutions for acute, temporary and chronic pain.
- Surgical Solutions, comprised of:
 - **Ultrasonics:** Our Ultrasonics business offers precision bone resection for patients with degenerative spine conditions and spinal deformities. This portfolio also enables precision ultrasonic neuro and general surgery to address brain tumors and pathologies of the liver and other organs.
 - **Bone Graft Substitutes (“BGS”):** Our product portfolio includes a range of products that facilitate optimal bone fusion following a surgical procedure.
- Restorative Therapies, comprised of:
 - **Fracture Care:** We provide low-intensity pulse ultrasound to help patients who suffer from bone fractures that do not heal through traditional methods. We plan to expand our United States clinical indications to address the healing of fresh fractures, especially for high-risk patients.

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 *Part II, Item 8. Financial Statements and Supplementary Data—Notes to the Consolidated Financial Statements—Note 14. Segments* of this Annual Report. Our products are described in additional detail below under “Our products.”

Our growth strategy

The four-pronged strategy to reach our goals across our patient-focused areas includes the following:

- 1) **Further develop and market our surgical solutions business.** We are focused on establishing BoneScalpel as a standard of care for spine applications by accelerating market penetration in spinal surgery through increased surgeon education and awareness. In parallel, we plan to leverage the versatility of our neXus platform and its existing install base to expand into additional specialties like neurosurgery and general surgery. To continue expanding our presence in target surgical markets, we plan to leverage our clinical data to solidify our BGS portfolio as a sustainable alternative to higher-priced premium biologics.
- 2) **Strategically grow our international markets.** We intend to focus our international business on current markets which present the greatest growth opportunities, and where our portfolio can maintain and increase profitable growth over time, either through direct or distributor-based channels. We also plan to strategically expand to new markets with our existing portfolio and intend to selectively pursue new market opportunities.
- 3) **Strengthen our leading position in Knee Osteoarthritis.** We are focused on continued market share growth of HA in the United States through targeted high-potential account execution. To increase pull-through, we plan to increase HCP awareness of the clinical differences of our single injection product, Durolane. We intend to expand beyond our unique positioning as the only company to offer one-, three- and five- injection treatment regimens by evaluating further potential portfolio opportunities in the KOA area.

- 4) **Expand our portfolio through strategic partnerships and internal development.** We are focused on broadening and innovating our portfolio of products within key market segments for our patient-focused areas. To achieve this, we will prioritize opportunities for strategic partnerships that provide the biggest benefit for patients, customers, and our business. Internally, we rely on a team of highly trained individuals to develop new products, conduct clinical investigations and assist in training healthcare providers on the clinical benefits and the safe and effective use of our products.

Our products

We offer a diverse portfolio of products to support physicians in relieving pain and addressing musculoskeletal challenges across indications and clinical areas, including knee, hand and upper extremities, foot and ankle, podiatry, trauma, general surgery, spine and neurosurgery. Our portfolio of products helps patients across care settings, such as a physician's office or clinic, ambulatory surgical centers ("ASCs") or in the hospital setting, and is grouped based on clinical use: (i) Pain Treatments, (ii) Surgical Solutions and (iii) Restorative Therapies.

Pain Treatments

Our Pain Treatment portfolio includes HA products for KOA and PNS devices for pain relief. Our HA products are designed to work with the body's biological processes, providing a natural lubricant into the joint and providing relief for mild to moderate pain, improving mobility, and helping the patient return to their normal activities. Our PNS product targets peripheral nerve pain at its source without the use of drugs and its small profile allows the system to be implanted in many locations on the body, depending on patient needs.

DUROLANE®

Durolane is an U.S. Food & Drug Administration-approved, sterile, transparent and viscoelastic gel that is a single injection therapy that is indicated in the United States for the symptomatic treatment of osteoarthritis ("OA") in the knee in patients who have failed to respond adequately to conservative non-pharmacological therapy and simple analgesics. Durolane is also indicated in certain markets outside the United States for the hip, ankle and shoulder, as well as for treatment of other small orthopedic joints. 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 internationally.



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 KOA in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics. The solution treats KOA by providing temporary replacement for the diseased synovial fluid and restoring the 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 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 KOA who failed to adequately respond to conservative nonpharmacological therapy and simple analgesics. The solution treats KOA 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 StimRouter Peripheral Nerve Stimulation 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. We currently market StimRouter in the United States and internationally.

Developmental and clinical pipeline for Pain Treatments



The TalisMann Pulse Generator and Receiver is an accessory to the StimRouter PNS system and is designed to provide more powerful stimulation to the targeted peripheral nerve, potentially enabling physicians to address chronic pain of a peripheral nerve origin in larger, deeper, or damaged nerves. TalisMann has a small profile and is attached to the StimRouter lead intraoperatively and pocketed under the skin after the StimRouter lead electrodes are placed near the targeted peripheral nerve. Though not currently available, the 510(k) submission to the FDA for market clearance of the TalisMann was completed in the fourth quarter of 2024.

Surgical Solutions

Our Surgical Solutions portfolio is comprised of two patient-focused areas – Ultrasonics and Bone Graft Substitutes. Our Ultrasonics products are used for precise bone cutting and sculpting, soft tissue management (i.e., tumor and liver resections) and tissue debridement in various surgeries including minimally invasive applications, primarily in the areas of orthopedic surgery, neurosurgery, general surgery, wound, plastics/reconstruction, and cranio-maxillo-facial surgery. Our surgical product portfolio is also comprised of clinically efficacious bone graft solutions to meet a broad range of patient needs and procedures. Bone grafting is a surgical procedure used to promote fusion of spinal vertebrae, fill bone voids, fix bones that are damaged from trauma or problem joints, or to facilitate growing bones around an implanted device, such as spinal hardware (i.e., cages and rods), total knee replacements and long bone fixation. Our products are designed to improve bone fusion rates following spine and other orthopedic surgeries, including trauma and reconstructive foot and ankle procedures.



The neXus Ultrasonic Surgical System (“neXus”) is a leading ultrasonic surgical platform that combines all the features of our Surgical Solutions applications, including BoneScalpel, BoneScalpel Access, SonaStar Elite, SonicOne and SonaStar into a single fully integrated system, setting a foundation for future developments to fulfill unmet customer needs. The neXus platform is driven by a proprietary digital algorithm designed to deliver more power, efficiency, and control for the surgeon. The device incorporates technology that allows for intuitive set-up and use. The neXus system allows for safe and efficient resection of hard and soft tissue, limiting collateral damage to adjacent tissue as compared to conventional surgical instruments, and can be used in a variety of different surgical specialties. In addition, neXus provides users a simple and intuitive system enabled via a digital touchscreen display and smart system set-up across all applications. This allows a hospital to access all of our Ultrasonic product offerings in this all-in-one console. We currently market the neXus Ultrasonic Surgical System in the United States and internationally.



The BoneScalpel is a state of the art, surgical solution enabling precise cuts in hard tissue (e.g., bone). The device allows for the preservation of surrounding soft tissue structures because of its mechanism-of-action, which is micro-reciprocating movements. This device enables 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.

In addition, the BoneScalpel Access handpiece and its accessories provide surgeons with a new option for confined spaces during minimally invasive surgery, enabling safe and powerful bone removal with maximum visualization. BoneScalpel Access allows for en bloc resection and the shaving and sculpting of bone, with built-in irrigation and aspiration with improved ergonomics for the end user. We currently market BoneScalpel and BoneScalpel Access in the United States and certain international markets.



The SonaStar System provides powerful and precise ablation and removal of soft tissue. SonaStar has been used for a wide variety of surgical procedures applying both open and minimally invasive approaches, including neurosurgery and general surgery. In addition to soft tissue applications, SonaStar may be used with hard tissue tips to enable precise shaping or shaving of bony structures that prevent access to partially or completely hidden soft tissue masses.

Our SonaStar Elite handpiece and accessories expand the frequency capabilities of the neXus System, adding 36 kHz capabilities. While the neXus system can be used in many clinical applications including neurosurgery, the SonaStar Elite handpiece has been cleared for resection of tumors with varying consistencies ranging from soft to firm, including the removal of brain and spinal tumors. The SonaStar Elite handpiece represents the latest innovation in the neXus ultrasonic surgical pipeline. We currently market SonaStar System and SonaStar Elite 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 healthy and viable tissue structures' higher elasticity and flexibility than necrotic tissue and resistance 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 faster patient healing. We currently market SonicOne primarily in the United States.



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 (e.g., fibers, putty, sponge and granules) that is processed with bone marrow cells to maintain the wide array of growth factors present in native bone. OSTEOAMP Flowable is designed to be moldable and easy to use, with a convenient, ready to use syringe. In the second quarter of 2024, we received FDA approval for the cannula-based delivery system, which allows us to target minimally invasive spine and other key orthopedic surgeries with enhanced delivery of our Flowable product. Donor bone is sourced from AATB-certified and FDA-registered tissue banks in the United States. All tissues are screened for the standard panel of infectious viruses. We currently market OSTEOAMP in the United States.



SIGNAFUSE contains a synergistic combination of biomaterials that supports new bone formation which is indicated for standalone 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 kick-start osteogenesis. In 2023, Bioventus received FDA clearance for expanded indications. We expect our expanded indication for the use of SIGNAFUSE in spinal procedures, specifically for filling cages, to continue driving growth of the product. We currently market SIGNAFUSE in the United States.



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. 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 United States. All tissues are screened for the standard panel of infectious viruses. We currently market PUREBONE in the United States.



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 of use during surgery. 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 of 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 in the extremities, posterolateral spine and pelvis. We currently market Reficio DBM in the United States.

Developmental and clinical pipeline for Surgical Solutions

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 Solutions portfolio. To meet growing market demand and specifically the needs of surgeons, we continue to partner or develop product extensions on our surgical technology platforms, including the neXus, OSTEOAMP and SIGNAFUSE platforms.

Restorative Therapies

Our Restorative Therapies business focuses on addressing patients whose healing is at-risk due to metabolic disorders and comorbidities, such as diabetes, smoking and osteoporosis. Our portfolio is positioned to expand our impact for patients by leveraging EXOGEN to serve as an adjunctive and preventative therapy for healthcare professionals to incorporate into their practice during early-stage fracture treatment.



EXOGEN is an ultrasound bone stimulation 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 30 years and is FDA-approved 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 stimulation 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 United States for the non-invasive treatment of established nonunion fractures excluding skull and vertebra fractures, 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 United States, Canada, Europe and Japan, and approved for marketing in Australia, New Zealand, Saudi Arabia, Turkey and the UAE.

Product revenue

Products from our Pain Treatments, Restorative Therapies and Surgical Solutions groups are sold by direct sales teams in the United States and a complementary indirect sales 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 integrated healthcare delivery networks (“IDNs”), GPOs and payers. Internationally, we sell our products through a mix of direct and indirect sales teams and distributors. 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 the activities of industry participants. We believe that the principal competitive factors in our markets are product features, value-added solutions, reliability, clinical and economic 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, greater R&D resources 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), Zimmer Biomet Holdings, Inc. and Sanofi S.A, OrthogenRx Inc. (Avanos) and for peripheral nerve stimulation specifically we compete with SPR Therapeutics, Nalu and Stimwave.

Our Surgical Solutions products compete with products from Medtronic, DePuy Orthopaedics, Inc. (Johnson & Johnson), Stryker Corporation, NuVasive, Inc., Orthofix Medical Inc., Zimmer Biomet Holdings, Inc., 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., Enovis and XFT 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, 2024, we owned 77 issued U.S. patents and four pending U.S. patent applications relating to our material products. We also owned 114 issued foreign patents and 21 pending foreign patent applications directed to our material products. Our patents and patent applications as of December 31, 2024 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 two issued U.S. patents, and 18 issued foreign patents directed to our OSTEOAMP product, including foreign patents in Europe, Asia, Canada and Australia. The issued U.S. patents are expected to expire in 2029. The issued foreign patents are expected to expire in 2029.

We also own 11 issued U.S. patents and 17 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 39 issued U.S. patents, 50 issued foreign patents, and 11 pending foreign patent applications directed to our BoneScalpel system, including foreign patents and patent applications in Australia, Canada, Europe, and Japan. The U.S. patents are expected to expire between 2025 and 2039, and the foreign patents are expected to expire between 2027 and 2039. The pending patent applications, if issued, are expected to expire between 2034 and 2039, without accounting for potential patent term extensions and adjustments.

We also own 19 issued U.S. patents, 20 issued foreign patents, and six pending foreign patent applications directed to our SonicOne System, including foreign patents and patent applications in Australia, Canada, and Europe. The U.S. patents are expected to expire between 2025 and 2039, and the foreign patents are expected to expire between 2026 and 2038. The pending patent applications, if issued, are expected to expire between 2037 and 2038, without accounting for potential patent term extensions and adjustments.

We also own two issued U.S. patents, two issued foreign patent, and one pending foreign patent application directed to our Sonastar System. The U.S. patents are expected to expire between 2030 and 2037, and the foreign patents are expected to expire in 2037.

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

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

Trademarks

We own registered trademarks for Bioventus, BoneScalpel, BoneScalpel Access, Durolane, EXOGEN, GELSYN-3, Misonix, neXus, OSTEOAMP, Osteofuse, PureBone, SIGNAFUSE, Sonastar, SonaStar Elite, SonicOne, TalisMann and StimRouter 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 Bioventus' confidential information and 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 such rights are irrevocable, no assurance can be given that these arrangements will continue to be made available to us on financial terms that are acceptable to us, or at all. The terms of our license 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 facility located in Cordova, Tennessee. We believe our manufacturing operations comply 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 and elsewhere.

Some of our products and product components are manufactured exclusively by single-source third-party manufacturers, pursuant to multi-year supply agreements that 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 may encounter difficulty in obtaining materials, supplies and components adequate for our anticipated short-term needs. 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 of products.

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

In the United States, the majority of our products are regulated as medical devices by the FDA. 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 premarket approval (“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 typically 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 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 PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendment 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. The 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. In such cases, 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 impose 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 the 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 Quality System Regulation ("QSR").

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitutes 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 provides 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 the FDA deems them 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”, which is an acronym for human cell, tissue, and cellular and tissue-based products. 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, Biological License Applications (“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 which 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 Section 361 HCT/Ps, HCT/Ps regulated as “Section 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 Investigational New Drug (“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, the 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

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 for human therapeutic or prophylactic use 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 or post-market 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 events, 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) and/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 by 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”). The majority of our current certificates have been granted under the EU Medical Devices Directive 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 all of our devices not currently certified under the new requirements set forth in the EU Medical Devices Regulation receive such certification when the 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 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 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. Generally, 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 continues to evolve. 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 their EU Medical Devices Directive certificate expires, 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.

Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices. The Regulation introduces a staggered extension of the transition period provided for in Regulation (EU) 2017/745 on medical devices (MDR), subject to certain conditions. The transition period of medical devices to MDR has been extended until December 31, 2027 or December 31, 2028 depending on the classification of the medical device. The transition provisions covers products with CE certificates issued under the Medical Devices Directive (MDD) set to expire before the date of application. The amended Article 120(2), the extension of validity for these devices will, however, apply only if one of the following conditions is met:

- (i) The manufacturer has signed a written agreement with a Notified Body for the conformity assessment of the device in question *at the moment* of expiry,
- (ii) a national competent authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59 of the MDR; or
- (iii) a national competent authority has required the manufacturer to carry out the conformity assessment procedure within a specific time period in accordance with Article 97 of the MDR.

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 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 EU Medical Devices 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. Legislation has been approved to extend the transition dates for the EU MDR to 2027/2028. Despite the extension, the notified bodies that are responsible for implementing the EU MDR guidelines must still adopt these changes into their current framework of procedures, which could take additional time.

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 Statute, False Claims Act and other healthcare laws

We are subject to a number of U.S. laws regulating healthcare fraud, waste, and abuse (“FWA”) including without limitation the federal Anti-Kickback Statute (“AKS”) and the federal Physician Self-Referral Law (known as the Stark Law), the Civil False Claims Act, the civil prohibition on beneficiary inducements, and the Health Insurance Portability and Accountability Act of 1996, as amended (“HIPAA”), as well as numerous state laws and regulations regarding healthcare and insurance services. These laws are enforced by, without limitation, CMS, other divisions of the U.S. Department of Health and Human Services (“HHS”), including the HHS Office of Inspector General (“OIG”), 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 aimed at curbing FWA, generally: (1) prohibit providing 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 FWA 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 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 that would otherwise be prohibited by the statute. Failure to meet the requirements of an applicable AKS exception or safe harbor, however, does not render an arrangement illegal. Rather, the government must 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 those arrangements may be subject to greater scrutiny by enforcement agencies. Criminal penalties and administrative sanctions for violating the AKS include civil penalties exceeding \$130,000 per violation plus three times the amount of the improper remuneration, criminal penalties up to \$100,000 per violation, prison terms, and exclusion from participation in the federal health care programs. Under the Civil Monetary Penalties statute, physicians who pay or accept kickbacks also face substantial civil penalties and treble damages.

Any 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”) is prohibited by the Stark Law 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 prohibited referral. Unlike the AKS, the Stark Law is a strict liability statute, meaning that the law has been 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. If the Stark Law applies and the elements of an applicable exception have not been met, then the government is prohibited from paying for such services and any amount paid pursuant to a non-compliant financial relationship must be reimbursed to the government. In addition to reimbursing the government any associated overpayment, violations of the Stark Law can lead to civil penalties of \$15,000 per claim or \$100,000 per willful violation, depending on the nature of the violation.

The FCA prohibits a person from knowingly presenting, or causing 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. In addition, knowingly concealing or decreasing an obligation to pay the government (or reimburse, in the case of an overpayment) can create liability under the reverse false claims provision of the statute. Overpayments must be repaid to the government within 60 days of the time the provider or supplier determines (or reasonably should have determined through the exercise of reasonable diligence) that it received an overpayment. 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, known as *qui tam* relators, are also able 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). Such relators, often current or former employees or competitors, share in any amounts paid to the government in fines or settlement. FCA liability can include three times the amount of damages sustained by the government due to the fraudulent activity, possible civil monetary penalties up to \$23,331 (adjusted annually for inflation) per claim, exclusion from participating in federal healthcare programs, and possible criminal charges, resulting in additional fines and imprisonment.

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 (also known as “beneficiary inducements”). Moreover, in certain cases, providers who routinely waive co-payments 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 beneficiary inducements prohibition is non-routine, unadvertised waivers of co-payments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The OIG 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 co-payments 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.

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.

Many states in which we operate have also adopted similar fraud and abuse laws to those 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 or state 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 (if 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.

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, average selling price (“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. Our SUPARTZ FX, GELSYN-3 and Durolane products are reimbursed under Medicare Part B and, as a result, we provide ASP data on these products to CMS on a quarterly basis.

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. The FCPA also requires us to maintain accurate books and records and have a system of internal controls sufficient to, among other things, provide reasonable assurances that transactions are executed and assets are accessed and accounted for in accordance with management’s authorization. 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. We are also subject to the United Kingdom and Brazilian equivalents, the United Kingdom Bribery Act and the Brazil Clean Company Act.

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 data 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, which may occur in connection with, among other things, 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, penalties, and damages 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, including without limitation the California Consumer Privacy Act (“CCPA”), the California Privacy Rights Act (“CPRA”), General Data Protection Regulation (“GDPR”) and the United Kingdom General Data Protection Regulation (“UK GDPR”), govern the privacy and data 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 data 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.

The current federal administration has granted the U.S. DOGE Service Temporary Organization, broad discretionary authority to eliminate inefficiency, fraud, waste, and abuse in government and to eliminate excessive regulation. It is unclear what effect these efforts at overhauling the federal administrative state will have on the administration or viability of federal healthcare programs and FDA and CMS' ability to oversee and administer those programs.

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.

Consolidated Appropriations Act

In July 2022, in connection with the Consolidated Appropriations Act, 2021 ("CAA"), the Centers for Medicare and Medicaid Services ("CMS") began utilizing new pricing information the Company reported to it pursuant to the newly adopted reporting obligations to adjust the Medicare payment to healthcare providers using our Durolane and GELSYN-3 products.

Employee and Human Capital Resources

As of December 31, 2024, we had approximately 930 employees, none of whom were covered by collective bargaining agreements. Most of these employees are located in the United States with approximately 98 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 our 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 noncontrolling interest representing the LLC Interests held by Smith & Nephew, Inc. (“Continuing LLC Owner”). Refer to *Part II, Item 8. Financial Statements and Supplementary Data—Notes to the Consolidated Financial Statements—Note 8. Stockholders’ equity* of this Annual Report for additional information about the organizational transactions completed as part of the IPO.

Information about our Executive Officers

The following table sets forth information concerning our executive officers as of March 1, 2025:

Name	Age	Position(s)
Robert E. Claypoole	53	President and Chief Executive Officer
Mark L. Singleton	56	Senior Vice President and Chief Financial Officer
Anthony D’Adamio	64	Senior Vice President and General Counsel
Katrina Church	63	Senior Vice President and Chief Compliance Officer

Robert Claypoole joined Bioventus in January 2024 as President and Chief Executive Officer and as a member of the Board of Directors from Mölnlycke Health Care (“Mölnlycke”), a world-leading medical products and solutions company, where he served as Executive Vice President of Wound Care since July 2021. In this role, Mr. Claypoole had full responsibility for a \$1.2 billion business. Before that, Mr. Claypoole served in several leadership positions with Mölnlycke from March 2017 to July 2021, including Executive Vice President and President, US for Mölnlycke and as an Officer of Mölnlycke Health Care US, LLC and Mölnlycke Manufacturing US, LLC. Prior to joining Mölnlycke in 2017, Mr. Claypoole served in various leadership roles at Medtronic Ltd. (now Medtronic plc (NYSE: MDT)), a global healthcare technology company, and Covidien, before it was acquired by Medtronic. Mr. Claypoole was Global Vice President & General Manager, Obesity & Metabolic Health (April 2016 to March 2017) and Global Vice President & General Manager of the Soft Tissue Repair & Hemostats business (December 2012 to April 2016). Before that, he was the Vice President, Executive Operations after serving as Vice President, Global Marketing while located in Trevoux, France. Prior to his time in France, Mr. Claypoole was the Vice President, US Marketing for the company’s Endomechanical & Intelligent Device business. Before joining Covidien in 2007, Mr. Claypoole held various marketing roles with increasing responsibility at Johnson & Johnson’s Vision Care division. Mr. Claypoole previously served on the board of directors of ZetrOz Inc. (January 2014 to January 2016) and the Association of periOperative Registered Nurses (December 2017 to December 2020). Mr. Claypoole received his Bachelor of Arts and his Masters of Business Administration from Cornell University.

Mark Singleton has served as our Senior Vice President and Chief Financial Officer since March 2022. Mr. Singleton previously served as Vice President of Finance, Americas Strategic Business Units at Teleflex Inc. (“Teleflex”), a provider of specialty medical devices, from February 2021 to March 2022 and prior to that, served as Teleflex’s Vice President of Finance, Vascular Strategic Business Unit from 2014 to 2020. Prior to Teleflex, Mr. Singleton held multiple leadership roles at Lenovo Group Limited, a multinational technology company, including as Executive Director, Think Business Group Chief Financial Officer (2013-2014), Executive Director, Western Europe Chief Financial Officer (2011-2012), Executive Director, North America Chief Financial Officer (2007-2011) and Director, U.S. Finance Manager (2005-2007). Mr. Singleton received his Bachelor of Science from Purdue University and his Master of Business Administration from Duke University, Fuqua School of Business.

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 Healthineers 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 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 from Duke University.

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 stockholder meetings, 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 are 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 financial position

Our Amended 2019 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 the Amended 2019 Credit Agreement, including, but not limited to:

- a minimum interest coverage ratio and a maximum debt leverage ratio requirement as defined in the Amended 2019 Credit Agreement;
- minimum Liquidity (as defined in the Amended 2019 Credit Agreement) of not less than \$10.0 million as of the end of each calendar month through October 29, 2025;
- 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 Amended 2019 Credit Agreement.

In the absence of a waiver from our lenders, any failure by us to comply with these covenants in the future might result in the declaration of an event of default, which could adversely affect our business, results of operations and financial position.

In addition, our indebtedness could have significant consequences on our financial position, 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; and
- limiting our ability to obtain additional financing for working capital, capital expenditures, debt service requirements and general corporate or other purposes.

See *Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations—Indebtedness* for further discussion concerning our indebtedness.

We might require additional capital to fund our financial and operating obligations and support business growth.

If our expected cash from operations together with available borrowings under our Amended 2019 Credit Agreement are not sufficient to fund our current financial and operating obligations, we might require additional capital. In addition, we intend to continue to make investments to support our business growth and might require additional funds to respond to business challenges or opportunities, including the need to further develop our current products and any new products, enhance our operating infrastructure, and acquire complementary businesses. Accordingly, we might need to engage in equity or additional debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer significant dilution, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock. Any additional debt financing secured by us could involve restrictive covenants relating to our capital-raising activities and other financial and operational matters, which might make it more difficult for us to obtain additional capital and to pursue business opportunities, including potential acquisitions. In addition, we might not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, our ability to continue to support our business growth and to respond to business challenges could be significantly limited.

Failure to establish and maintain effective financial controls could cause us to have material weaknesses and financial misstatements due to error, which could adversely affect our business and stock price.

We are required to comply with the SEC's rules implementing Sections 302, 404 and 906 of the Sarbanes-Oxley Act of 2002, which require management to certify financial and other information in our quarterly and annual reports, provide quarterly and annual management reports on the effectiveness of disclosure controls and procedures, and provide annual management reports on the effectiveness of internal controls over financial reporting. Though we are required to disclose changes made in our internal controls and procedures on a quarterly basis and assess internal controls over financial reporting on an annual basis, our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 until we are no longer an emerging growth company pursuant to the provisions of the JOBS Act. 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.

We have undertaken various actions to comply with the requirements of being a public company. However, 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 financial misstatements due to error or material weaknesses. If we identify any material weaknesses in the future that we cannot fully remediate, the accuracy and timing of our financial reporting may be adversely affected. Testing and maintaining financial controls can also divert our management's attention from other matters that are important to the operation of our business. Ineffective disclosure controls and procedures or internal control over financial reporting could cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our Class A common stock.

Additionally, when evaluating our financial controls, we may identify material weaknesses in our internal controls 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 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.

We maintain our cash and cash equivalents at financial institutions, in accounts where the balance exceeds federally insured limits (“FDIC”).

We maintain the majority of our cash and cash equivalents in accounts at a banking institution in the United States that we believe is of high quality. Cash held in these accounts exceed the FDIC insurance limits. If such banking institution were to fail we could lose all or a portion of the amounts held in excess of such insurance limitations. In the event of failure of the financial institution where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or any delay in accessing these funds could adversely affect our business and financial position.

Risks related to our business

We are currently subject derivative shareholder lawsuits and have been defendants in securities class action litigation and may be subject to similar or other litigation in the future, which will require significant management time and attention, result in significant legal expenses and may result in unfavorable outcomes, which may have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock.

We are, and may in the future become, subject to various legal proceedings and claims that arise in or outside the ordinary course of business. In particular, we are a party to derivative shareholder litigation described under the below heading “Legal Proceedings.”

The results of such lawsuits and any future legal proceedings might not be able to be predicted with certainty. Also, our assets may be insufficient to cover any claimed amounts that exceed our insurance coverage, and we may have to pay damage awards or otherwise may enter into settlement arrangements in connection with such claims. Regardless of the merits of these claims, any such payments or settlement arrangements in current or future litigation could have a material adverse effect on our business, operating results or financial condition. Even if the plaintiffs’ claims are not successful, current or future litigation could result in substantial costs and significantly and adversely impact our reputation and divert management’s attention and resources, which could have a material adverse effect on our business, operating results and financial condition, and negatively affect the price of our common stock. In addition, such lawsuits may make it more difficult to finance our operations.

We are highly dependent on a limited number of products for revenue generation and profitability.

Our HA products accounted for 46%, 43% and 42% of our total revenue for the years ended December 31, 2024, 2023 and 2022, 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 in each of our current product areas. If the supply and distribution agreements for any of our HA products were terminated, or if our efforts to commercialize these products prove unsuccessful, 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 may be limited by our inability 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 across our current product portfolio, our long-term growth may be negatively affected.

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.

If we fail to properly manage growth or scale our business processes, systems, and data management, our business could suffer.

We may, in the future, 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 supply chain, inventory management, product services, sales processes and distributor network require significant management, training, financial and other supporting resources. System limitations may result in increased cost, delayed execution, and errors. Any failure by us to manage our growth effectively could adversely affect our ability to achieve our development and commercialization goals.

To achieve our long-term revenue goals, we also will need to 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 during any growth period, 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.

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 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.

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

Third-party manufacturers generally manufacture our HA products, EXOGEN components, certain Surgical Solutions products, PNS and our rehabilitation devices. We have developed in-house assembly capabilities for certain of our products, such as our EXOGEN system. We and our third-party manufacturers are required to comply with the Quality System Regulation (“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 and complaint handling, 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.

Our reliance on different contractor manufacturers to supply certain of our products and their components may result in wide variability in manufacturing processes, product quality and regulatory compliance. If we or our third-party manufacturers fail to maintain facilities in accordance with the FDA’s QSR, our products may suffer from product quality issues and the noncomplying party could lose the ability to manufacture our products on a commercial scale. Such issues may result in increased costs, disruptions in supply, contamination and mislabeling of products, and 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 (including natural events caused by or intensified by climate change), global pandemics, 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.

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 Orthopedic and Rehabilitation Devices Panel of the FDA Medical Devices Advisory Committee met and ultimately voted in favor of the FDA's proposal to down-classify non-invasive bone growth stimulators.

While the 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 is not deemed medically necessary or otherwise does not meet applicable payment criteria or if the policyholder's healthcare insurance benefits are limited. Further, 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.

Private payers may adopt coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services ("CMS"), the federal agency that administers the Medicare program in the United States, as guidelines in setting their coverage and reimbursement policies. In addition, CMS periodically reviews medical study literature to determine how the literature addresses certain procedures and therapies in the Medicare population. 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 establish additional limitations on coverage of our products, 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.

Further, legislative or other regulatory reforms that have been adopted or may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies or other downward pressure on the pricing or reimbursement we or our customers receive for our products. For example, the Consolidated Appropriations Act, 2021 ("CAA") was signed into law on December 27, 2020, and pursuant to implementing regulations promulgated by CMS, expanded price reporting obligations for manufacturers of certain products reimbursed under Medicare Part B beginning January 1, 2022, including all of our HA viscosupplements. In July 2022, CMS began utilizing the new pricing information we reported to it pursuant to these newly adopted reporting obligations to adjust the Medicare payment to healthcare providers using our Durolane and GELSYN-3 products. As a result, the rates available for those products beginning in July 2022 were reduced from those previously available and are subject to future reporting and adjustment, which may affect the demand for those products or our ability to sell them profitably. We cannot predict the extent to which this law, or other reimbursement reform proposals or other healthcare cost containment measures that might be enacted in the future, may impact the demand or commercial success of our HA viscosupplements and other products we sell or plan to commercialize in the future.

In addition, due to the manner in which rebates are calculated and paid under certain of our contracts with private payers, changes in the ASP for our HA viscosupplements may result in larger than expected rebates payments for the sale of these products. In addition, we are dependent on these payers to provide timely and accurate invoices for the rebates that we are obligated to pay under these contractual relationships. If the information is not received timely or is inaccurate, we may not be able to correctly forecast the amounts due under those agreements, which may adversely affect our operating results and financial condition.

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.

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 for our HA viscosupplements, have been issued by the White House and proposed and enacted by Congress.

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 Group Purchasing Organization ("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, IDNs 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, which may vary significantly across our product portfolio. 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 potential acquisitions. 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.

We may not realize the anticipated strategic or financial benefits from our business divestitures, which may adversely affect our results of operations and financial condition.

We have in the past divested of certain of our businesses, including most recently our Advanced Rehabilitation business, to help improve our focus on our core businesses and improve our liquidity. However, we may be unable to achieve some or all of the anticipated strategic and financial benefits following our business divestitures, as their anticipated benefits are based on a number of assumptions, some of which may prove incorrect. Any divestiture we undertake is subject to a variety of known and unknown risks and uncertainties. In addition, the anticipated benefits related to any divestiture may take longer to realize than expected, and a failure to achieve the anticipated financial and strategic benefits of a divestiture could be disruptive to our operations and could have a material adverse impact on our business, results of operations, financial condition and cash flows. Further, even if we do realize some or all of the anticipated strategic and financial benefits following our divestitures, we may face indemnity and other liability claims by the acquirer or other parties.

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, IDNs and GPOs have intensified competitive pricing pressure as a result of industry trends and new technologies. Purchasing decisions are 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 that third-party payers are willing to reimburse our customers for procedures using our products, including as 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 healthcare 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 is 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 competitors 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 have 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, change levels of coverage and/or reimbursement for our HA products 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 and to execute our strategic plans, depends on our ability to attract, retain and motivate our senior management team and other 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 cost 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, including 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, such awards may cease to be viewed as valuable and 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.

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 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 policies that we believe provide appropriate levels of coverage, 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 46%, 43% and 42% of total net sales for the years ended December 31, 2024, 2023 and 2022, respectively. 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, certain of our devices require circuit boards and other electronic components that could be 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 of our bone graft substitute 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, 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.

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 access to or disclosure of information, cyberattacks, or other incidents or the perception that personal and/or other sensitive or confidential information in our possession or control or in the possession or control of our vendors or service providers 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 directly and through third-party vendors and service providers a large amount of information, including personally identifiable information, protected health information 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 comply 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 and other forms of cyberattacks, misplaced or lost data, programming and/or human errors, and other similar events. A party, whether internal or external, that is able to circumvent our security measures or those of our third-party vendors and service providers could, among other things, misappropriate or misuse sensitive or confidential information, misappropriate 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 those of our vendors and service providers, and we expect that we may in the future continue to experience, among other things, external attacks on our network, and attempts to gain unauthorized access to sensitive and confidential information, such as reconnaissance probes, denial of service attempts, malware attacks, malicious software attacks and phishing attacks, such as an external phishing incident that occurred in January 2023, targeting an employee with plausible-sounding prompts to send information to Company leadership. This security incident did not expose protected health information, or affect any of the company's systems, and was reported to authorities in the relevant regions. 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, level of persistence, and sophistication, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. 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 cyberattacks on companies have resulted in the unauthorized access to and acquisition of significant amounts of sensitive and confidential information and the disruption of important systems and services. These incidents demonstrate the sophistication of the threat actors and magnitude of the threat posed to companies across the nation, including the health care industry. For example, a vendor informed us that Change Healthcare, a subsidiary of UnitedHealth Group that acts as an intermediary for processing certain of our claims for reimbursement related to our EXOGEN device to commercial payers, experienced an incident in which a cybersecurity threat actor gained access to some of its information technology systems. As a result of the Change Healthcare incident, certain of our patient billing and collections processes were disrupted. We have identified an alternative claim processing intermediary and resumed claims submissions, but this incident caused delays in a portion of our claims submissions to some commercial payers thereby delaying the related cash remittances to us. As of the date of this Annual Report, UnitedHealth Group is still investigating this incident, including any potential impact on claims and patient data. We do not presently believe that the Change Healthcare incident has materially affected, or is reasonably likely to materially affect the Company, including with respect to our claims collection and cash flows. We continue to evaluate the impact of the Change Healthcare incident on our Company.

If an individual or entity is able to gain unauthorized access to our systems or those of our vendors or service providers, the individual or entity could access, acquire, or alter any information located therein or cause interruptions to our operations. Security breaches and other incidents could also damage our reputation and expose us to a risk of monetary loss and/or litigation, fines, sanctions, and reputational damage. We also face risks associated with security breaches and other incidents affecting third parties that conduct business with us or our customers and others who interact with our data, as well as incidents affecting service providers of these third parties.

We cannot assure you that our vendors or 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, cyberattacks or other incidents negatively impacting the privacy or security of sensitive or confidential information or our vendors' or service providers' ability to provide services to us, 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 due diligence safeguards will protect us from the risks associated with the processing, storage and transmission of such information by vendors, service providers and others acting on our behalf.

While we maintain insurance that covers certain security and privacy breaches, we may not carry 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.

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, cyberattacks, terrorism, energy loss, telecommunications failure, security breaches, 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, some of our manufacturing facilities and suppliers of our products and product components are located outside the United States, including in Israel. Accordingly, our future results could be harmed by a variety of factors associated with international sales and operations, including:

- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- unexpected changes in tariffs, trade barriers and regulatory requirements, export licensing requirements or other restrictive actions by the United States or foreign governments;
- 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;
- exposure of our foreign operations to liability under 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 disadvantages of competing against companies from countries that are not subject to 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;
- 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;
- exposure to liability under a variety of local, national and multinational laws and regulations in multiple jurisdictions, including data privacy laws, healthcare and pharmaceutical laws, antitrust and competition laws, anti-bribery and anti-corruption laws and international trade laws;
- 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 (including the current conflicts between Russia and Ukraine and between Israel and Hamas), global pandemics or natural disasters including earthquakes, hurricanes, floods and fires. If the current conflicts between Russia and Ukraine and between Israel and Hamas escalate or spill over to or otherwise impacts additional regions, it could heighten many of the other risk factors included in our SEC filings.

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.

International tariffs, including tariffs applied to goods traded between the United States and countries such as Mexico, Canada, China, and, other countries and 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 countries such as Mexico, Canada, China, and other countries, may adversely affect our business, results of operations and financial condition. Since the beginning of 2018, there has been increasing discussion, 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. In 2025, the new political administration in the United States has indicated that it intends to impose tariffs in pursuing government policy and has already imposed several new tariffs, including tariffs on goods and materials from Mexico, Canada and China. When changes are made to United States tariffs, other countries may reciprocate, and have reciprocated, with tariffs imposed against the United States. Whether and to what extent these tariffs will remain in place or additional tariffs will be imposed remains uncertain, but if tariffs are imposed or increased by either the United States or other countries, it may impact the cost of goods, the price of our products and demand for our products, particularly in countries impacted by such tariffs. The institution of trade tariffs globally also carries the risk of adversely affecting overall global economic conditions, which could have a negative impact on us.

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 the 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.

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;
- post market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury;
- post market 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 Regulations 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. Refer to *Part I, Item 1A. Risk Factors—Risks related to government regulation—Regulatory reforms, such as the EU Medical Devices Regulation, could limit our ability to market and distribute our products after clearance, approval or certification is obtained and make it more difficult or costly for us to obtain regulatory clearance, approval or certification of any future products, which could adversely affect our competitive position and materially affect our business and financial results.*

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 and could lead to significant civil or criminal penalties and other liability.

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 Certificates of Medical Necessity (“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 to oversee, train and monitor our employees’ compliance with those procedures, 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 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 state 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 the 510(k) pathway or approval of an application for Pre-market Approval (“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 Pain Treatment products, including Durolane, GELSYN-3 and SUPARTZ FX, and our EXOGEN system, have obtained a PMA. 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 its 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. If the mass layoffs that began at the FDA in February 2025 continue, or are not reversed, then the clearance and approval process may be extended even longer. 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. If the FDA disagrees with our decision not to seek a new 510(k) or PMA 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:

- if we are unable 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;
- if the data from our preclinical studies and clinical trials may be insufficient to support clearance or approval, where required; and
- if 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 post market 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 applications for a PMA or foreign regulatory approvals of new products, new intended uses or modifications to existing products;
- withdrawals of current 510(k) clearances, 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 and the EU, 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 introduced that could significantly change the statutory provisions and regulations governing the approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, the 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.

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 United States, 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. 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, cGMP, 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, PMA or BLA approvals before marketing. 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, a PMA, 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 a PMA, 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 “Section 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.

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, is 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 and/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 and StimRouter products. As a result, we could be subject to regulatory or enforcement actions if we are 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 liability risks to us for product and medical malpractice related claims. 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 and related 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 medical device reporting 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 medical device reporting 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 FDA's 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. 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 drugs, devices and similar 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. In addition, we have in the past and may in the future decide to voluntarily recall our products if certain deficiencies are found. For example, in December 2020 we undertook 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 was 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 and notified patients to discard gel bottles from affected 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-party contractors 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, non-clinical and preclinical programs. Switching or adding additional third-party contractors 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 abroad, legislative and regulatory reforms 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, 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. Efforts to reform the marketplace for healthcare services are ongoing and are expected to increase in the new administration, and 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, the Budget 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. 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. Legislative and regulatory reforms and executive actions intended to reduce the costs of prescription drugs and medical devices are also ongoing in the United States and abroad. 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, could 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.

In our capacity as a pharmaceutical and medical device manufacturer, as a supplier of covered items and services to federal healthcare program beneficiaries, and with respect to items and services for which we submit claims for reimbursement from such programs, we are subject to healthcare fraud, waste 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. Penalties for violating the AKS include civil penalties of up to \$124,732 per violation plus three times the amount of the improper remuneration, criminal penalties up to \$100,000 per violation, prison terms of up to ten years, and exclusion from participation in the federal healthcare programs. Under the Civil Monetary Penalties statute, physicians who pay or accept kickbacks also face penalties of up to \$50,000 per kickback plus three times the amount of the prohibited remuneration;
- the federal physician self-referral law, the Stark Law, which, subject to certain enumerated statutory and regulatory exceptions, prohibits physicians from referring Medicare or Medicaid patients to an entity for the provision of certain designated health services, or “DHS”, which includes both prescription drugs and medical devices, 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. In addition to reimbursing the government any associated overpayment, violations of the Stark Law can lead to: (1) civil penalties of nearly \$30,868 per claim (in 2024, adjusted annually for inflation); (2) three times the amount of damages suffered by the government; and (3) potential exclusion from participation in federal healthcare programs;
- 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. Penalties for a violation of the FCA include fines up to \$27,894 for each false claim, plus up to three times the amount of damages caused by each false claim. 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 beneficiary inducement provisions of the Civil Monetary Penalties Law, which prohibits, 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. Violations of the CMPL may result in CMPs of \$24,947 and in administrative penalties ranging up to \$100,000 per violation depending on the conduct involved;
- 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. Civil monetary penalties of up to \$1,000,000 as adjusted annually may be imposed on reporting entities if they fail to report information in a timely, accurate or complete manner;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm customers;
- federal government price reporting laws;

- privacy and data security requirements imposed by HIPAA, including the Privacy Rule, the Security Rule, and the Breach Notification Rule promulgated pursuant to HIPAA; 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 substantial 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 and related overpayment obligations, 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 related to this matter to the OIG pursuant to the OIG's Provider Self-Disclosure Protocol. 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 in resolution of this matter.

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 privacy and data security, including, in the United States, HIPAA and, in the EU, the GDPR. New privacy laws and regulations are being enacted in the United States, particularly at the state level, and globally, and existing ones are being updated and strengthened. Complying with these numerous, complex, and often changing regulations is expensive and difficult. We strive to comply with all applicable laws and other legal obligations relating to privacy, data security, and data protection. However, given that the scope, interpretation, and application of these laws and regulations are often uncertain and may be conflicting, it is possible that these obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and/or in a manner that conflicts with our practices. Failure or perceived failure by us or our vendors or service providers to comply with any privacy, data security, or data protection laws or other obligations, or any security incident or data breach experienced by us, one of our vendors service providers, or another party, could adversely affect our business. Such impacts include but are not limited to: investigation costs, legal fees, fines and penalties; compensatory, special, punitive, and statutory damages; enforcement actions; litigation; reputational damage; consent orders regarding our privacy and security practices; requirements that we provide consumer notices, credit monitoring services, and/or credit restoration services or other relevant services to individuals impacted by a data breach; adverse actions against our licenses to do business; and injunctive relief.

In the United States, HIPAA, as amended, and regulations implemented thereunder (collectively referred to as “HIPAA”) imposes, among other things, certain standards relating to the privacy and security of protected health information (“PHI”) on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that generally involve creating, receiving, maintaining or transmitting PHI 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 administrative, physical and technical safeguards to protect PHI. HHS recently updated the HIPAA Privacy Rule and proposed updates to the HIPAA Security Rule. These developments could pose compliance challenges for us.

Additionally, under the HIPAA Breach Notification Rule, covered entities must report breaches of unsecured PHI to affected individuals without unreasonable delay, not to exceed 60 days following discovery of the breach or, if earlier, the date on which the breach would have been discovered through the exercise of reasonable diligence. Notification also must be made to the U.S. Department of Health and Human Services Office for Civil Rights and, in certain circumstances, 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 or, if earlier, the date on which the breach would have been discovered through the exercise of reasonable diligence. All U.S. states, the District of Columbia, Guam, Puerto Rico, and the U.S. Virgin Islands have enacted data breach notification laws. Some of these breach notification laws impose notification obligations that are in addition to, or inconsistent with, the HIPAA Breach Notification Rule, which can present compliance challenges.

Entities that are found to be in violation of HIPAA, which may occur in connection with, among other things, 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. The HHS Office for Civil Rights actively enforces HIPAA and frequently issues significant fines and penalties. HIPAA also authorizes state Attorneys General to file suit on behalf of residents of their states. 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.

U.S. states have adopted various 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 California Consumer Privacy Act (“CCPA”), as amended by the California Privacy Rights Act (“CPRA”), creates individual privacy rights for California residents and imposes additional privacy and security obligations on covered businesses, including data use limitations and audit requirements. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches. The CPRA created the California Privacy Protection Agency, which is authorized to issue substantive regulations and enforce law. Additional states, including Colorado, Connecticut, Delaware, Florida, Indiana, Iowa, Kentucky, Maryland, Minnesota, Montana, Nebraska, New Hampshire, New Jersey, Oregon, Rhode Island, Tennessee, Texas, Utah, and Virginia have enacted similar comprehensive privacy laws. Other states, including Nevada and Washington, have recently enacted robust health privacy laws. Legislation has been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. These developments are likely to result in increased privacy and data security enforcement. Additional compliance investment and potential business process changes may be required, and the enactment of new laws could have potentially conflicting requirements that would make compliance challenging and burdensome.

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, including based on allegations that companies are engaged in unfair or deceptive trade practices. 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 addition to enforcing against organizations, the FTC has made clear that it may seek to hold officers personally liable for privacy or security violations of their organizations, having done so in the past.

In Europe, the GDPR imposes strict requirements for processing personal data. 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 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 in 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board (“EDPB”). The United States and the EU agreed to a new data transfer mechanism to replace the Privacy Shield known as the EU-U.S. Data Privacy Framework, which may be subject to legal challenges. In addition to the GDPR, EU member states impose additional, and sometimes inconsistent, data protection requirements. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the SCCs cannot be used, and take additional enforcement actions, 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, impose challenges associated with the geographical location or segregation of our relevant systems and operations, and adversely affect our financial results. Failure to comply with the GDPR can result in fines up to the greater of €20 million (approximately \$21 million), or 4% of global revenue.

Additionally, following the United Kingdom’s departure from the EU, we have also had to comply with 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 \$22 million), or 4% of global revenue. However, the relationship between the United Kingdom and the EU 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 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, among other things, to 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, other anti-bribery legislation, including the UK Bribery Act and the Brazil Clean Company Act, or 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 and the Department of State. These regulations limit our ability to market, sell, distribute or otherwise transfer our products or technology to prohibited countries or persons, or for prohibited end-uses. 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, billing, and claims 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.

Regulatory reforms, such as the EU Medical Devices Regulation, could limit our ability to market and distribute our products after clearance, approval or certification is obtained and make it more difficult or costly for us to obtain regulatory clearance, approval or certification of any future products, which could adversely affect our competitive position and materially affect our business and financial results.

The EU Medical Devices Regulation, which became effective in May 2021, was adopted with the aim of ensuring better protection of public health and patient safety. Among other things, the EU Medical Devices Regulation (“MDR”) imposed 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 Europe after the effective date of the EU MDR until the associated CE mark certificates expire, securing renewals of our existing CE mark certificates to allow for continued marketing of the product after CE mark expiration or obtaining certifications for new products requires the performance of certain conformity assessment procedures by a notified body. Notified bodies are independent organizations designated by EU member states which are responsible for, among other things, auditing and examining a product’s technical dossiers and the manufacturers’ quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which allows the manufacturer to place the CE mark on the device and for it to be marketed throughout the EU. Given the additional requirements of the MDR, the renewal of our existing CE mark certificates once they expire or obtaining certifications for new products is more challenging, time consuming and costly.

For example, technical documentation for certain of our products requiring recertification, such as our single injection HA treatment Durolane, and EXOGEN Bone Stimulation System have been submitted to our notified body. While Durolane recently received EU MDR certification, we are actively engaged with our notified body to renew the CE marks for these and our other products. The inability to timely review and obtain CE mark certificates for these and other of our products could prohibit their distribution and marketing in EU member states, which would adversely affect our business, prospects, financial condition and results of operations.

We may be subject to environmental, social and governance (“ESG”) regulations or stakeholder requirements which may negatively impact our business or adversely affect our relationship with customers.

Across industries, companies are facing increasing requirements to disclose information about social and environmental risks and increasing pressure to improve performance on aspects of sustainability, such as climate impact and product environmental performance, that go beyond currently enacted legislative or regulatory mandates. Several of our customers are adopting, or may adopt in the future, sustainability policies that influence how they make purchasing decisions. Due to the complex nature of our supply chain, we may not always have direct influence over our ability to meet new customer sustainability expectations or policies, which may harm our customer relationships and reputation and may result in an impact on our revenue. Further, new and emerging ESG reporting and disclosure requirements may be unpredictable and expensive to comply with. Our ability to meet stakeholder ESG expectations may not keep up with industry peers which may negatively impact our ability to attract and retain talent.

Recent environmental regulatory actions regarding medical device sterilization facilities could result in disruptions in the supply of certain of our products and could adversely affect our business, results of operations and financial condition.

Our disposable products that are used with our neXus Ultrasonic Surgical Aspirator System require sterilization using ethylene oxide prior to sale. Ethylene oxide sterilization is a common and scientifically proven sterilization method that is widely used in the medical device industry. We contract with third-party sterilizers to perform this service. Concerns about unsafe levels of ethylene oxide emissions in the air around some sterilization facilities have resulted in certain state environmental protection agency actions against those facilities that have impacted available capacity for medical device manufacturers to sterilize their devices. For example, recently the operations of certain of our contracted sterilization providers were temporarily suspended by the supplier as a voluntary response to a state environmental agency investigation. While such actions have not disrupted our ability to supply products and the previously shut down facilities have been permitted to resume certain operations after implementation of increased emissions controls, it is uncertain as to whether these facilities will be shut down or experience capacity reductions related to environmental, health and safety concerns. In March 2024, the U.S. Environmental Protection Agency finalized rules governing emissions from ethylene oxide sterilization facilities. It is unknown whether any other sterilization facilities we may contract with in the future will experience reduced capacity related to new regulatory requirements or will be required to shut down, either temporarily related to upgrading emissions controls or permanently due to inability to comply with the new environmental regulations. To the extent that our third-party sterilizers are unable to sterilize our products, whether due to these regulatory or other limitations (such as capacity, reductions in operations, or availability of materials for sterilization), we may be unable to transition to other third-party sterilizers, sterilizer locations or sterilization methods in a timely or cost effective manner, or at all, which could have a material adverse impact on our 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.

We do not have redundant manufacturing facilities and have one primary location for manufacturing in the Memphis, Tennessee area. 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 disasters (including events caused by or intensified by climate change) 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.

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, copyright, trade secret and trademark laws, and nondisclosure, confidentiality and other contractual restrictions in our consulting, employment, and other 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 other third parties 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, superior to, or otherwise competitive with those of ours, and our business could suffer. In addition, the patents we own or have licenses to 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 patent 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 the inventors of any patents licensed to us 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 or the owners of any patent rights licensed to us 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, similar to, or competitive with 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 in each jurisdiction in which the product is marketed. 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 or 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 the scope 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 or other ultimate owner of such patents 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 or other ultimate owners of such patents 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, the inventors of any in-licensed patent rights, 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, the filing party(ies) of any in-licensed patent rights, 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 TRA, which we expect could be significant. See *Part III, Item 13. Certain Relationships and Related Transactions, and Director Independence-Tax Receivable Agreement* in this Annual Report 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 the 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 changes 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 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 December 31, 2024, the Original LLC Owners control approximately 41.8% 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.

Risks related to our ownership of our Class A common stock

The dilution of our Class A common stockholders upon the exchange of the outstanding common membership interests in BV LLC could adversely affect the market price of our Class A common stock and the resale of such shares could cause the market price of our Class A common stock to fall.

As provided in the amended and restated limited liability agreement of Bioventus LLC (“BV LLC”), the holders (the “Selling Securityholders”) of common membership interests in BV LLC (the “LLC Interests”) may, from time to time, exchange their LLC Interests for newly issued shares of our Class A common stock on a one-for-one basis. On October 25, 2024, the Company filed a registration statement on Form S-3 (“Form S-3”) to in part register for resale 35,038,052 shares of our Class A common stock held by the Selling Securityholders, of which 15,786,737 shares are issuable upon the exchange of their outstanding LLC Interests. The issuance of shares of our Class A common stock upon the exchange of LLC Interests would significantly dilute the ownership interest of our Class A common stockholders and the resale of such shares by the Selling Securityholders pursuant to the Form S-3 once declared effective, or the perception in the market that the Selling Securityholders intend to sell such shares, could adversely affect the market price of our Class A common stock.

Our stock price may be volatile or may decline regardless of our operating performance, and you may not be able to resell your shares of Class A common stock at or above the price at which you purchase them.

The stock market historically has experienced extreme price and volume fluctuations. As a result of this volatility, you might not be able to sell your Class A common stock common stock at or above the price at which you purchase it. From our initial public offering in February 2021 through February 27, 2025, the per share trading price of our Class A common stock has been as high as \$19.94 and as low as \$0.80. It might continue to fluctuate significantly in response to various factors, some of which are beyond our control. These factors include:

- our operating performance and the operating performance of similar companies;
- the overall performance of the equity markets;
- any major change in our management;
- changes in laws or regulations relating to our products;
- announcements by us or our competitors of acquisitions, business plans, or commercial relationships;
- threatened or actual litigation;
- publication of research reports or news stories about us, our competitors, or our industry, or positive or negative recommendations;
- general political and economic conditions.

Additionally, securities class action litigation has often been instituted against companies following periods of volatility in the overall market and in the market price of a company’s securities. This litigation, if instituted against us, could result in substantial costs, divert our management’s attention and resources, and harm our business, operating results, and financial condition.

Our amended and restated certificate of incorporation, as amended, 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, as amended, 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.

Certain 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.

Certain provisions of our amended and restated certificate of incorporation, as amended, our second amended and restated bylaws and Delaware law could render more difficult, delay or prevent transactions that stockholders consider favorable, including transactions in which you might otherwise receive a premium for your shares of our common stock. These provisions might also prevent or frustrate attempts by our stockholders to replace or remove management, and include provisions that:

- authorize 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;
- establish a classified Board so that not all members of our Board are elected at one time, which is currently being phased out and will be discontinued beginning with our 2026 annual meeting of stockholders;
- provide the removal of directors only for cause, provided directors may be removed with or without cause beginning with our 2026 annual meeting of stockholders;
- prohibit the use of cumulative voting for the election of directors;
- limit the ability of stockholders to call special meetings or amend our bylaws;
- require all stockholder actions to be taken at a meeting of our stockholders; and
- establish 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, which could in turn limit the opportunity for our stockholders to receive a premium for their shares of our common stock and affect the price that some investors are willing to pay for our common stock.

Our amended and restated certificate of incorporation, as amended, provides that the Court of Chancery of the State of Delaware will be, to the fullest extent permitted by law, 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, as amended, provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware, or the Court of Chancery, will be, to the fullest extent permitted by law, 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, as amended, or our second amended and restated 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 in our amended and restated certificate of incorporation, as amended does not designate the Court of Chancery as the exclusive forum for any claim for which the applicable statute creates exclusive jurisdiction in another forum and, accordingly, does not apply to any claims brought to enforce any liability or duty created by the Exchange 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, as amended, 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.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced disclosure requirements applicable to us will make our Class A common stock less attractive to investors.

We are 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 reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including, for example, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, 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 of our periodic reports, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements 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 some of these reduced reporting obligations and exemptions in our SEC filings and expect to continue to do so in future SEC filings.

In addition, emerging growth companies can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. However, we have chosen 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 we have annual gross revenues of at least \$1.235 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,” as such terms is defined in the Exchange Act rules.

Even after we no longer qualify as an emerging growth company, we may still qualify as a smaller reporting company and rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations including regarding executive compensation.

We cannot predict if investors will find our Class A common stock less attractive because we may rely on the reduced disclosure requirements and exemptions applicable to emerging growth companies and/or smaller reporting companies. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

Bioventus maintains a cybersecurity risk management program that is designed to enable us to assess, identify, and manage risk associated with cybersecurity threats (the “Cybersecurity Program”). Our Cybersecurity Program is based on standards promulgated by the National Institute of Standards and Technology (“NIST”) and the United States Cybersecurity and Infrastructure Security Agency (“CISA”) and includes the following elements:

- Identification and assessment of cybersecurity threats based on periodic internal and external assessments and monitoring, information from internal stakeholders, and external publications and resources such as those made available by CISA.
- Technical and organizational safeguards designed to protect against identified threats, including documented policies and procedures, technical controls, and employee education and awareness.
- Processes designed to detect the occurrence of cybersecurity events and to respond to and recover from cybersecurity incidents.
- A third-party risk management process designed to manage cybersecurity risks associated with our service providers, suppliers, and vendors.

Our Cybersecurity Program is regularly evaluated by internal and external experts with the results of those reviews reported to senior management and the Audit and Risk Committee of the Board of Directors. We also actively engage with key vendors, industry participants and threat intelligence communities as part of our continuing efforts to evaluate and enhance the effectiveness of the Cybersecurity Program.

Integration of Risk Management Process

Assessing, identifying, and managing cybersecurity-related risks is integrated into our overall risk management framework. The Cybersecurity Program is integrated into our enterprise risk management program and framework. These programs are designed to foster a company-wide culture of appropriate cybersecurity risk management. Our IT Security team works closely with stakeholders across technology, legal, risk, and business operations to implement and monitor the effectiveness of the Cybersecurity Program.

Engagement of Third Parties in Connection with Risk Management

The Company engages a range of external experts to assist in its assessment, identification, and management of risks from cybersecurity threats. These include cybersecurity consultants and external auditors to review the Company's cybersecurity posture and responsive efforts. Our relationships with these external partners enable us to leverage their expertise with the goal of maintaining best practices.

Oversight of Third-Party Risks

Our third-party service providers, suppliers, and vendors face their own risks from cybersecurity threats that could impact Bioventus in certain circumstances. We have implemented processes for overseeing and managing these risks. Those processes include assessing the third parties' information security practices before allowing them to access our information systems or data, requiring the third parties to implement appropriate cybersecurity controls and otherwise agree to contractual requirements designed to address cybersecurity risks in our agreements with them, and conducting ongoing monitoring of their compliance with those requirements.

Risks from Cybersecurity Threats

As of the date of this Annual Report, we have not encountered any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect the Company, including its business strategy, results of operations, or financial condition. However, incidents impacting data processed and systems maintained or operated by us or on our behalf, and incidents otherwise impacting our operations, can and do occur. For example, Change Healthcare, a subsidiary of UnitedHealth Group that acts as an intermediary for processing certain of our claims for reimbursement related to our EXOGEN device to commercial payers experienced an incident in which a cybersecurity threat actor gained access to some of its information technology systems. As a result of the Change Healthcare incident, certain of our patient billing and collections processes were disrupted. We have identified an alternative claim processing intermediary and have resumed claims submissions, but this incident caused delays in a portion of our claims submissions to some commercial payers thereby delaying the related cash remittances to us. As of the date of this Annual Report, UnitedHealth Group is still investigating this incident, including any potential impact on claims and patient data. We do not presently believe that the Change Healthcare incident has materially affected, or is reasonably likely to materially affect the Company, including with respect to our claims collection and cash flows. We continue to evaluate the impact of the Change Healthcare incident on our Company.

Governance

The oversight of Bioventus' Cybersecurity Program falls under the purview of the Company's Director of IT Security, Risk and Compliance, who has over 25 years of combined technical and leadership experience, with the past 18 years focused on information security and technology risk management, and holds Certified Information Systems Security Professional (CISSP) and Certified Information Security Manager (CISM) certifications.

The Audit and Risk Committee of the Board of Directors is primarily responsible for the oversight of risks from cybersecurity threats, and is regularly briefed on the Company's Cybersecurity Program by the Vice President of Information Technology and/or Director of IT Security, Risk and Compliance. These briefs include updates on the Company's cyber risks and threats, the status of projects to strengthen our information security systems, assessments of the information security program, and the emerging cybersecurity threat landscape.

The Director of IT Security, Risk and Compliance implements and oversees our processes for regularly monitoring our information systems and detecting and reporting cybersecurity incidents. That process includes convening an incident response team composed of the Director of IT Security, Risk and Compliance, Vice President of Information Technology, Chief Compliance Officer, and General Counsel. The incident response team is responsible for overseeing the assessment of and response to any cybersecurity incident and for monitoring the Company's mitigation and remediation efforts. The incident response team is also responsible for informing executive management, the Audit and Risk Committee and, where appropriate, the Board of Directors, regarding the detection, mitigation, and remediation of cybersecurity incidents.

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, and Valencia, California. In addition, our international operations occupy leased office spaces in Hoofddorp, Netherlands and Mississauga, Canada. 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.

Bioventus shareholder litigation

On January 12, 2023, the Company and certain of its current and former directors and officers were named as defendants in a putative class action lawsuit filed in the Middle District of North Carolina (the “Court”), *Ciarciello v. Bioventus Inc.*, No. 1:23–CV – 00032–CCE–JEP (M.D.N.C. 2023). The complaint asserted violations of Sections 10(b) and 20(a) of the Exchange Act and of Sections 11 and 15 of the Securities Act and generally alleges that the Company failed to disclose certain information regarding rebate practices, its business and financial prospects, and the sufficiency of internal controls regarding financial reporting. The complaint seeks damages in an unspecified amount. On April 12, 2023, the Court appointed Wayne County Employees’ Retirement System as lead plaintiff. The plaintiff’s amended consolidated complaint was filed with the Court on June 12, 2023. On July 17, 2023, the defendants filed a motion to dismiss the complaint raising a number of legal and factual deficiencies with the amended consolidated complaint. In response to the defendants’ motion to dismiss, the lead plaintiff filed a second amended complaint on July 31, 2023. The defendants moved to dismiss the second amended complaint on August 21, 2023, which the Court granted in part and denied in part on November 6, 2023. The Court dismissed the plaintiff’s Securities Act claims, but allowed the plaintiff’s Exchange Act claims to proceed into discovery.

On July 15, 2024, a Stipulation and Agreement of Settlement (the “Settlement Agreement”) by and between the lead plaintiff and the defendants was filed with the Court and the Court preliminarily approved the Settlement Agreement on August 13, 2024. The Court entered judgment on December 18, 2024, granting final approval of the terms of the Settlement Agreement and dismissing all claims against the defendants, including the Company. The parties settled without any admission of liability or wrongdoing by any party. The settlement amount of \$15.3 million, together with interest earned thereon, has been paid by the defendants and/or the defendant’s insurers. The Company incurred \$13.8 million of net shareholder litigation costs (including estimated settlement and reimbursement) during the year ended December 31, 2024 under the Settlement Agreement, which were recorded in selling, general and administrative expense within the consolidated condensed statements of operations and comprehensive loss.

On October 4, 2023, certain of the Company’s current and former directors and officers were named as defendants in a derivative shareholder lawsuit (in which the Company is a nominal defendant) filed in the United States District Court for the District of Delaware, *Grogan, on behalf of Bioventus Inc., v. Reali, et al.*, No. 1:23-CV-01099-RGA (D. Del. 2023). The complaint asserts violations of Section 14(a) of the Exchange Act, breaches of fiduciary duties and related state law claims, and a claim for contribution, and generally alleges the same purported misconduct as alleged in the *Ciarciello* case. On January 12, 2024, the Court agreed to stay this case pending resolution of the *Ciarciello* case.

On February 9, 2024, another plaintiff filed a derivative shareholder lawsuit against certain of the Company’s current and former directors and officers (in which the Company is a nominal defendant) in the United States District Court for the District of Delaware, *Sanderson, on behalf of Bioventus Inc., v. Reali, et al.*, No. 1:24-cv-00180-RGA (D. Del. 2024). Like the *Grogan* case, this case asserts violations of Section 10(b) of the Exchange Act, breaches of fiduciary duties and related state law claims, and a claim for contribution, and generally alleges the same purported misconduct as alleged in the *Ciarciello* case. On May 1, 2024, the parties filed a stipulation to consolidate the two derivative matters and stay them on terms similar to those entered in the *Grogan* case. On May 2, 2024, the United States District Court for the District of Delaware granted the stipulation and ordered the consolidation of the *Sanderson* and *Grogan* cases, captioned *In re Bioventus Inc. Derivative Litigation*, Case No.: 1:23-cv-01099-RGA. The Court also stayed the consolidated case. Following resolution of the *Ciarciello* case, on December 30, 2024, the plaintiffs in the consolidated case filed an amended complaint asserting the same claims as in the *Grogan* case against certain of the Company’s current and former directors and officers. On January 6, 2025, the Court entered a scheduling order, under which the defendants had until March 3, 2025, to file a motion to dismiss the amended complaint. On February 21, 2025, the parties submitted a joint stipulation to stay the proceedings to allow the parties time to negotiate a settlement, which the company expects to be in the form of governance reforms.

On July 31, 2024, another plaintiff filed a derivative complaint against certain of the Company’s current and former officers and directors, naming Bioventus as a nominal defendant only, in the United States District Court for the Middle District of North Carolina, captioned *Vince v. Reali*, No. 1:24-cv-006390CCEJEP (M.D.N.C. 2024). Like the *Grogan* case, the *Vince* case asserts violations of Section 14(a) of the Exchange Act, breaches of fiduciary duties, unjust enrichment, contribution, and waste and generally alleges the same purported misconduct as alleged in the in the *Ciarciello* case. On November 11, 2024, the defendants filed a motion to transfer the *Vince* case to the United States District Court for the District of Delaware, pursuant to the forum selection clause in Bioventus’s certificate of incorporation. On January 14, 2025, the Court granted the motion and transferred the *Vince* case to the District of Delaware. On February 14, 2025, the plaintiff requested voluntary dismissal of the *Vince* case without prejudice and the Court granted the request that same day.

On February 20, 2025, plaintiff Jeffrey Vince refiled a Verified Stockholder Derivative Complaint against certain of Bioventus' current and former officers and directors, naming Bioventus as a nominal defendant only, in Delaware Chancery Court, captioned *Jeffrey Vince v. Kenneth M. Reali et al.*, C.A. No. 2025-0192-LWW (Del. Ch.). Like his prior complaint, which he voluntarily dismissed, *Vince* asserts breaches of fiduciary duties, unjust enrichment, contribution, and waste, and generally alleges the same purported misconduct as alleged in the *Ciarciello* case. The Defendants have not yet been served.

On February 26, 2025, plaintiff James Bouchereau filed a Verified Stockholder Derivative Complaint against certain of Bioventus's current and former officers and directors, naming Bioventus as a nominal defendant only, in Delaware Chancery Court, captioned *James Bouchereau v. Kenneth M. Reali et al.*, C.A. No. 2025-____-____ (Del. Ch.). The complaint is identical to the *Vince* complaint and asserts breaches of fiduciary duties, unjust enrichment, contribution, and waste, and generally alleges the same purported misconduct as alleged in the *Ciarciello* case. The Defendants have not yet been served.

On February 6, 2025, purported stockholder Jae Hyung Jung served a litigation demand, requesting that the Board take action against certain directors and officers for alleged breaches of fiduciary duties, gross mismanagement, unjust enrichment, waste, aiding and abetting in connection with the same conduct at issue in the litigations. On February 7, 2025, the same purported stockholder, Jung, served a settlement demand, requesting that the Company adopt certain corporate governance reforms and agree to certain monetary payments. The Company has not yet responded to either demand.

The Company believes the claims alleged in the above derivative matters lack merit and intends to defend itself vigorously. Except as described above, the outcomes of these matters are not presently determinable, and any loss is neither probable nor reasonably estimable.

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 and Holders

On February 11, 2021, we closed an initial public offering ("IPO") and our 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 February 27, 2025, we had approximately 256 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 February 27, 2025 was \$9.73. As of February 27, 2025, we had one holder of record of our Class B common stock.

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.

Equity-based Compensation Plans

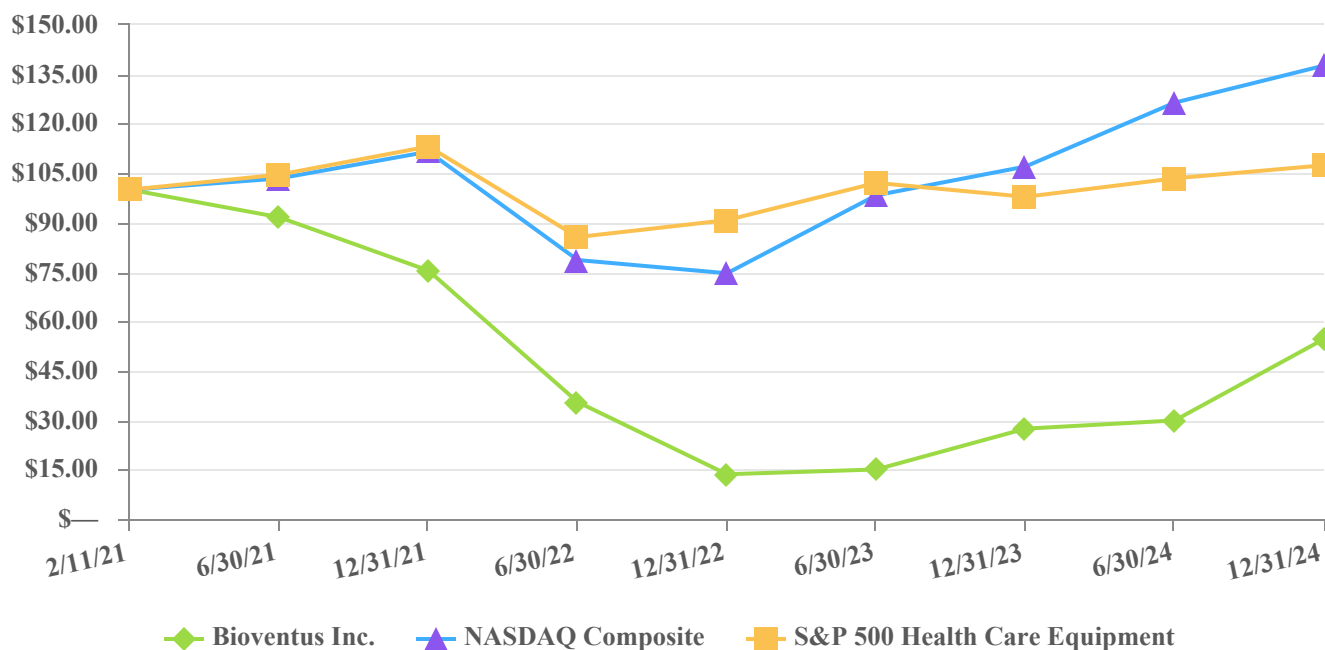
The information required by Item 5 of Form 10-K regarding equity-based compensation plans is incorporated herein by reference to *Part III, Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters*.

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 or the Exchange Act, except to the extent we specifically incorporate this information by reference.

The following performance graph compares the 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, 2024 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, except to the extent we specifically incorporate. Note that historic stock price performance is not necessarily indicative of future stock price performance.

Comparison of 47 Month Cumulative Total Return



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 I, Item 1A. Risk Factors and elsewhere in this Annual Report. A discussion of the year ended December 31, 2023 compared to the year ended December 31, 2022 has been reported previously in our Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on March 12, 2024, 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 helping patients recover and live life to the fullest by relieving pain and addressing musculoskeletal challenges through a diverse portfolio of high-quality, innovative, and clinically-proven solutions. We operate our business through two reporting segments, U.S. and International, and our portfolio of products is comprised of five patient-focused areas, grouped into three businesses based on clinical use: (i) Pain Treatments, (ii) Surgical Solutions and (iii) Restorative Therapies.

- Pain Treatments, comprised of:
 - **Knee Osteoarthritis (“KOA”) area:** Our product portfolio includes a range of intra-articular, hyaluronic acid (“HA”) injections that help relieve patient discomfort and improve quality of life.
 - **Peripheral Nerve Stimulation (“PNS”) area:** We are focused on developing a full portfolio of peripheral nerve stimulation products with solutions for acute, temporary and chronic pain.
- Surgical Solutions, comprised of:
 - **Ultrasonics:** Our Ultrasonics business offers precision bone resection for patients with degenerative spine conditions and spinal deformities. This portfolio also enables precision ultrasonic neuro and general surgery to address brain tumors and pathologies of the liver and other organs.
 - **Bone Graft Substitutes (“BGS”):** Our product portfolio includes a range of products that facilitate optimal bone fusion following a surgical procedure.
- Restorative Therapies, comprised of:
 - **Fracture Care:** We provide low-intensity pulse ultrasound to help patients who suffer from bone fractures that do not heal through traditional methods. We plan to expand our United States clinical indications to address the healing of fresh fractures, especially for high-risk patients.

The following table sets forth total net sales, net loss and Adjusted EBITDA for the periods presented:

	Years Ended December 31,	
	2024	2023
(in thousands, except for loss per share)		
Net sales	\$ 573,280	\$ 512,345
Net loss from continuing operations	\$ (43,833)	\$ (121,196)
Adjusted EBITDA ⁽¹⁾	\$ 108,882	\$ 88,862
Loss per Class A common stock, basic and diluted		
Continuing operations	\$ (0.52)	\$ (1.54)
Discontinued operations	—	(0.95)
Loss per Class A common stock, basic and diluted	<u>\$ (0.52)</u>	<u>\$ (2.49)</u>

⁽¹⁾ See below under Results of Operations-Adjusted EBITDA for a reconciliation of net loss to Adjusted EBITDA.

Significant developments

Advanced Rehabilitation Business

On September 30, 2024, we entered into a Purchase and Sale Agreement (the “Purchase Agreement”) with a third-party purchaser to sell certain products within our advanced rehabilitation business, including the L100, L300 Go, L360, H200, Vector Gait & Safety System and Bioness Integrated Therapy System (BITS) (collectively, the “Advanced Rehabilitation Business”). On December 31, 2024, we closed the sale of the Advanced Rehabilitation Business and received \$24.7 million at closing, net of transactional fees, subject to a post-closing adjustment for net working capital. We may also receive an aggregate of \$20.0 million in potential earn-out payments, which are based on the achievement of certain revenue and financial metric thresholds in respect to sales of products from the Advanced Rehabilitation Business during the 2025 and 2026 fiscal years. We have incurred \$2.5 million in transactional fees resulting from the divestiture of the Advanced Rehabilitation Business. The sale of the Advanced Rehabilitation Business is expected to enhance our strategic focus on our remaining businesses and improve liquidity, as the proceeds, net of transactional fees, were used to pay \$20.0 million in long-term debt obligations.

We evaluated the Advanced Rehabilitation Business for impairment due to its divestiture. As a result of this evaluation, we recorded impairments totaling \$33.9 million for the year ended December 31, 2024 under the U.S. reporting segment within the consolidated condensed statements of operations and comprehensive loss. The impairment losses reduced the intangible assets of the Advanced Rehabilitation Business to reflect their respective fair values less any costs to sell. The fair value of its intangibles was based on the consideration agreed to with the purchaser for the Advanced Rehabilitation Business.

Reclassification

We reclassified SonicOne revenue and expense of the SonicOne Ultrasonic Cleansing and Debridement Systems (“SonicOne”) from the Restorative Therapies to the Surgical Solutions business in the first quarter of 2024. SonicOne’s capabilities to remove devitalized or necrotic tissue and fiber deposits more closely aligns with Surgical Solutions’ soft tissue management. SonicOne revenue reclassified for the year ended December 31, 2023 totaled \$6.8 million for the U.S. reporting segment and \$0.3 million for the International reporting segment.

Allograft Delivery Device

The Allograft Delivery Device, a customized delivery system for our OSTEOAMP Flowable product, received FDA clearance in June 2024. OSTEOAMP is an allograft-derived bone graft with growth factors used for reconstructive bone grafting procedures. The Allograft Delivery Device is intended to be used for the delivery of hydrated allograft to an orthopedic site, therefore assisting with the use of OSTEOAMP Flowable, the fastest growing product in our bone graft substitutes portfolio, in minimally invasive surgical procedures as well as open procedures.

EU MDR

The European Union Medical Devices Regulation (“EU MDR”), which became effective in May 2021, was adopted with the aim of ensuring better protection of public health and patient safety. Among other things, the EU MDR imposed changes to 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 labeling changes. We were able to continue marketing our currently certified products in the European Union (“EU”) after the effective date of EU MDR until the associated certifications expire. In April 2024, we received EU certification for our EXOGEN Bone Stimulation System, which will allow us to market it throughout the EU. The certificate is valid for 5 years.

Wound Business

On May 22, 2023, we closed the sale of certain assets within its Wound Business, including the TheraSkin and TheraGenesis products (collectively, the “Wound Business” or the “Disposal Group”), for potential consideration of \$84.7 million, including \$34.7 million at closing, \$5.0 million deferred for 18 months and up to \$45.0 million in potential earn-out payments, which are based on the achievement of certain revenue thresholds by the purchaser of the Wound Business for sales of the TheraSkin and TheraGenesis products during the 2024, 2025 and 2026 fiscal years. We received the deferred payment in November 2024, which was used to pay \$5.0 million of long-term debt obligations.

We incurred \$3.9 million in transactional fees resulting from the sale of the Wound Business. The loss resulting from the deconsolidation of the Disposal Group totaled \$1.5 million for the year ended December 31, 2023 and was recorded in loss on disposals within the consolidated statements of operations and comprehensive loss. We used the proceeds from the sale of the Wound Business to prepay \$30.0 million of long-term debt obligations.

We evaluated the Wound Business for impairment prior to its sale and recorded a \$78.6 million impairment within the consolidated statements of operations and comprehensive loss during the year ended December 31, 2023 as a result of this evaluation to reduce the intangible assets of the Disposal Group to reflect their respective fair values less any costs to sell. The fair value of the Disposal Group's intangibles was determined based on the consideration received for the Wound Business.

Credit and Guaranty Agreement

On January 18, 2024, we further amended the 2019 Credit Agreement to modify certain financial covenants under the 2019 Credit Agreement. Refer to *Liquidity and Capital Resources—Credit Facilities* for further information regarding the January 2024 amendment.

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, which manages and maintains the sales relationship with healthcare providers, distribution centers or specialty pharmacies. Certain Surgical Solutions 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 *Item 8. Financial Statements and Supplementary Data—Notes to Consolidated Financial Statements—Note 2. Significant accounting policies* for further information.

We generally recognize revenue at the point in time when control is transferred to the customer, for example, when the product is 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 consists 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 marketed products. Certain products are manufactured by or obtained from third-party suppliers primarily located in Japan, Switzerland, Sweden and the United States.

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 marketization 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-based 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 portfolio across all products and undertake clinical research to support their marketization. As a result, we expect our research and development expenses to vary from low 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. Clinical and preclinical development timelines, the probability of success and development costs can differ materially from expectations.

Restructuring costs

We have restructured portions of our operations and future restructuring activities are possible. Identifying and calculating the cost to exit operations requires certain assumptions to be made, the most significant of which are anticipated future liabilities. Although our 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.

Restructuring costs primarily consist of employee severance, legal, consulting and temporary labor expenses. Restructuring costs recorded in 2023 and 2022 are the result of aligning our organizational and management cost structure to improve profitability and cash flow.

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 Amended 2019 Credit Agreement. We have previously 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.

Other (income) expense

Other (income) expense 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 (income) expense may also include certain nonrecurring items.

Income tax expense

The Company's subsidiary, 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 tax receivable agreement ("TRA"), which could be significant. The TRA obligates us to pay to Smith & Nephew, Inc. ("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 *Item 8. Financial Statements and Supplementary Data—Notes to Consolidated Financial Statements—Note 11. Income taxes* 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 that management uses to measure operating performance and 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 loss from continuing operations before depreciation and amortization, provision of income taxes and interest expense, net, 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 divestiture related costs, certain shareholder litigation costs, impairments of assets, restructuring and succession charges, equity-based compensation expense, financial restructuring costs 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.

Non-GAAP financial measures have limitations as an analytical tool and should not be considered in isolation or as a substitute for, or superior to, the financial information prepared and presented in accordance with U.S. GAAP. These measures might exclude certain normal recurring expenses. Therefore, these measures might not provide a complete understanding of the Company's performance and should be reviewed in conjunction with the U.S. GAAP financial measures. Additionally, other companies might define their non-GAAP financial measures differently than we do. Investors are encouraged to review the reconciliation of the non-GAAP measure provided in this Annual Report on Form 10-K, including all tables referencing Adjusted EBITDA to its most directly comparable U.S. GAAP measure.

Results of Continuing 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,	
	2024	2023
Net sales	100.0 %	100.0 %
Cost of sales (including depreciation and amortization)	32.3 %	35.9 %
Gross profit	67.7 %	64.1 %
Selling, general and administrative expense	59.5 %	59.4 %
Research and development expense	2.4 %	2.6 %
Restructuring costs	— %	0.2 %
Change in fair value of contingent consideration	0.2 %	0.1 %
Depreciation and amortization	1.3 %	1.7 %
Impairment of assets	6.3 %	15.4 %
Loss on disposals	0.1 %	0.7 %
Operating loss	(2.1%)	(16.0%)

The following table presents a reconciliation of net loss from continuing operations to Adjusted EBITDA for the periods presented:

(in thousands)	Years Ended December 31,	
	2024	2023
Net loss from continuing operations	\$ (43,833)	\$ (121,196)
Interest expense, net	38,792	40,676
Income tax expense (benefit), net	(5,293)	85
Depreciation and amortization ^(a)	49,555	57,365
Acquisition and related costs ^(b)	1,339	5,694
Shareholder litigation costs ^(c)	13,802	—
Restructuring and succession charges ^(d)	(57)	2,331
Equity-based compensation ^(e)	10,058	2,722
Financial restructuring costs ^(f)	351	7,291
Impairment of assets ^(g)	36,357	78,615
Loss on disposal of a business ^(h)	292	1,539
Other items ⁽ⁱ⁾	7,519	13,740
Adjusted EBITDA	\$ 108,882	\$ 88,862

^(a) Includes for the years ended December 31, 2024 and 2023, respectively, depreciation and amortization of \$41.9 million and \$48.5 million in cost of sales and \$7.7 million and \$8.9 million in operating expenses presented in the consolidated statements of operations and comprehensive loss.

^(b) Includes acquisition and integration costs related to completed acquisitions and changes in fair value of contingent consideration.

^(c) Costs incurred as a result of certain shareholder litigation unrelated to our ongoing operations.

^(d) Costs incurred were the result of adopting restructuring plans to reduce headcount, contract termination, reorganize management structure and consolidate certain facilities.

^(e) Includes compensation expense resulting from awards granted under our equity-based compensation plans. The year ended December 31, 2024 includes increased award activity as a result of certain annual employee bonuses granted in the form of equity awards. The year ended December 31, 2023 includes the reversal of \$3.8 million in equity-based compensation expenses related to the transition of our executive leadership.

^(f) Financial restructuring costs include advisory fees and debt amendment related costs.

^(g) Activity in 2024 includes: (i) a non-cash impairment charge of \$33.9 million for intangible assets solely attributable to our Advanced Rehabilitation Business due to the decision to divest the business and (ii) a non-cash impairment charge of \$2.5 million for rented right-of-use assets involving exited office and warehouse spaces. Activity in 2023 relates to the non-cash impairment charge attributable to our divested Wound Business.

^(h) Represents the loss on the disposal of the Advanced Rehabilitation and Wound Businesses for the years ended December 31, 2024 and 2023, respectively.

⁽ⁱ⁾ Other items primarily include charges associated with strategic transactions, such as potential acquisitions or divestitures and a transformative project to redesign systems and information processing. During the year ended December 31, 2024, other items primarily consisted of the following: (i) divestiture costs related to the Company's Advanced Rehabilitation Business, including transactional fees, totaled \$4.7 million; (ii) transformative project costs of \$1.7 million; and (iii) strategic transaction costs of \$0.4 million.

During the year ended December 31, 2023, other items mainly consisted of the following: (i) strategic transaction costs totaling \$4.8 million, including divestiture costs of \$1.1 million related to Advanced Rehabilitation; (ii) transformative project costs of \$4.5 million; (iii) transition and severance costs of \$2.8 million; and (iv) \$1.0 million in costs related to the discontinuance of MOTYS.

Net sales

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
U.S.				
Pain Treatments	\$ 234,936	\$ 197,954	\$ 36,982	18.7%
Surgical Solutions	167,706	141,888	25,818	18.2%
Restorative Therapies	104,167	110,018	(5,851)	(5.3%)
Total U.S. net sales	<u>506,809</u>	<u>449,860</u>	<u>56,949</u>	12.7%
International				
Pain Treatments	26,353	22,847	3,506	15.3%
Surgical Solutions	21,549	19,715	1,834	9.3%
Restorative Therapies	18,569	19,923	(1,354)	(6.8%)
Total International net sales	<u>66,471</u>	<u>62,485</u>	<u>3,986</u>	6.4%
Total net sales	<u>\$ 573,280</u>	<u>\$ 512,345</u>	<u>\$ 60,935</u>	11.9%

U.S.

Net sales increased \$56.9 million, or 12.7%, compared to the prior year. Changes by major product groups were: (i) Pain Treatments—\$37.0 million increase due to volume growth primarily driven by Durolane; (ii) Surgical Solutions—\$25.8 million net sales increase due to volume growth; and (iii) Restorative Therapies—\$5.9 million net sales decrease due primarily to the divestiture of our Wound Business (\$11.1 million of revenue in 2023) and lower volume from the Advanced Rehabilitation Business, partly offset by increased volumes and higher average selling price related to our EXOGEN Bone Stimulation System in 2024.

International

Net sales increased \$4.0 million, or 6.4%, due to volume growth in Pain Treatments and Surgical Solutions, partially offset with a volume decline in Restorative Therapies.

Gross profit and gross margin

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
U.S.	\$ 348,953	\$ 294,366	\$ 54,587	18.5%
International	39,273	33,827	5,446	16.1%
Total	<u>\$ 388,226</u>	<u>\$ 328,193</u>	<u>\$ 60,033</u>	18.3%
	Years Ended December 31,		Change	
	2024	2023		
U.S.	68.9 %	65.4 %	3.5%	
International	59.1 %	54.1 %	5.0%	
Total	67.7 %	64.1 %	3.6%	

U.S.

Gross profit increased \$54.6 million, or 18.5%, primarily due to volume growth in Pain Treatments, Surgical Solutions and our EXOGEN Bone Stimulation System, partially offset by the Wound Business divestiture. Gross margin increased due to product mix.

International

Gross profit increased \$5.4 million, or 16.1% compared with the prior period, which is primarily due to an increase in volume for Pain Treatments, specifically Durolane, and Surgical Solutions. Gross margin increased due to product mix.

Selling, general and administrative expense

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
Selling, general and administrative expense	\$ 340,894	\$ 303,879	\$ 37,015	12.2%

Selling, general and administrative expense increased \$37.0 million, or 12.2%, primarily due to increases in: (i) compensation and related costs of \$24.4 million; (ii) accounting and legal costs of \$10.8 million, mostly related to the settlement of shareholder litigation; and (iii) equity-based compensation of \$8.2 million. These increases were partially offset with a \$12.2 million decrease in consulting expenses resulting from fewer strategic transactions, project initiatives and debt refinancing costs in 2024 compared to 2023.

Research and development expense

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
Research and development expense	\$ 13,639	\$ 13,446	\$ 193	1.4%

Research and development expense remained consistent with the prior year comparable period.

Restructuring costs

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
Restructuring costs	\$ (52)	\$ 840	\$ (892)	(106.2%)

There were expense reversals during the year ended December 31, 2024 primarily due to employee transitions associated with prior restructuring initiatives. Costs incurred for the year ended December 31, 2023 were primarily the result of an initiative to align the Company's organizational and management cost structure to improve profitability and cash flow through reducing headcount and third-party related costs.

Change in fair value of contingent consideration

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
Change in fair value of contingent consideration	\$ 1,423	\$ 719	\$ 704	97.9%

Changes in fair value for both periods relates to contingent consideration associated with the acquisition of Bioness in March 2021.

Depreciation and amortization

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
Depreciation and amortization	\$ 7,652	\$ 8,842	\$ (1,190)	(13.5%)

Depreciation and amortization decreased during the year ended December 31, 2024 compared with the prior year primarily due to the write-off of consigned fixed assets and fewer assets to depreciate due to divestitures.

Impairment of assets

We evaluated the Advanced Rehabilitation Business for impairment during the second quarter of 2024 due our decision to divest the business. As a result of this evaluation, we recorded a \$33.9 million impairment to reduce the intangible assets of the Advanced Rehabilitation Business to reflect their respective fair values less any costs to sell. We based the fair value of its intangibles on the consideration agreed to with the purchaser for the Advanced Rehabilitation Business. We also recorded impairment losses of \$2.5 million during the year ended December 31, 2024 for 2 right-of-use assets, specifically office and warehouse spaces, which the Company exited during 2024.

Our decision to divest the Wound Business required us to evaluate whether certain of its assets were impaired. We recorded a \$78.6 million non-cash impairment charge in 2023 as a result of this evaluation to reduce the intangible assets to their fair values less costs to sell. We determined the fair value of intangibles of the Wound Business based on the consideration offered for the Wound Business.

Loss on disposals

The loss on disposals during the year ended December 31, 2024 resulted from the sale of the Advanced Rehabilitation Business. The loss on disposals during the year ended December 31, 2023 resulted from \$1.5 million in working capital adjustments associated with the sale of our Wound Business and a \$2.0 million loss on fixed assets disposed of during the integration of acquisitions.

Other (income) expense

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
Interest expense, net	\$ 38,792	\$ 40,676	\$ (1,884)	(4.6%)
Other (income) expense	\$ (1,645)	\$ (1,290)	\$ (355)	27.5%

Interest expense, net decreased during the year ended December 31, 2024 compared to the prior year primarily due to less debt outstanding and a decrease in interest rates. Other (income) expense during 2024 primarily consisted of an increase of \$1.0 million in foreign currency gains, resulting from recognizing previously unrealized gains and losses on the assets and liabilities of the Advanced Rehabilitation Business, which was sold in the fourth quarter of 2024. Activity during 2023 primarily included a \$1.5 million receipt from the settlement of a legal claim.

Income tax (benefit) expense, net

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
Income tax (benefit) expense, net	\$ (5,293)	\$ 85	\$ (5,378)	NM
Effective tax rate	10.8%	(0.1)%		10.9%

NM - Not Meaningful

The \$5.4 million change in income taxes was due to the recognition of deferred tax benefits resulting from the impairments recorded.

Noncontrolling interest

Subsequent to the IPO and related transactions, we are the sole managing member of BV LLC of which we owned 80.6% and 80.0% at December 31, 2024 and 2023, respectively. 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 noncontrolling interest representing the 19.4% that is owned by the Continuing LLC Owner. Noncontrolling interest activity during year ended December 31, 2024 was the result of losses recorded.

Segment Adjusted EBITDA

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

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
U.S.	\$ 95,421	\$ 78,668	\$ 16,753	21.3%
International	\$ 13,461	\$ 10,194	\$ 3,267	32.0%

U.S.

Adjusted EBITDA increased \$16.8 million, or 21.3%, due to revenue growth and increased gross profit.

International

Adjusted EBITDA increased \$3.3 million or 32.0%, due to increased gross profit.

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 market new products and further our expansion into international markets.

We believe that we have enough liquidity to continue operations for the next twelve months. We anticipate that to the extent that we require capital, we will obtain funding through additional equity financings or the incurrence of other indebtedness or a combination of these potential sources of capital. As of December 31, 2024, we have the ability to borrow up to \$40.0 million using our Revolving Credit Facility and available letters of credit. We may explore divestiture opportunities for non-core assets to improve our liquidity position. 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. The covenants under the Amended 2019 Credit Agreement limit our ability to obtain additional debt financing. Debt financing, if allowed under the Amended 2019 Credit Agreement and if available, would result in increased payment obligations and might 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 might be necessary to relinquish valuable rights to our products, future revenue streams or product candidates, or to grant licenses on terms that might not be favorable to us. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any failure to raise capital in the future might have a negative impact on our financial condition and our ability to pursue our business strategies.

Future cash requirements

The following table summarizes certain estimated future cash requirements under our various contractual obligations committed to as of December 31, 2024 in total and disaggregated into current and long-term obligations.

(in thousands)	Current	Long-Term	Total
Long-term debt ^(a)	\$ 27,339	\$ 310,525	\$ 337,864
Interest payments on long-term debt obligations ^(a)	28,974	21,442	50,416
Lease liabilities ^(b)	5,104	20,104	25,208
Purchase commitments ^(c)	29,196	1,223	30,419
	<u>\$ 90,613</u>	<u>\$ 353,294</u>	<u>\$ 443,907</u>

^(a) Refer to *Item 8. Financial Statements and Supplementary Data—Notes to the Consolidated Financial Statements—Note 5. Financial instruments* in this Annual Report for further information regarding long-term debt obligations.

^(b) Refer to *Item 8. Financial Statements and Supplementary Data—Notes to the Consolidated Financial Statements—Note 12. Commitments and contingencies* in this Annual Report for further information regarding operating and finance lease liabilities.

^(c) Amounts that are contractually committed to as of December 31, 2024 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 *Item 8. Financial Statements and Supplementary Data* in this Annual Report.

Tax Receivable Agreement

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 within 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.

Indebtedness

Our 2019 Credit Agreement (as amended on August 29, 2021 and October 29, 2021), and in effect from October 29, 2021 to July 11, 2022, consisted of a \$360.8 million term loan (“Term Loan”) and a \$50.0 million revolving credit facility (the “Revolver”). The Company amended the 2019 Credit Agreement on August 29, 2021, and then again on October 29, 2021 in connection with the acquisition of Misonix, Inc. On July 11, 2022, the Company further amended the 2019 Credit Agreement in conjunction with the acquisition of CartiHeal.

The Company was not in compliance with certain financial covenants under the 2019 Credit Agreement in effect as of December 31, 2022. As a result, on March 31, 2023, we entered into another amendment to the 2019 Credit Agreement to, among other things, modify certain financial covenants, waive the noncompliance at December 31, 2022 and modify interest rates applicable to borrowings under the agreement. The Revolver’s capacity was reduced \$5.0 million on December 31, 2023 and again on June 30, 2024 in accordance with the amendments to the 2019 Credit Agreement resulting in a maximum capacity of \$40.0 million as of December 31, 2024. We were in compliance with the financial covenants as of December 31, 2024 and 2023 as stated within the 2019 Credit Agreement then in effect.

On January 18, 2024 (the “Closing Date”), we further amended the 2019 Credit Agreement (collectively, with the August 2021, October 2021, July 2022 and March 2023 amendments, the “Amended 2019 Credit Agreement”), to modify certain financial covenants under the 2019 Credit Agreement. With respect to Term Loan Facilities and the Revolver outstanding as of the Closing Date, we may elect either SOFR or Base Rate 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 Adjusted EBITDA as defined in the Amended 2019 Credit Agreement for four consecutive quarters as of the end of each period. Pursuant to the Amended 2019 Credit Agreement, the margin at each applicable leverage ratio will be increased by 1.00% per annum. SOFR loans and base rate loans had a margin of 3.25% and 2.25%, respectively, subsequent to July 11, 2022 and prior to the Closing Date. Subsequent to the March 31, 2023 amendment, SOFR loans and base rate loans had a margin of 4.25% and 3.25%, respectively. 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 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 certain distributions on or in respect of Bioventus LLC’s equity interests, restrictions on acquisitions, investments and certain other payments, limitations on the incurrence of new indebtedness, limitations on transfers, sales and other dispositions of assets of Bioventus LLC and its subsidiaries, as well as limitations on making changes to the business and organizational documents of Bioventus LLC and its subsidiaries. Financial covenant requirements include (i) a maximum debt leverage ratio of not greater than 4.50 to 1.00 for the testing period ending December 31, 2024, 4.25 to 1.00 for the testing period ending March 31, 2025, 4.00 to 1.00 for the testing period ending June 30, 2025 and at the end of each testing period occurring thereafter, and beginning on March 31, 2025, to be subject to a temporary increase to 4.50 to 1.00 upon certain events; and (ii) an interest coverage ratio not less than 2.00 to 1.00 for the testing period ending December 31, 2024, 2.00 to 1.00 for the testing period ending March 31, 2025, 2.25 to 1.00 for the testing period ending June 30, 2025, 2.50 to 1.00 for the testing period ending September 30, 2025 and 3.00 to 1.00 for the testing period ending December 31, 2025 and each testing period thereafter. In addition, during the period commencing on the Closing Date and ending upon the satisfaction of certain conditions occurring not prior to October 29, 2025, the Company will be subject to certain additional requirements and covenants, including a requirement to maintain Liquidity (as defined in the Amended 2019 Credit Agreement) of not less than \$10.0 million as of the end of each calendar month during such period.

The Term Loan Facilities matures on October 29, 2026 and the Revolver matures on October 29, 2025.

Refer to *Item 8. Financial Statements and Supplementary Data—Notes to the Consolidated Financial Statements—Note 5. Financial instruments* in this Annual Report for further details on the Company’s indebtedness.

Information regarding cash flows

Cash and cash equivalents as of December 31, 2024 totaled \$41.6 million, compared to \$37.0 million as of December 31, 2023. As of December 31, 2024, \$22.1 million and \$19.5 million of our cash and cash equivalents was held within the U.S. and International segments, respectively. The change in cash was primarily due to the following:

(in thousands, except for percentage)	Years Ended December 31,		Change	
	2024	2023	\$	%
Cash flows from continuing operations:				
Net cash from operating activities	\$ 38,795	\$ 17,513	\$ 21,282	121.5%
Net cash from investing activities	22,963	27,313	(4,350)	(15.9%)
Net cash from financing activities	(54,580)	(26,653)	(27,927)	104.8%
Net cash from discontinued operations	—	(13,675)	13,675	(100.0%)
Effect of exchange rate changes on cash	(2,560)	629	(3,189)	NM
Net change in cash and cash equivalents	<u>\$ 4,618</u>	<u>\$ 5,127</u>	<u>\$ (509)</u>	(9.9%)

Operating Activities

Net cash in operating activities from continuing operations increased \$21.3 million, due to cash collections from sales growth and the timing of working capital payments. These operating inflows were partially offset with: (i) increases in employee compensation due to higher bonus payments in 2024 compared to prior year; (ii) an increase in inventory purchases; and (iii) an increase in interest payments.

Investing Activities

Net cash flows in investing activities from continuing operations decreased \$4.4 million, primarily due to \$10.0 million less net cash received from the sale of businesses, partially offset with \$6.4 million less in capital expenditures.

Financing Activities

Cash flows from financing activities decreased \$27.9 million, primarily due to: (i) net outflows totaling \$30.0 million related to our revolving credit facility as \$15 million was repaid in 2024 compared to \$15 million in net borrowings during 2023; and (ii) an increase of \$6.3 million in debt principal payments. These outflows were partially offset with: (i) a deferred consideration receipt of \$4.5 million in 2024 resulting from the prior year sale of the Wound Business; (ii) \$2.5 million less debt financing costs paid in 2024; and (iii) \$1.7 million more in proceeds from the issuance of stock as stock option exercises increased in 2024 compared to 2023.

Discontinued Operations

Net cash flows from discontinued operations in 2023 were primarily the result of \$10.2 million in fees used to settle the CartiHeal disposition and \$1.4 million in cash held by the CartiHeal entity at the time of disposal.

Recently Issued Accounting Pronouncements

Refer to *Item 8. Financial Statements and Supplementary Data—Notes to the Consolidated Financial Statements—Note 2. Significant accounting policies* for information regarding accounting pronouncements that may impact our financial statements in future periods.

Critical Accounting 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.

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 *Item 8. Financial Statements and Supplementary Data—Notes to the Consolidated Financial Statements—Note 2. Significant accounting policies* for a further description of our significant accounting policies, however, we believe that the following accounting estimates are considered critical to our business in order to obtain a full understanding and to evaluate our reported financial results. The critical accounting estimates addressed below reflect our most significant judgments and estimates used in the preparation of our consolidated financial statements.

Revenue recognition estimates

Variable consideration estimates

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, 2024 and 2023.

Accounts receivable allowances 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.

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 (“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 product.

Contingent consideration

We recognize contingent consideration liabilities resulting from business combinations at estimated fair value on the acquisition date, and at each subsequent reporting period. Significant judgment is employed in determining the appropriateness of the estimates and assumptions as of the acquisition date and in post-acquisition periods. 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. 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. 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 loss.

Impairment of goodwill and indefinite-lived intangible assets

We evaluate goodwill for impairment annually during the fourth quarter, or more frequently if events or changes in circumstances indicate that the asset might be impaired. We analyze all other indefinite-lived intangible assets qualitatively to determine if it is more likely than not that an impairment exists. If we meet the criteria, we perform a quantitative analysis to determine if an impairment exists. Our reporting units are U.S. and International and we analyze each reporting unit separately in our impairment evaluations.

Our impairment process includes applying a quantitative impairment analysis to the fair value of the reporting unit and comparing it to its carrying value. We used independent third-party valuation specialists in 2024 and 2023 using year-to-date October data in each year to assist management in performing our annual impairment evaluation. 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 analysis 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 estimates and assumptions could materially affect the determination of fair value for each reporting unit and could result in an impairment charge, which could be material to our financial position and results of operations.

On November 8, 2022, due to a significant decline in the value of our Class A common stock, circumstances became evident that a possible impairment existed as of the third quarter balance sheet date. We concluded that the carrying value of the U.S. reporting unit exceeded its fair value. We recorded a non-cash goodwill impairment charge within the U.S. reporting unit for the year ended December 31, 2022. The impairment was recorded within impairment of goodwill on the consolidated statements of operations and comprehensive loss. There were no goodwill impairment charges for the years ended December 31, 2024 and 2023. Refer to *Item 8. Financial Statements and Supplementary Data—Notes to the Consolidated Financial Statements—Note 3. Balance sheet information.*

Equity-based compensation

Equity-based compensation expense generated from the granting of 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 the 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.

Income taxes

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 we have 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.

Emerging Growth Company and Smaller Reporting Company Status

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 we have annual gross revenues of \$1.235 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 second fiscal 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).

Additionally, we are considered a “smaller reporting company,” as defined by Rule 12b-2 of the Exchange Act, which was determined as of the last day of our second fiscal quarter of 2024 (a “determination date”). We will continue to be categorized as a smaller reporting company—accelerated filer until our public float reaches \$250 million at a future determination date.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations including regarding executive compensation.

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 may 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 loss in the period incurred.

Interest rate risk

Our cash and cash equivalents balance as of December 31, 2024 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 Amended 2019 Credit Agreement, which bear interest at a floating rate based on three-month SOFR plus an applicable borrowing margin. As of December 31, 2024, a 1.0% increase in interest rate would result in \$5.9 million increase in total interest payable over the remaining life of the Amended 2019 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 Amended 2019 Credit Agreement, 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, subject to any applicable limitations in our financing arrangements.

Foreign exchange risk management

We operate in countries other than the United States and are exposed to foreign currency risks. We bill most direct sales outside of the United States 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, subject to any applicable limitations in our financing arrangements.

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.

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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, 2024 and 2023, the related consolidated statements of operations and comprehensive loss, changes in stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2024, and the related notes collectively referred to as the financial statements. In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2024, in conformity with 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, 2025

Bioventus Inc.
Consolidated Statements of Operations and Comprehensive Loss
Years Ended December 31, 2024, 2023 and 2022
(Amounts in thousands, except share amounts)

	2024	2023	2022
Net sales	\$ 573,280	\$ 512,345	\$ 512,117
Cost of sales (including depreciation and amortization of \$41,882, \$48,503 and \$45,622, respectively)	185,054	184,152	181,037
Gross profit	388,226	328,193	331,080
Selling, general and administrative expense	340,894	303,879	332,134
Research and development expense	13,639	13,446	23,854
Restructuring costs	(52)	840	6,779
Change in fair value of contingent consideration	1,423	719	1,102
Depreciation and amortization	7,652	8,842	9,748
Impairment of assets	36,357	78,615	—
Impairment of goodwill	—	—	124,697
Loss on disposals	292	3,577	—
Operating loss	(11,979)	(81,725)	(167,234)
Interest expense, net	38,792	40,676	12,021
Other (income) expense	(1,645)	(1,290)	9,770
Other expense	37,147	39,386	21,791
Loss before income taxes	(49,126)	(121,111)	(189,025)
Income tax (benefit) expense, net	(5,293)	85	(44,374)
Net loss from continuing operations	(43,833)	(121,196)	(144,651)
Loss from discontinued operations, net of tax	—	(74,429)	(68,740)
Net loss	(43,833)	(195,625)	(213,391)
Loss attributable to noncontrolling interest - continuing operations	10,291	24,458	40,732
Loss attributable to noncontrolling interest - discontinued operations	—	14,937	13,955
Net loss attributable to Bioventus Inc.	<u>\$ (33,542)</u>	<u>\$ (156,230)</u>	<u>\$ (158,704)</u>
Net loss	\$ (43,833)	\$ (195,625)	\$ (213,391)
Other comprehensive loss, net of tax			
Change in prior service cost and unrecognized gain (loss) for defined benefit plan adjustment	13	(8)	133
Change in foreign currency translation adjustments	(4,194)	1,140	(501)
Comprehensive loss	(48,014)	(194,493)	(213,759)
Comprehensive loss attributable to noncontrolling interest - continuing operations	11,105	24,230	40,811
Comprehensive loss attributable to noncontrolling interest - discontinued operations	—	14,937	13,955
Comprehensive loss attributable to Bioventus Inc.	<u>\$ (36,909)</u>	<u>\$ (155,326)</u>	<u>\$ (158,993)</u>
Loss per share of Class A common stock from:			
Continuing operations, basic and diluted	\$ (0.52)	\$ (1.54)	\$ (1.70)
Discontinued operations, basic and diluted	—	(0.95)	(0.89)
Loss per share of Class A common stock, basic and diluted	<u>\$ (0.52)</u>	<u>\$ (2.49)</u>	<u>\$ (2.59)</u>
Weighted-average shares of Class A common stock outstanding, basic and diluted:	<u>64,547,474</u>	<u>62,647,554</u>	<u>61,389,107</u>

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

Bioventus Inc.
Consolidated Balance Sheets as of December 31, 2024 and 2023
(Amounts in thousands, except share amounts)

	2024	2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 41,582	\$ 36,964
Accounts receivable, net	127,393	122,789
Inventory	92,475	91,333
Prepaid and other current assets	14,160	16,913
Total current assets	275,610	267,999
Property and equipment, net	27,012	36,605
Goodwill	7,462	7,462
Intangible assets, net	404,729	482,350
Operating lease assets	6,506	13,353
Deferred tax assets	4,745	—
Investment and other assets	1,892	3,141
Total assets	<u>\$ 727,956</u>	<u>\$ 810,910</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 23,690	\$ 23,038
Accrued liabilities	135,879	119,795
Current portion of long-term debt	27,339	27,848
Current portion of contingent consideration	19,573	—
Other current liabilities	3,917	4,816
Total current liabilities	210,398	175,497
Long-term debt, less current portion	308,288	366,998
Deferred income tax liabilities	564	1,213
Contingent consideration	—	18,150
Other long-term liabilities	23,102	27,934
Total liabilities	542,352	589,792
Commitments and contingencies (Note 12)		
Stockholders' Equity:		
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 as of December 31, 2024 and December 31, 2023, 65,758,341 and 63,267,436 shares issued and outstanding as of December 31, 2024 and December 31, 2023, respectively	66	63
Class B common stock, \$0.001 par value, 50,000,000 shares authorized, 15,786,737 shares issued and outstanding as of December 31, 2024 and December 31, 2023	16	16
Additional paid-in capital	505,509	494,254
Accumulated deficit	(355,078)	(321,536)
Accumulated other comprehensive (loss) income	(2,573)	794
Total stockholders' equity attributable to Bioventus Inc.	147,940	173,591
Noncontrolling interest	37,664	47,527
Total stockholders' equity	185,604	221,118
Total liabilities and stockholders' equity	<u>\$ 727,956</u>	<u>\$ 810,910</u>

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

Bioventus Inc.
Consolidated Statements of Changes in Stockholders' Equity
Years Ended December 31, 2024, 2023 and 2022
(Amounts in thousands, except share amounts)

	Class A Common Stock		Class B Common Stock		Additional Paid-in Capital	Accumulated other comprehensive income (loss)	Accumulated Deficit	Non- controlling Interest	Total Stockholders' Equity
	Shares	Amount	Shares	Amount					
December 31, 2021	59,548,504	\$ 59	15,786,737	\$ 16	\$ 473,318	\$ 179	\$ (6,602)	\$ 140,686	\$ 607,656
Issuance of Class A common stock for equity plans	2,514,510	3	—	—	5,819	—	—	—	5,822
Deferred taxes on equity rebalancing	—	—	—	—	(1,977)	—	—	—	(1,977)
Net loss	—	—	—	—	—	—	(158,704)	(54,687)	(213,391)
Tax withholdings on equity-based compensation awards	—	—	—	—	(3,352)	—	—	—	(3,352)
Deconsolidation of noncontrolling interest	—	—	—	—	—	—	—	247	247
Equity-based compensation	—	—	—	—	14,180	—	—	3,405	17,585
Change in noncontrolling interest allocation	—	—	—	—	2,588	—	—	(2,588)	—
Other comprehensive loss	—	—	—	—	—	(289)	—	(79)	(368)
December 31, 2022	62,063,014	\$ 62	15,786,737	\$ 16	\$ 490,576	\$ (110)	\$ (165,306)	\$ 86,984	\$ 412,222
Issuance of Class A common stock for equity plans	1,204,422	1	—	—	777	—	—	—	778
Net loss	—	—	—	—	—	—	(156,230)	(39,395)	(195,625)
Equity-based compensation	—	—	—	—	2,388	—	—	334	2,722
Change in noncontrolling interest allocation	—	—	—	—	513	—	—	(513)	—
Distributions to members	—	—	—	—	—	—	—	(111)	(111)
Other comprehensive income	—	—	—	—	—	904	—	228	1,132
December 31, 2023	63,267,436	\$ 63	15,786,737	\$ 16	\$ 494,254	\$ 794	\$ (321,536)	\$ 47,527	\$ 221,118
Issuance of Class A common stock for equity plans	2,490,905	3	—	—	2,439	—	—	—	2,442
Net loss	—	—	—	—	—	—	(33,542)	(10,291)	(43,833)
Equity-based compensation	—	—	—	—	8,321	—	—	1,737	10,058
Change in noncontrolling interest allocations	—	—	—	—	495	—	—	(495)	—
Other comprehensive loss	—	—	—	—	—	(3,367)	—	(814)	(4,181)
December 31, 2024	65,758,341	\$ 66	15,786,737	\$ 16	\$ 505,509	\$ (2,573)	\$ (355,078)	\$ 37,664	\$ 185,604

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

Bioventus Inc.
Consolidated Statements of Cash Flows
Years Ended December 31, 2024, 2023 and 2022
(Amounts in thousands)

	2024	2023	2022
Operating activities:			
Net loss	\$ (43,833)	\$ (195,625)	\$ (213,391)
Less: Loss from discontinued operations, net of tax	—	(74,429)	(68,740)
Loss from continuing operations	(43,833)	(121,196)	(144,651)
Adjustments to reconcile net loss to net cash from operating activities:			
Depreciation and amortization	49,555	57,365	55,398
(Benefit) provision for expected credit losses	(434)	(1,103)	5,190
Equity-based compensation from 2021 Stock Incentive Plan	10,058	2,722	17,585
Change in fair value of contingent consideration	1,423	719	1,102
Change in fair value of interest rate swap	—	—	(6,396)
Deferred income taxes	(5,394)	(2,377)	(46,658)
Impairments of assets	36,357	78,615	134,982
Loss on disposals	292	3,577	—
Unrealized (gain) loss on foreign currency fluctuations	(259)	665	1,383
Other, net	2,810	1,707	388
Changes in operating assets and liabilities:			
Accounts receivable	(10,666)	10,055	(17,672)
Inventory	(16,435)	(5,991)	(18,618)
Accounts payable and accrued expenses	17,846	(5,275)	(3,099)
Other current and noncurrent assets and liabilities	(2,525)	(1,970)	9,659
Net cash from operating activities - continuing operations	38,795	17,513	(11,407)
Net cash from operating activities - discontinued operations	—	(2,169)	(2,130)
Net cash from operating activities	38,795	15,344	(13,537)
Investing activities:			
Proceeds from sale of a business	24,678	34,675	—
Purchase of property and equipment	(1,006)	(7,362)	(1,478)
Investments and acquisition of distribution rights	(709)	—	(10,042)
Other	—	—	(75)
Net cash from investing activities - continuing operations	22,963	27,313	(11,595)
Net cash from investing activities - discontinued operations	—	(11,506)	(104,841)
Net cash from investing activities	22,963	15,807	(116,436)
Financing activities:			
Proceeds from issuance of Class A and B common stock	2,442	778	5,822
Tax withholdings on equity-based compensation	—	—	(3,352)
Receipt of deferred consideration	4,500	—	—
Borrowing on revolver	—	64,000	25,000
Payment on revolver	(15,000)	(49,000)	(25,000)
Proceeds from the issuance of long-term debt, net of issuance costs	—	—	79,659
Debt financing costs	(1,180)	(3,661)	—
Payments on long-term debt	(44,584)	(38,264)	(20,038)
Other, net	(758)	(506)	(15)
Net cash from financing activities	(54,580)	(26,653)	62,076
Effect of exchange rate changes on cash	(2,560)	629	521
Net change in cash, cash equivalents and restricted cash	4,618	5,127	(67,376)
Cash, cash equivalents and restricted cash at the beginning of the period	36,964	31,837	99,213
Cash, cash equivalents and restricted cash at the end of the period	<u>\$ 41,582</u>	<u>\$ 36,964</u>	<u>\$ 31,837</u>
Supplemental disclosure of noncash investing and financing activities			
Accrued liabilities for distribution rights and member distributions	\$ —	\$ 709	\$ —
Accounts payable for purchase of property, plant and equipment	<u>\$ 42</u>	<u>\$ 1,311</u>	<u>\$ 419</u>

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 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.

On February 16, 2021, the Company completed its initial public offering (“IPO”), which was conducted through what is commonly referred to as an umbrella partnership C Corporation (“UP-C”) structure. The Company has majority interest, sole voting interest and controls the management of BV LLC. As a result, the Company consolidates the financial results of BV LLC and reports a noncontrolling interest representing the interest of BV LLC held by its continuing LLC owner.

The Company is focused on helping patients recover and live life to the fullest by relieving pain and addressing musculoskeletal challenges through a diverse portfolio of high-quality, innovative and clinically-proven solutions. The Company is headquartered in Durham, North Carolina and had approximately 930 employees at December 31, 2024.

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 2024 ended on March 30, June 29 and September 28. Comparable periods for 2023 ended on April 1, July 1 and September 30. The fourth and first quarters may vary in length depending on the calendar year.

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 noncontrolling ownership interests held by third parties in the operating results and financial position of the Company’s controlled subsidiaries are reported as noncontrolling interests. All intercompany balances and transactions have been eliminated in consolidation.

Reclassifications

Certain prior period amounts have been reclassified to conform to current period presentation. During the first quarter of 2024, the Company reclassified revenue and expense of the SonicOne Ultrasonic Cleansing and Debridement Systems (“SonicOne”) from the Restorative Therapies to the Surgical Solutions business as its capabilities to remove devitalized or necrotic tissue and fiber deposits more closely align with Surgical Solutions’ soft tissue management. The reclassification of SonicOne activity affected prior presentation of disaggregated revenue by business, which is detailed further in *Note 13. Revenue recognition*. The reclassification had no effect on previously reported total revenues, net loss, other comprehensive loss, stockholders’ equity or cash flows. Unless otherwise noted, all financial information in the consolidated financial statement footnotes reflects 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 President and 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, 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.

2. Significant accounting policies

Recently issued accounting pronouncements not yet adopted

In addition to being both a smaller reporting company and an emerging growth company, the Company is an accelerated filer under SEC rules and regulations.

In December 2023, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update 2023-09 (“ASU 2023-09”), Income Taxes, which enhances the transparency of income tax disclosures by expanding annual disclosure requirements related to the rate reconciliation and income taxes paid. The amendments are effective for fiscal years beginning after December 15, 2024. Early adoption is permitted. The amendments should be applied on a prospective basis. Retrospective application is permitted. The Company is currently evaluating ASU 2023-09 to determine its impact on the Company's disclosures.

In November 2024, the FASB issued Accounting Standards Update 2024-03 (“ASU 2024-03”), Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures, which requires additional disclosures regarding income statement expense categories. The additional disclosures will further disaggregate relevant expense captions in tabular form within the notes to the consolidated financial statements because they include one or more expense categories such as: (1) purchases of inventory, (2) employee compensation, (3) depreciation, (4) intangible asset amortization and (5) depreciation, depletion and amortization recognized as part of oil- and gas-producing activities or other types of depletion expenses. ASU 2024-03 also requires: (i) disclosure of certain amounts that are already required to be disclosed under current requirements in the same disclosure as the other disaggregation requirements; (ii) a qualitative description of the amount remaining in relevant expense captions that are not separately disaggregated quantitatively; and (iii) disclosure of the total amount of selling expenses. In January 2025, the FASB issued Accounting Standards Update 2025-01, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures: Clarifying the Effective Date, further defining that ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and interim periods within the annual reporting periods beginning after December 15, 2027. The Company is currently evaluating ASU 2024-03 to determine the impact on the Company's disclosures and plans to adopt ASU 2024-03 in the Company's annual report on Form 10-K for the fiscal year ending December 31, 2027. The Company expects that further disaggregation of income statement captions will be necessary, which will be disclosed in the notes to the consolidated financial statements.

Accounting pronouncements recently adopted

In November 2023, the FASB issued Accounting Standards Update 2023-07 (“ASU 2023-07”), Segment Reporting, which improves reportable segment disclosure requirements. ASU 2023-07 primarily enhances disclosures about significant segment expenses by requiring that a public entity disclose significant segment expenses that are regularly provided to the CODM and included within each reported measure of segment profit or loss. ASU 2023-07 also (i) requires that a public entity disclose, on an annual and interim basis, an amount for other segment items by reportable segment, and a description of its composition; (ii) requires that all annual disclosures are provided in the interim periods; (iii) clarifies that if the CODM uses more than one measure of profitability in assessing segment performance and deciding how to allocate resources, that one or more of those measures may be reported; (iv) requires disclosure of the title and position of the CODM and a description of how the reported measures are used by the CODM in assessing segment performance and in deciding how to allocate resources; (v) requires that an entity with a single segment provide all new required disclosures. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024 and requires retrospective application. Early adoption is permitted. The amendments under ASU 2023-07 relate to financial disclosures and its adoption will not have an impact on the Company's results of operations, financial position or cash flows. The Company adopted the provisions of ASU 2023-07 on December 31, 2024. Refer to *Note 14. Segments* 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 the 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 period 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 loss as a separate component of equity.

Foreign currency transaction gains and losses are included in other (income) expense on the consolidated statements of operations and other comprehensive loss. There was a gain of \$1,306 and \$351 for the years ended December 31, 2024 and December 31, 2023, respectively, and a loss of \$250 for the year ended December 31, 2022.

Comprehensive loss

Comprehensive loss consists of two components: net loss and other comprehensive loss, which refers to gains and losses that are recorded under U.S. GAAP as an element of stockholders' equity and is excluded from net loss. The Company's other comprehensive loss 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 has historically used 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 loss. The Company had 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") pain treatments, which are hyaluronic acid ("HA"), viscosupplementation therapies and peripheral nerve stimulation products, (ii) Surgical Solutions portfolio, which includes bone graft substitutes, tissue resection, ultrasonic bone cutting and sculpting systems and other surgical products, and (iii) Restorative Therapies portfolio, which includes minimally invasive fracture treatments and rehabilitation 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, 2024, 2023 and 2022.

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 products 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 bases 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 consistently recognizes revenue from sales of its ultrasonic products 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 \$76 and \$257 as of December 31, 2024 and 2023, 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 \$1,679 and \$2,347 as of December 31, 2024 and 2023, respectively, and 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 loss.

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 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 loss. 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.

The Company recorded an impairment loss of \$33,901 for the year ended December 31, 2024 within the U.S. reporting segment for net intellectual property attributable to the Company's Advanced Rehabilitation Business, which includes products such as the L100, L300 Go, L360, H200, Vector Gait & Safety System and Bioness Integrated Therapy System (BITS). The loss was recorded in impairment of assets within the consolidated statements of operations and comprehensive loss. Refer to *Note 4. Acquisitions and divestitures* for further information regarding the sale of advanced rehabilitation products and the impairment loss.

The Company recorded impairment losses during the year ended December 31, 2024 within the U.S. reporting segment for two right-of-use assets related to office and warehouse spaces. The Company ceased to use these assets during 2024, but has the intent and ability to sublease them. During the fourth quarter of 2024, the probability of subleasing the spaces declined due to continued market saturation and being closer to the end of these leases. The Company performed a recoverability analysis, concluding that the carrying value of the right-of-use assets exceeded the undiscounted future cash flows on potential subleases, triggering an impairment calculation. The Company utilized prices for similar assets in their respective markets and probability-based assumptions on future sublease opportunities to determine the fair value of the right-of-use assets. The carrying values of the right-of-use assets exceed their fair values, which resulted in a \$2,456 loss recorded in impairment of assets within the consolidated statements of operations and comprehensive loss.

The Company recorded an impairment loss of \$78,615 for the year ended December 31, 2023 in the U.S. reporting segment of net intellectual property attributable to the TheraSkin and TheraGenesis products, which were sold in May 2023. The loss was recorded in impairment of assets within the consolidated statements of operations and comprehensive loss. Refer to *Note 4. Acquisitions and divestitures* for further information regarding this impairment.

Except for the previously described impairments of intangibles, there were no other events, facts or circumstances for the years ended December 31, 2024, 2023 and 2022 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. Refer to *Note 12. Commitments and contingencies* for further details regarding leased assets. 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	7
Leasehold improvements	7
Machinery and equipment	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 weighted average useful lives in years are as follows:

	<u>Weighted Average Useful Life</u>
Intellectual property	19.4
Distribution rights	10.7
Developed technology	9.8

Goodwill

Goodwill is evaluated for impairment annually or more frequently if events or changes in circumstances indicate that goodwill might be impaired. The Company assesses goodwill impairment by applying a quantitative impairment analysis comparing the carrying value of the Company's reporting units to their respective fair values. A goodwill impairment exists if the carrying value of the reporting unit exceeds its fair value.

The Company has two reporting units and assesses impairment based upon qualitative factors and if necessary, quantitative factors. A reporting unit's fair value is determined using the income approach and discounted cash flow models by utilizing Level 3 inputs and assumptions such as future cash flows, discount rates, long-term growth rates, market value and income tax considerations. Specifically, 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, 2024 and 2023.

On November 8, 2022, due to a significant decline in the Company's Class A common stock, circumstances became evident that a possible goodwill impairment existed as of the third quarter balance sheet date. The Company concluded that the carrying value of the U.S. reporting unit exceeded its fair value. The Company recorded a non-cash goodwill impairment charge within the U.S. reporting unit for the year ended December 31, 2022. The impairment was recorded within impairment of assets on the consolidated statements of operations and comprehensive loss. Refer to *Note 3. Balance sheet information* for further details.

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 \$37,621 and \$36,782 as of December 31, 2024 and 2023 and the related accumulated amortization totaled \$33,324 and \$28,040, respectively. Amortization expense was \$5,578, \$6,694 and \$4,449 for the years ended December 31, 2024, 2023 and 2022, 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.

Concentration of risk

The Company provides credit to its customers in the normal course of business. 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:

	2024	2023	2022
Supplier A	31%	27%	25%
Supplier B	18%	17%	15%
Supplier C	7%	8%	10%
Supplier D	7%	7%	7%

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

	2024	2023
Supplier A	\$ 8,876	\$ 5,839
Supplier B	\$ 948	\$ 535
Supplier C	\$ 1,077	\$ 940
Supplier D	\$ 2,911	\$ 1,417

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

	2024	2023	2022
Product A	31%	27%	25%
Product B	13%	14%	14%
Product C	18%	17%	15%
Product D	7%	8%	10%
Product E	7%	7%	7%

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 loss 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 loss. Advertising costs were \$4,422, \$3,853 and \$5,203 for the years ended December 31, 2024, 2023 and 2022, respectively.

Research and development expense

Research and development expense consists 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 stockholders, 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 stockholders, 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

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:

	2024	2023
Accounts receivable.....	\$ 130,257	\$ 127,008
Less: Allowance for credit losses	(2,864)	(4,219)
	<u>\$ 127,393</u>	<u>\$ 122,789</u>

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 or more of sales. The Company had one customer representing approximately 20.4% and 16.0% of the accounts receivable balance as of December 31, 2024 and 2023, respectively. Historically, the Company's reserves have been adequate to cover credit losses.

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

	2024	2023
Beginning balance	\$ (4,219)	\$ (7,022)
Benefit for expected credit losses	434	1,103
Write-offs	4,334	2,827
Recoveries	(3,640)	(1,557)
Disposals	227	430
Ending balance	<u>\$ (2,864)</u>	<u>\$ (4,219)</u>

Inventory

Inventory consisted of the following as of December 31:

	2024	2023
Raw materials and supplies	\$ 22,098	\$ 21,062
Finished goods	70,377	70,271
	<u>\$ 92,475</u>	<u>\$ 91,333</u>

Property and equipment, net

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

	2024	2023
Computer equipment and software	\$ 41,355	\$ 37,860
Demonstration and consignment inventory	9,695	9,341
Leasehold improvements	4,095	3,763
Furniture and fixtures	4,586	4,163
Finance leases	15,737	15,737
Machinery and equipment	1,461	2,180
Assets not yet placed in service	269	4,065
	<u>77,198</u>	<u>77,109</u>
Less accumulated depreciation	(50,186)	(40,504)
	<u>\$ 27,012</u>	<u>\$ 36,605</u>

Depreciation expense from continuing operations was \$10,533, \$12,121 and \$5,688 for the years ended December 31, 2024, 2023 and 2022, respectively. The Company incurred a \$2,038 disposal loss on fixed assets during the year ended December 31, 2023 as a result of the integration of acquisitions. The loss is recorded in loss on disposals within the consolidated condensed statements of operations and other comprehensive loss.

Goodwill

The Company's goodwill totaled \$7,462 as of December 31, 2024 and 2023, which fully resides within the International business segment. Accumulated impairment charges totaled \$189,197 as of December 31, 2024, resulting from a significant decline in the Company's Class A common stock during the year ended December 31, 2022. The non-cash goodwill impairment charge was recorded within the United States reporting unit, of which \$124,697 was recorded in the impairment of assets and \$64,500 in loss on discontinued operations, net of tax within the consolidated statements of operations and comprehensive loss.

Intangible assets, net

Intangible assets consisted of the following as of December 31:

	2024	2023
Intellectual property ^{(a)(b)}	\$ 626,007	\$ 677,258
Distribution rights	61,325	61,325
Customer relationships	57,700	57,950
IPR&D	5,500	5,500
Developed technology and other	13,998	13,998
Total carrying amount	764,530	816,031
Less accumulated amortization:		
Intellectual property ^{(a)(b)}	(237,829)	(218,031)
Distribution rights	(54,280)	(49,301)
Customer relationships	(57,700)	(57,950)
Developed technology and other	(8,486)	(7,521)
Total accumulated amortization	(358,295)	(332,803)
Intangible assets, net before currency translation	406,235	483,228
Currency translation	(1,506)	(878)
	<u>\$ 404,729</u>	<u>\$ 482,350</u>

(a) The Company recorded an impairment loss of \$33,901 for the year ended December 31, 2024 within the U.S. reporting segment relating to the net intellectual property solely attributable to the Company's Advanced Rehabilitation Business. The loss was recorded in impairment of assets within the consolidated statements of operations and comprehensive loss. Refer to *Note 4. Acquisitions and divestitures* for further details regarding businesses held for sale.

(b) The Company recorded an impairment loss of \$78,615 for the year ended December 31, 2023 in the U.S. reporting segment of net intellectual property attributable to the TheraSkin and TheraGenesis products, which were sold in May 2023. The loss was recorded in impairment of assets within the consolidated statements of operations and comprehensive loss. Refer to *Note 4. Acquisitions and divestitures* for further details regarding businesses held for sale.

Amortization expense from continuing operations related to intangible assets was \$39,022, \$45,244 and \$55,715 for the years ended December 31, 2024, 2023 and 2022, respectively, of which \$24,841, \$23,848 and \$20,975 are included in ending inventory at December 31, 2024, 2023 and 2022, respectively. Estimated amortization expense for the years ended December 31, 2025 through 2029 is expected to be \$37,445, \$33,886, \$33,535, \$32,728 and \$29,914, respectively.

Accrued liabilities

Accrued liabilities consisted of the following as of December 31:

	2024	2023
Gross-to-net deductions	\$ 66,405	\$ 59,592
Bonus and commission	32,647	19,437
Compensation and benefits	7,598	9,709
Accrued interest	5,324	6,606
Income and other taxes	3,868	4,749
Other liabilities	20,037	19,702
	<u>\$ 135,879</u>	<u>\$ 119,795</u>

4. Acquisitions and divestitures

Advanced Rehabilitation Business

On September 30, 2024, the Company entered into a Purchase and Sale Agreement (the “Purchase Agreement”) with a third-party purchaser to sell certain products within its advanced rehabilitation business, including the L100, L300 Go, L360, H200, Vector Gait & Safety System and Bioness Integrated Therapy System (“BITS”) (collectively, the “Advanced Rehabilitation Business”).

The Company evaluated the Advanced Rehabilitation Business for impairment due to its divestiture. As a result of this evaluation, the Company recorded impairments totaling \$33,901 for the year ended December 31, 2024 under the U.S. reporting segment within the consolidated condensed statements of operations and comprehensive loss. The impairment losses reduced the intangible assets of the Advanced Rehabilitation Business to reflect their respective fair values less any costs to sell. The fair value of its intangibles was based on the consideration agreed to with the purchaser for the Advanced Rehabilitation Business.

On December 31, 2024, the Company closed the sale of the Advanced Rehabilitation Business and received \$24,678 at closing, net of transactional fees, subject to a post-closing adjustment for net working capital. The Company may also receive an aggregate of \$20,000 in potential earn-out payments, which are based on the achievement of certain revenue and financial metric thresholds in respect to sales of products from the Advanced Rehabilitation Business during the 2025 and 2026 fiscal years. The Company had incurred \$2,500 in transactional fees resulting from the divestiture of the Advanced Rehabilitation Business.

The Advanced Rehabilitation Business was considered non-core and required additional research and development expenditures to achieve its next stage of growth. The sale of the Advanced Rehabilitation Business is expected to enhance the Company’s strategic focus on its remaining businesses and improve liquidity, as the proceeds, net of transactional fees, were used to pay \$20,000 in long-term debt obligations. Refer to *Note 5. Financial instruments* for further information regarding the Company’s outstanding long-term debt obligations.

Wound Business

On May 22, 2023, the Company closed the sale of certain assets within its Wound Business, including the TheraSkin and TheraGenesis products (collectively, the “Wound Business” or the “Disposal Group”), for potential consideration of \$84,675, including \$34,675 at closing, \$5,000 deferred for 18 months and up to \$45,000 in potential earn-out payments, which are based on the achievement of certain revenue thresholds by the purchaser of the Wound Business for sales of the TheraSkin and TheraGenesis products during the 2024, 2025 and 2026 fiscal years. The Company received the deferred payment in November 2024, which was used to pay \$5,000 of long-term debt obligations.

The Company incurred \$3,880 in transactional fees resulting from the sale of the Wound Business. The loss resulting from the deconsolidation of the Disposal Group totaled \$1,539 for the year ended December 31, 2023 and was recorded in loss on disposals within the consolidated statements of operations and comprehensive loss. The Company used the proceeds from the sale of its Wound Business to prepay \$30,000 of long-term debt obligations. Refer to *Note 5. Financial Instruments* for further details regarding the Company’s outstanding long-term debt obligations.

The Company evaluated the Wound Business for impairment prior to its sale and recorded a \$78,615 impairment within the consolidated statements of operations and comprehensive loss during the year ended December 31, 2023 as a result of this evaluation to reduce the intangible assets of the Disposal Group to reflect their respective fair values less any costs to sell. The fair value of the Disposal Group's intangibles was determined based on the consideration received for the Wound Business.

CartiHeal (2009) Ltd.

On July 12, 2022, the Company completed the acquisition of 100% of the remaining shares in CartiHeal (2009) Ltd. ("CartiHeal"), in which the Company previously held an equity interest. CartiHeal is 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 joints. The acquisition of CartiHeal involved an aggregate purchase price of approximately \$315,000 and an additional \$135,000, payable after closing upon the achievement of a certain sales milestone ("CartiHeal Contingent Consideration"). The Company paid \$100,000 of the aggregate purchase price upon closing, deferred \$215,000 (the "Deferred Amount") of the aggregate purchase price otherwise due at closing and paid \$8,622 in transaction-related fees and expenses. The Deferred Amount was to be paid in five tranches based upon certain medical and research achievements and was subject to an 8.0% annual interest rate.

On February 13, 2023, the first tranche of the Deferred Amount plus applicable interest became due. The Company subsequently entered into a settlement agreement (the "Settlement Agreement") with Elron Ventures Ltd. ("Elron" and together with the Company, the "Parties") as representative of CartiHeal's selling securityholders (collectively, the "Former Securityholders"). Pursuant to the Settlement Agreement, Elron, on behalf of the Former Securityholders, agreed to forbear from initiating any legal action or proceedings relating to non-payment of any obligations arising under the previously entered into Option and Equity Purchase Agreement with CartiHeal (the "Option Agreement") during a period of 30 calendar days (the "Interim Period") in exchange for (i) a one-time non-refundable amount of \$10,000 and (ii) a one-time non-refundable payment of \$150 to Elron to be used in accordance with the expense fund provisions under the Option Agreement. The Interim Period expired on March 29, 2023 and the Company did not exercise its right to extend the Interim Period as the Company was not able to find a financing solution to fund the payment obligations under the Option Agreement on terms the Company believed to be favorable to it and its shareholders. In addition, the Parties mutually released any further claims under the Option Agreement and related transaction documents, including without limitation a release by the Former Securityholders of any rights to enforce the provision of the Option Agreement or make further monetary claims against the Company and/or its respective affiliates and representatives. The release of obligations includes liabilities associated with the Deferred Amount and CartiHeal Contingent Consideration.

The Company transferred 100% of its shares in CartiHeal to a trustee (the "Trustee") for the benefit of the Former Securityholders pursuant to the Settlement Agreement. The Company had no ownership interest and no voting rights during the Interim Period. Accordingly, the Company concluded that upon execution of the Settlement Agreement, the Company ceased to control CartiHeal for accounting purposes, and therefore, deconsolidated CartiHeal effective February 27, 2023. CartiHeal was part of the Company's International reporting segment. The Company treated the deconsolidation of CartiHeal as a discontinued operation. The loss upon disposal was \$60,639 and was recorded within discontinued operations, net of tax within the consolidated statements of operations and comprehensive loss. The loss on disposal is comprised of the book value of CartiHeal's net assets at the time of disposal, goodwill attributable to CartiHeal and the previously discussed non-refundable payments made to Elron.

Other

On August 23, 2021, the Company purchased shares of Trice Medical, Inc.'s ("Trice") Series D Preferred Stock for \$10,000, representing an 8.4% ownership interest of its fully diluted shares. Trice is a privately held company that develops and markets minimally invasive technologies for sports medicine and orthopedic surgical procedures and it did not have a readily determinable fair value. The investment in Trice was 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. In December 2022, the Company recognized an impairment of \$10,285 representing its entire ownership interest due to Trice's liquidity situation. The impairment was recorded within other (income) expense on the consolidated statements of operations and comprehensive loss for the year ended December 31, 2022.

5. Financial instruments

Long-term debt consisted of the following as of December 31:

	2024	2023
Amended Term Loan due October 2026 (9.26% at December 31, 2024)	\$ 337,864	\$ 382,448
Revolver due October 2025 (9.26% at December 31, 2024)	—	15,000
Less:		
Current portion of long-term debt	(27,339)	(27,848)
Unamortized debt issuance cost	(1,147)	(917)
Unamortized discount	(1,090)	(1,685)
	<u>\$ 308,288</u>	<u>\$ 366,998</u>

Amended Term Loan

On December 6, 2019, the Company entered into a Credit and Guaranty Agreement (the “2019 Credit Agreement”) that was comprised of a \$200,000 term loan (“Original Term Loan”) and a \$50,000 revolving facility (the “Revolver”). The Company amended the 2019 Credit Agreement on August 29, 2021, and then again on October 29, 2021 in connection with the acquisition of Misonix, Inc. in which the Company prepaid \$80,000 on the Original Term Loan. The 2019 Credit Agreement, as amended, subsequent to the prepayment, was comprised of a \$360,750 term loan (“Term Loan”) and the Revolver.

On July 11, 2022, the Company further amended the 2019 Credit Agreement in conjunction with the acquisition of CartiHeal. Pursuant to that amendment, an \$80,000 term loan facility (the “July 2022 Term Loan” and, together with the Term Loan, the “Term Loan Facilities”) was extended to the Company to be used for: (i) the financing of the acquisition of CartiHeal; (ii) the payment of related fees and expenses; (iii) repayment of the draws made on the Revolver; and (iv) working capital needs and general corporate purposes of the Company, including without limitation for permitted acquisitions.

The Company was not in compliance with certain financial covenants as of December 31, 2022. As a result, on March 31, 2023, the Company entered into another amendment to the 2019 Credit Agreement to, among other things, modify certain financial covenants, waive the noncompliance at December 31, 2022, and to modify interest rates applicable to borrowings under the 2019 Credit Agreement.

On January 18, 2024 (the “Closing Date”), the Company further amended the 2019 Credit Agreement (collectively, with the August 2021, October 2021, July 2022 and March 2023 amendments, the “Amended 2019 Credit Agreement”), to further modify certain financial covenants under the 2019 Credit Agreement. The Company was in compliance as of December 31, 2024 and 2023 with the financial covenants as stated within the 2019 Credit Agreement then in effect.

The Term Loan Facilities matures on October 29, 2026 (“Maturity”). The Revolver matures on October 29, 2025.

Secured overnight financial rate (“SOFR”) loans and base rate loans had a margin of 3.25% and 2.25%, respectively, subsequent to July 11, 2022 and prior to the Closing Date. Subsequent to the March 31, 2023 amendment, SOFR loans and base rate loans had a margin of 4.25% and 3.25%, respectively. 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 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 certain distributions on or in respect of Bioventus LLC’s equity interests, restrictions on acquisitions, investments and certain other payments, limitations on the incurrence of new indebtedness, limitations on transfers, sales and other dispositions of assets of Bioventus LLC and its subsidiaries, as well as limitations on making changes to the business and organizational documents of Bioventus LLC and its subsidiaries. Financial covenant requirements include (i) a maximum debt leverage ratio of not greater than 4.50 to 1.00 for the testing period ending December 31, 2024, 4.25 to 1.00 for the testing period ending March 31, 2025, 4.00 to 1.00 for the testing period ending June 30, 2025 and at the end of each testing period occurring thereafter, and beginning on March 31, 2025, to be subject to a temporary increase to 4.50 to 1.00 upon certain events; and (ii) an interest coverage ratio not less than 2.00 to 1.00 for the testing period ending December 31, 2024, 2.00 to 1.00 for the testing period ending March 31, 2025, 2.25 to 1.00 for the testing period ending June 30, 2025, 2.50 to 1.00 for the testing period ending September 30, 2025 and 3.00 to 1.00 for the testing period ending December 31, 2025 and each testing period thereafter. In addition, during the period commencing on the Closing Date and ending upon the satisfaction of certain conditions occurring not prior to October 29, 2025, the Company will be subject to certain additional requirements and covenants, including a requirement to maintain Liquidity (as defined in the Amended 2019 Credit Agreement) of not less than \$10,000 as of the end of each calendar month during such period.

The January 2024 amendment had deferred financing costs of \$1,180, of which \$325 was expensed and \$855 was capitalized. The March 2023 amendment had deferred financing costs of \$3,661, of which \$1,617 was expensed and \$2,044 was capitalized. There were no losses on debt refinancing and modification as a result of either the January 2024 or March 2023 amendments. Deferred financing costs expensed resulting from the amendments were recorded in selling, general and administrative expense within the consolidated statements of operations and other comprehensive loss and amounts capitalized were recorded primarily in long-term debt, less current portion within the consolidated balance sheets.

As of December 31, 2024, \$335,627 was outstanding on the Term Loan Facilities, net of original issue discount of \$1,090 and deferred financing costs of \$1,147. Capitalized deferred fees are amortized to interest expense on a straight-line basis over the term of the Term Loan Facilities, which approximates the effective interest method. The Company recorded \$1,524, \$1,706 and \$853 for deferred cost amortization in interest expense for the years ended December 31, 2024, 2023 and 2022, respectively. Scheduled quarterly principal payments for the Term Loan Facilities are \$5,301 in the third quarter of 2025, \$22,038 in the fourth quarter of 2025, three quarterly payments of \$11,019 during 2026 with a final payment of \$277,469 at Maturity. Contractual maturities of long term debt for the next two years are as follows: 2025—\$27,339 and 2026—\$310,525.

The Company may voluntarily prepay the Term Loan Facilities without premium or penalty upon prior notice. The Company may be required to make additional principal payments on the Term Loan Facilities 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 Facilities and then the Eurodollar portions.

The estimated fair value of the Term Loan Facilities was \$338,708 as of December 31, 2024. The fair value of these obligations was determined based on the midpoint of the Bloomberg Valuation, as of December 31, 2024. This is classified as a Level 2 instruments within the fair value hierarchy.

Revolver

The Revolver was a five-year revolving credit facility, that was subsequently reduced to a four-year revolving credit facility in the Amended 2019 Credit Agreement, that includes revolving and swingline loans as well as letters of credit (“LOC”) and, inclusive of all, cannot exceed \$40,000 at any one time. The Revolver’s capacity was reduced \$5,000 on December 31, 2023 and June 30, 2024 in accordance with the Amended 2019 Credit Agreement. 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, 2024, the Company had three LOCs outstanding leaving approximately \$37,800 available. The Revolver had no outstanding borrowings as of December 31, 2024 and \$15.0 million at December 31, 2023.

Interest

The Term Loan Facilities and Revolver permit the Company to elect either the secured overnight financial rate (“SOFR”) or base interest rate (“BR”) options for the entire amount or certain portions of the loans. Both the SOFR and BR options 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. BR portions of the Term Loan Facilities have interest due the last day of each calendar quarter-end. Pursuant to the Amended 2019 Credit Agreement, the margin at each applicable leverage ratio will be increased by 1.00% per annum. SOFR portions of the Term Loan Facilities have one, 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.

Pricing grids are used to determine the applicable loan margins based on the type of loan and the leverage ratio. The loan margin is adjusted after the quarterly financial statements are delivered to the lenders in accordance with the below pricing grid, which reflects the margins in effect under the Amended 2019 Credit Agreement:

Leverage ratio	SOFR	BR
> 4.00 to 1.00	4.25 %	3.25 %
≥ 3.50 to 1.00 and < 4.00 to 1.00	3.75 %	2.75 %
≥ 3.00 to 1.00 and < 3.50 to 1.00	3.25 %	2.25 %
≥ 2.50 to 1.00 and < 3.00 to 1.00	3.00 %	2.00 %
< 2.50 to 1.00	2.75 %	1.75 %

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, 2024. 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 below pricing grid under the Amended 2019 Credit Agreement:

Leverage ratio	Commitment Fee Rate
≥ 2.50 to 1.00	0.30 %
< 2.50 to 1.00	0.20 %

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. The Company's effective weighted average interest rate was 9.30% for all outstanding debt as of December 31, 2024. Cash paid for interest totaled \$38,507, \$32,470 and \$18,043 for the December 31, 2024, 2023 and 2022, respectively.

Interest rate swap

The Company historically entered into interest rate swap agreements to limit its exposure to changes in the variable interest rate on its long-term debt. The Company had one non-designated interest rate swap agreement that was terminated on October 28, 2022 and subsequently received \$7,738 upon its termination. The swap was carried at fair value on the balance sheet with changes in fair value recorded as interest income or expense within the consolidated statements of operations and comprehensive loss. Net interest income of \$6,396 was recorded related to the change in fair value of the interest rate swap for the year ended December 31, 2022.

6. Fair value measurements

There were no assets measured at fair value on a recurring basis and there were no liabilities valued at fair value using Level 1 or Level 2 inputs at December 31, 2024 and 2023. The following table provides information for assets and liabilities measured at fair value on a recurring basis using Level 3 inputs:

	December 31, 2024		December 31, 2023	
	Total	Level 3	Total	Level 3
Liabilities:				
Current portion of contingent consideration	\$ 19,573	\$ 19,573	\$ —	\$ —
Contingent consideration	—	—	18,150	18,150
Total liabilities:	<u>\$ 19,573</u>	<u>\$ 19,573</u>	<u>\$ 18,150</u>	<u>\$ 18,150</u>

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. After the initial valuation, the Company generally uses its best estimate to measure contingent consideration at each subsequent reporting period using unobservable Level 3 inputs.

Unobservable inputs

A summary of unobservable Level 3 inputs utilized for the above liabilities are as follows:

	Valuation Technique	Unobservable inputs	Range
Contingent consideration	Discounted cash flow	Payment discount rate	6.4% - 6.8%
		Payment period	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 acquisition of Bioness, Inc. (“Bioness”) on March 30, 2021 and 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. Contingent consideration resulting from the acquisition of Bioness includes maximum earn-out payments of \$50,000 as follows: (i) \$20,000 for meeting net sales targets for certain implantable products over a three year period ending on June 30, 2025 at the latest; (ii) 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 (iii) \$20,000 for maintaining Centers for Medicare & Medicaid Services coverage and reimbursement for certain products at specified levels as of December 31, 2024. The Company met criteria (iii) as of December 31, 2024 and will make the related payment in the first half of fiscal year 2025.

Contingent consideration is adjusted quarterly based upon the passage of time or the anticipated success or failure of achieving certain milestones. Changes in contingent consideration related to the Bioness Acquisition totaled \$1,423, \$719 and \$1,102 for the years ended December 31, 2024, 2023 and 2022, respectively, and were recorded as the change in fair value of contingent consideration within the consolidated statements of operations and comprehensive loss.

7. Equity-based compensation

2021 Plan

The Company operates an equity-based compensation plan (“2021 Plan”), which 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”). As of December 31, 2024, 19,564,333 shares of Class A common stock were authorized to be awarded and 9,383,955 shares were available for 2021 Plan Awards.

2023 Plan

The Company also operates the 2023 Retention Equity Award Plan (the “2023 Plan” and, together with the 2021 Plan, the “Plans”), the purpose of which is to retain and motivate critical personnel over the short-term by providing them additional incentives in the form of RSUs (the “Retention Awards” and together with the “2021 Plan Awards,” the “Awards”). As of December 31, 2024, 600,000 shares of Class A common stock were authorized to be awarded under the 2023 Plan and 69,050 shares were available for Retention Awards.

Activity under the Plans

Expense

Equity-based compensation expense for Awards granted under the Plans and inducement awards for the years ended December 31, 2024, 2023 and 2022 totaled \$9,613, \$2,370 and \$17,114, respectively. The expense is primarily included in selling, general and administrative expense with a nominal amount in research and development expense on the consolidated statements of operations and comprehensive loss based upon the classification of the employee. There were no income tax benefits related to equity-based compensation expense for the years ended December 31, 2024 and 2023. Income tax benefits totaled \$2,951 related to compensation expense for the year ended December 31, 2022.

Restricted Stock Units

During the years ended December 31, 2024 and 2023, the Company granted time-based RSUs which vest at various dates through December 4, 2027. RSU compensation expense is recognized over the vesting period, which is typically between 1 and 4 years. Unamortized compensation expense related to the RSUs totaled \$4,930 at December 31, 2024, and is expected to be recognized over a weighted average period of approximately 3.31 years.

A summary of the RSU award activity for the years ended December 31, 2024 and 2023 are as follows (number of units in thousands):

	Number of units	Weighted-average grant-date fair value per unit
Unvested at December 31, 2022	1,189	\$ 11.96
Granted	2,067	2.34
Vested	(641)	8.74
Forfeited or canceled	(549)	8.53
Unvested at December 31, 2023	2,066	4.51
Granted	2,563	5.66
Vested	(1,839)	4.45
Forfeited or canceled	(378)	5.74
Unvested at December 31, 2024	2,412	\$ 5.52

Stock Options

During the years ended December 31, 2024 and 2023, the Company granted time-based stock options which vest over 1 to 4 years following the date of grant and expire within 10 years. The fair value of time-based stock options is determined using the Black-Scholes valuation model, with such value recognized as expense over the service period, which is typically 1 to 4 years, net of actual forfeitures. A summary of the Company's assumptions used in determining the fair value of the stock options granted during the years ended December 31, 2024 and 2023 are shown in the following table:

	2024	2023
Risk-free interest rate	3.9% - 4.3%	3.5% - 4.7%
Expected dividend yield	— %	— %
Expected stock price volatility	36.1% - 38.2%	35.2% - 36.4%
Expected life of stock options (years)	6.25	5.50 - 6.25

The weighted-average grant date fair value of options granted during the year ended December 31, 2024 was \$2.36 per share. The expected term of the options granted is estimated using the simplified method. Expected volatility is based on the historical volatility of the Company's 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. Unamortized compensation expense related to the options totaled \$2,832 at December 31, 2024, and is expected to be recognized over a weighted average period of approximately 3.97 years.

A summary of stock option activity is as follows for the years ended December 31, 2024 and 2023 (number of options in thousands):

	Number of options	Weighted-average exercise price	Weighted average remaining contractual term (in years)	Aggregate intrinsic value ⁽¹⁾
Outstanding at December 31, 2022	8,910	\$ 11.65	7.74	\$ 3
Granted	1,226	1.28		
Exercised	(67)	2.68		
Forfeited or canceled	(5,722)	11.80		
Outstanding at December 31, 2023	4,347	8.68	7.31	\$ 4,383
Granted	1,835	5.42		
Exercised	(422)	7.18		
Forfeited or canceled	(1,131)	9.26		
Outstanding at December 31, 2024	4,629	7.73	7.14	\$ 17,049
Exercisable and vested at December 31, 2024	1,816	\$ 10.29	4.95	\$ 1,624

⁽¹⁾ The aggregate intrinsic value is based upon the difference between the Company's closing stock price at the date of the consolidated balance sheets and the exercise price of the stock option for in-the-money stock options. The intrinsic value of outstanding stock options fluctuates based upon the trading value of the Company's Class A common stock.

Employee Stock Purchase Plan

The Company operates a non-qualified Employee Stock Purchase Plan (“ESPP”), which provides for the issuance of shares of the Company’s Class A common stock to eligible employees of the Company that elect to participate in the plan and purchase shares of Class A common stock through payroll deductions at a discounted price. As of December 31, 2024, the aggregate number of shares reserved for issuance under the ESPP was 1,289,837. A total of 229,767, 516,976 and 279,000 shares were issued and \$445, \$352 and \$471 of expense was recognized during the years ended December 31, 2024, 2023 and 2022, respectively.

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 United States, the Company provides a 401(k) defined contribution plan (“U.S. Plan”) that covers substantially all U.S. employees that meet minimum age requirements. The Company matches 100% of the employees’ contribution up to 4% of the employees’ wages and 50% on the next 2%. The U.S. Plan also provides for an additional 1% to 3% at the Company’s discretion.

Company contributions totaled \$6,715, \$5,836, and \$6,407 for all global plans during the years ended December 31, 2024, 2023 and 2022, respectively. 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 loss based upon the classification of the employee.

8. Stockholders’ equity

On February 16, 2021, the Company closed an IPO of 9,200,000 shares of Class A common stock through an UP-C structure with BV LLC. In connection with the IPO, the Company amended and restated the limited liability agreement of BV LLC (“BV LLC Agreement”) to provide for a new single class of common membership interests in BV LLC (“LLC Interests”) and exchange all of the existing membership interests in BV LLC (the “Original BV LLC Owners”) for new LLC Interests. The Company also amended its certificate of incorporation to authorize the following shares: (i) 250,000,000 shares of Class A common stock with a par value of \$0.001 per share; (ii) 50,000,000 shares of Class B common stock with a par value of \$0.001 per share, which have voting rights but no economic interest, and some of which were issued to the Original BV LLC Owners; and (iii) 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company’s board of directors. In connection with the completion of the IPO, the Company acquired, by merger, certain entities that were part of the Original BV LLC Owners (“Former BV LLC Owners”), for which the Company issued 31,838,589 Class A common stock as merger consideration (“IPO Mergers”) and cancelled the Class B common stock held by such Former BV LLC Owners. The IPO Mergers are deemed to be a recapitalization transaction.

Holders of the Company’s 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 Smith & Nephew, Inc. (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.

Noncontrolling interest

In connection with any redemption pursuant to the BV LLC Agreement, the Company will receive a corresponding number of LLC Interests, increasing its 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 years ended December 31, 2024 and 2023. The following table summarizes the ownership interest in BV LLC as of December 31 (number of units in thousands):

	2024		2023	
	LLC Interests	Ownership %	LLC Interests	Ownership %
Number of LLC Interests owned				
Bioventus Inc.	65,758	80.6 %	63,267	80.0 %
Continuing LLC Owner	15,787	19.4 %	15,787	20.0 %
Total	81,545	100.0 %	79,054	100.0 %

9. Earnings per share

The following table sets forth the computation of basic and diluted loss per share of Class A common stock (amounts in thousands, except share and per share data) for the years ending December 31:

	2024	2023	2022
Numerator:			
Net loss from continuing operations	\$ (43,833)	\$ (121,196)	\$ (144,651)
Net loss attributable to noncontrolling interests — continuing operations	10,291	24,458	40,732
Net loss attributable to Bioventus Inc. Class A common stockholders — continuing operations	<u>\$ (33,542)</u>	<u>\$ (96,738)</u>	<u>\$ (103,919)</u>
Numerator:			
Net loss from discontinued operations	\$ —	\$ (74,429)	\$ (68,740)
Net loss attributable to noncontrolling interests — discontinued operations	—	14,937	13,955
Net loss attributable to Bioventus Inc. Class A common stockholders — discontinued operations	<u>\$ —</u>	<u>\$ (59,492)</u>	<u>\$ (54,785)</u>
Denominator:			
Weighted-average shares of Class A common stock outstanding - basic and diluted	<u>64,547,474</u>	<u>62,647,554</u>	<u>61,389,107</u>
Net loss per share of Class A common stock, from continuing operations, basic and diluted	\$ (0.52)	\$ (1.54)	\$ (1.70)
Net loss per share of Class A common stock, from discontinued operations, basic and diluted	—	(0.95)	(0.89)
Net loss per share of Class A common stock, basic and diluted	<u>\$ (0.52)</u>	<u>\$ (2.49)</u>	<u>\$ (2.59)</u>

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 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 for the years ending December 31:

	2024	2023	2022
LLC Interests held by Continuing LLC Owner ^(a)	15,786,737	15,786,737	15,786,737
Stock options	2,289,436	5,860,516	7,679,780
RSUs	11,052	595,030	710,807
Total	18,087,225	22,242,283	24,177,324

(a) Class A Shares reserved for future issuance upon redemption or exchange of LLC Interests by the Continuing LLC Owner.

10. Restructuring costs

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 costs in the consolidated statements of operations and comprehensive loss. Liabilities associated from restructuring costs are recorded in accrued liabilities on the consolidated balance sheets.

The Company's prior restructuring plans adopted in 2021 and 2022 focused on aligning its organizational and management cost structure to improve profitability and cash flow, reduce headcount and consolidate facilities. These plans have been completed. There was a restructuring expense reversal of \$52 during the year ended December 31, 2024 primarily due to employee transitions associated with the sale of the Advanced Rehabilitation Business. Restructuring expenses totaled \$840 and \$6,779 during the years ended December 31, 2023 and 2022, respectively.

The Company's restructuring charges and payments for plans related to businesses acquired comprised of the following:

	Employee severance and temporary labor costs	Other charges	Total
Balance at December 31, 2022	\$ 3,760	\$ —	\$ 3,760
Expenses incurred	648	192	840
Payments made	(3,092)	(192)	(3,284)
Balance at December 31, 2023	1,316	—	1,316
Expense reversal	(52)	—	(52)
Payments made	(1,139)	—	(1,139)
Balance at December 31, 2024	\$ 125	\$ —	\$ 125

11. Income taxes

Bioventus Inc. is 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 United States 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, on a pro rata basis. The components of loss before income taxes for the years ended December 31 are as follows:

	2024	2023	2022
United States	\$ (59,448)	\$ (125,676)	\$ (187,571)
International	10,322	4,565	(1,454)
Loss before income taxes - continuing operations	\$ (49,126)	\$ (121,111)	\$ (189,025)

The provision for income taxes on operations consists of the following for the years ended December 31:

	2024	2023	2022
Current:			
United States federal	\$ (1,295)	\$ (734)	\$ 2,092
United States state and local	(152)	2,085	(96)
International	1,548	1,111	296
Total current	101	2,462	2,292
Deferred:			
United States federal	(4,377)	(2,881)	(38,678)
United States state and local	(1,017)	(1,951)	(7,897)
International	—	2,455	(91)
Total deferred	(5,394)	(2,377)	(46,666)
Total income tax (benefit) expense - continuing operations	<u>\$ (5,293)</u>	<u>\$ 85</u>	<u>\$ (44,374)</u>

Cash paid for income taxes totaled \$1,341, \$2,955 and \$1,518 for the years ended December 31, 2024, 2023 and 2022, 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:

	2024	2023	2022
U.S. statutory federal corporate income tax rate	21.0%	21.0%	21.0%
Noncontrolling interest	(7.3)	(6.6)	(6.4)
LLC flow-through structure	11.9	15.7	5.4
Non-deductible expenses	(2.2)	(1.1)	—
State and local income taxes, net of federal benefit	2.2	0.2	4.2
Change in valuation allowance	(17.6)	(29.1)	(0.4)
Research and other tax credits	0.8	0.5	0.3
Organizational Transactions	—	—	(0.6)
Uncertain tax positions	3.1	1.1	(0.9)
Foreign rate differential	(0.6)	(0.2)	—
GAAP impairment	—	—	(3.5)
Stock compensation	0.7	(4.0)	—
Other	(1.2)	2.4	4.4
Effective income tax rate	<u>10.8%</u>	<u>(0.1%)</u>	<u>23.5%</u>

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:

	2024	2023
Deferred tax assets:		
Capital loss carryforward	\$ 18,440	\$ 17,407
Interest	18,692	13,374
Net operating losses and tax credit carryforwards	9,224	10,792
Tax credits	1,381	1,567
Investment in Bioventus LLC	7,362	1,221
Transaction costs	711	975
Stock-based compensation	283	947
Research & Development	50	69
Fixed assets	—	18
Accrued liabilities	10	7
Other	467	470
Gross deferred tax asset	56,620	46,847
Valuation allowance	(51,875)	(46,007)
Total deferred tax assets	4,745	840
Deferred income tax liabilities:		
Intangibles	564	2,053
Gross deferred income tax liabilities	564	2,053
Net deferred tax (asset) liability	\$ (4,181)	\$ 1,213

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 \$5,868. The valuation allowance at December 31, 2024 is primarily against NOLs, interest carryover and capital loss carryforward. The valuation allowance at December 31, 2023 principally relates to recognizing a full valuation allowance against foreign NOLs.

Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminated the option to deduct research and development expenditures immediately in the year incurred and requires companies to amortize such expenditures over five or fifteen years for tax purposes, depending on whether the activities were incurred in the United States or outside of the United States. This change resulted in an increase to gross deferred tax assets and cash tax liabilities in 2023 and 2024.

As of December 31, 2024, the Company had approximately \$33,720 in U.S. federal NOL carryforwards and \$1,153 in federal tax credits. Certain US federal NOL carryforwards begin to expire in 2031, while others were generated after the enactment of the Tax Cuts and Jobs Act (the “Act”) and as such do not expire, but can only be utilized to offset up to 80% of taxable income in any given year. The federal tax credits start to expire at various dates beginning in 2026. As of December 31, 2024, the Company had approximately \$51,313 in state NOL carryforwards and \$354 in state tax credits. If not utilized, some state NOL carryforwards will expire at various dates beginning in 2025.

The Company evaluated its tax positions and had unrecognized tax benefits of \$3,735 and \$4,725 as of December 31, 2024 and 2023, respectively. The Company had \$1,508 and \$2,047 accrued for payment of interest and penalties as of December 31, 2024 and 2023, respectively. If the \$3,735 of unrecognized tax benefit is recognized, it would not impact the effective tax rate due to the valuation allowance on the Company's net U.S. deferred tax assets. The Company does expect a material decrease of approximately \$2,334 in the twelve months following December 31, 2024 in its uncertain tax positions due to various statute expirations during 2025.

The Company files U.S. federal income tax returns as well as income tax returns in many United States and foreign jurisdictions. In general, the tax years 2021 - 2024 remain open to examination by the major jurisdictions in which the Company is subject to tax.

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

	2024	2023
Beginning of the period	\$ 4,725	\$ 5,883
Additions for current year tax positions	456	142
Expiration of statutes	(1,446)	(1,300)
End of the period	<u>\$ 3,735</u>	<u>\$ 4,725</u>

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 the Company making 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, 2024, 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. The remaining lease terms range from 1 month to 8.3 years. 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 in order to record the combination 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 components of lease cost were as follows for the years ended December 31:

	2024	2023	2022
Operating lease cost	\$ 3,404	\$ 3,921	\$ 4,557
Short-term lease cost ^(a)	883	840	691
Financing lease cost:			
Amortization of finance lease assets	602	1,175	36
Interest on lease liabilities	866	823	4
Total lease cost	<u>\$ 5,755</u>	<u>\$ 6,759</u>	<u>\$ 5,288</u>

^(a) Includes variable lease cost and sublease income, which are immaterial.

Supplemental cash flow information and non-cash activity related to operating leases were as follows for the years ended December 31:

	2024	2023	2022
Cash paid for amounts included in measurement of lease liabilities:			
Operating cash flows from operating leases	\$ 4,619	\$ 4,516	\$ 4,374
Operating cash flows from financing leases	\$ 866	\$ 793	\$ 5
Financing cash flows from finance leases	\$ 758	\$ 506	\$ 53
Right-of-use assets obtained in exchange for lease obligations:			
Operating lease obligations	\$ 761	\$ 344	\$ 4,792
Finance lease obligations	\$ —	\$ 15,567	\$ —

Supplemental balance sheet and other information related to operating leases were as follows for the years ended December 31:

	2024	2023
Operating lease assets ^(a)	\$ 6,506	\$ 13,353
Operating lease liabilities - other current liabilities	\$ 3,102	\$ 4,057
Operating lease liabilities - other long-term liabilities	6,940	10,573
Total operating lease liabilities	\$ 10,042	\$ 14,630

Financing leases

Property, plant and equipment - net	\$ 12,703	\$ 14,279
Finance lease liabilities - other current liabilities	\$ 815	\$ 759
Finance lease liabilities - other long-term liabilities	9,571	10,386
Total financing lease liabilities	\$ 10,386	\$ 11,145

Weighted average remaining lease term (years):

Operating leases	3.1	3.8
Finance leases	8.3	9.3

Weighted average discount rate:

Operating leases	5.1 %	4.7 %
Finance leases	8.1 %	8.1 %

^(a) As previously discussed in *Note 2. Significant accounting policies*, the Company incurred an impairment of right-of-use assets totaling \$2,456 during the year ended December 31, 2024.

Future maturities of operating and finance lease liabilities are as follows:

	Operating leases	Finance Leases
2025	\$ 3,487	\$ 1,617
2026	3,329	1,630
2027	2,659	1,662
2028	1,367	1,696
2029	10	1,730
Thereafter	—	6,021
Total undiscounted cash flows	10,852	14,356
Less imputed interest	(810)	(3,970)
Present value of future lease payments	\$ 10,042	\$ 10,386

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 its 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 United States 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.

The Company is presently unable to predict the duration, scope, or result of these 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, is not within the Company's complete control and might 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.

Bioventus shareholder litigation

On January 12, 2023, the Company and certain of its current and former directors and officers were named as defendants in a putative class action lawsuit filed in the Middle District of North Carolina (the "Court"), *Ciarciello v. Bioventus Inc.*, No. 1:23-CV – 00032-CCE-JEP (M.D.N.C. 2023). The complaint asserted violations of Sections 10(b) and 20(a) of the Exchange Act and of Sections 11 and 15 of the Securities Act and generally alleges that the Company failed to disclose certain information regarding rebate practices, its business and financial prospects, and the sufficiency of internal controls regarding financial reporting. The complaint seeks damages in an unspecified amount. On April 12, 2023, the Court appointed Wayne County Employees' Retirement System as lead plaintiff. The plaintiff's amended consolidated complaint was filed with the Court on June 12, 2023. On July 17, 2023, the defendants filed a motion to dismiss the complaint raising a number of legal and factual deficiencies with the amended consolidated complaint. In response to the defendants' motion to dismiss, the lead plaintiff filed a second amended complaint on July 31, 2023. The defendants moved to dismiss the second amended complaint on August 21, 2023, which the Court granted in part and denied in part on November 6, 2023. The Court dismissed the plaintiff's Securities Act claims, but allowed the plaintiff's Exchange Act claims to proceed into discovery.

On July 15, 2024, a Stipulation and Agreement of Settlement (the "Settlement Agreement") by and between the lead plaintiff and the defendants was filed with the Court, and the Court preliminarily approved the Settlement Agreement on August 13, 2024. The Court entered judgment on December 18, 2024, granting final approval of the terms of the Settlement Agreement and dismissing all claims against the defendants, including the Company. The parties settled without any admission of liability or wrongdoing by any party. The settlement amount of \$15,250, together with interest earned thereon, has been paid by the defendants and/or the defendant's insurers. The Company incurred \$13,802 of net shareholder litigation costs (including estimated settlement and reimbursement) during the year ended December 31, 2024 under the Settlement Agreement, which were recorded in selling, general and administrative expense within the consolidated condensed statements of operations and comprehensive loss.

On October 4, 2023, certain of the Company's current and former directors and officers were named as defendants in a derivative shareholder lawsuit (in which the Company is a nominal defendant) filed in the United States District Court for the District of Delaware, *Grogan, on behalf of Bioventus Inc., v. Real, et al.*, No. 1:23-CV-01099-RGA (D. Del. 2023). The complaint asserts violations of Section 14(a) of the Exchange Act, breaches of fiduciary duties and related state law claims, and a claim for contribution, and generally alleges the same purported misconduct as alleged in the *Ciarciello* case. On January 12, 2024, the Court agreed to stay this case pending resolution of the *Ciarciello* case.

On February 9, 2024, another plaintiff filed a derivative shareholder lawsuit against certain of the Company's current and former directors and officers (in which the Company is a nominal defendant) filed in the United States District Court for the District of Delaware, *Sanderson, on behalf of Bioventus Inc., v. Realı, et. al.*, No. 1:24-cv-00180-RGA (D. Del. 2024). Like the *Grogan* case, this case asserts violations of Section 10(b) of the Exchange Act, breaches of fiduciary duties and related state law claims, and a claim for contribution, and generally alleges the same purported misconduct as alleged in the *Ciarciello* case. On May 1, 2024, the parties filed a stipulation to consolidate the two derivative matters and stay them on terms similar to those entered in the *Grogan* case. On May 2, 2024, the United States District Court for the District of Delaware granted the stipulation and ordered the consolidation of the Sanderson and Grogan cases, captioned *In re Bioventus Inc. Derivative Litigation*, Case No.: 1:23-cv-01099-RGA. The Court also stayed the consolidated case. Following resolution of the *Ciarciello* case, on December 30, 2024, the plaintiffs in the consolidated case filed an amended complaint asserting the same claims as in the *Grogan* case against certain of the Company's current and former directors and officers. On January 6, 2025, the Court entered a scheduling order, under which the defendants had until March 3, 2025 to file a motion to dismiss the amended complaint. On February 21, 2025, the parties submitted a joint stipulation to stay the proceedings to allow the parties time to negotiate a settlement, which the company expects to be in the form of governance reforms.

On July 31, 2024, another plaintiff filed a derivative complaint against certain of the Company's current and former officers and directors, in which Bioventus is a nominal defendant only, in the United States District Court for the Middle District of North Carolina, captioned *Vince v. Realı*, No. 1:24-cv-006390CCEJEP (M.D.N.C. 2024). Like the *Grogan* case, the *Vince* case asserts violations of Section 14(a) of the Exchange Act, breaches of fiduciary duties, unjust enrichment, contribution, and waste, and generally alleges the same purported misconduct as alleged in the *Ciarciello* case. On November 11, 2024, the defendants filed a motion to transfer the *Vince* case to the United States District Court for the District of Delaware, pursuant to the forum selection clause in Bioventus's certificate of incorporation. On January 14, 2025, the Court granted the motion and transferred the *Vince* case to the District of Delaware. On February 14, 2025, the plaintiff requested voluntary dismissal of the *Vince* case without prejudice and the Court granted the request that same day.

On February 20, 2025, plaintiff Jeffrey Vince refiled a Verified Stockholder Derivative Complaint against certain of Bioventus' current and former officers and directors, naming Bioventus as a nominal defendant only, in Delaware Chancery Court, captioned *Jeffrey Vince v. Kenneth M. Realı et al.*, C.A. No. 2025-0192-LWW (Del. Ch.). Like his prior complaint, which he voluntarily dismissed, *Vince* asserts breaches of fiduciary duties, unjust enrichment, contribution, and waste, and generally alleges the same purported misconduct as alleged in the *Ciarciello* case. The Defendants have not yet been served.

On February 26, 2025, plaintiff James Bouchereau filed a Verified Stockholder Derivative Complaint against certain of Bioventus's current and former officers and directors, naming Bioventus as a nominal defendant only, in Delaware Chancery Court, captioned *James Bouchereau v. Kenneth M. Realı et al.*, C.A. No. 2025-____-____ (Del. Ch.). The complaint is identical to the *Vince* complaint and asserts breaches of fiduciary duties, unjust enrichment, contribution, and waste, and generally alleges the same purported misconduct as alleged in the *Ciarciello* case. The Defendants have not yet been served.

On February 6, 2025, purported stockholder Jae Hyung Jung served a litigation demand, requesting that the Board take action against certain directors and officers for alleged breaches of fiduciary duties, gross mismanagement, unjust enrichment, waste, aiding and abetting in connection with the same conduct at issue in the litigations. On February 7, 2025, the same purported stockholder, Jung, served a settlement demand, requesting that the Company adopt certain corporate governance reforms and agree to certain monetary payments. The Company has not yet responded to either demand.

The Company believes the claims alleged in the above derivative matters lack merit and intends to defend itself vigorously. Except as described above, the outcomes of these matters are not presently determinable, and any loss is neither probable nor reasonably estimable.

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 payment of \$853 was made in 2022 upon the transfer of certain seller customer data. If the Company is able to obtain a Medical Device Regulation Certification ("MDR Certification") for the product, \$1,707 (the "Milestone Payment") will be paid to the seller within five days. On March 8, 2023, the parties amended the agreement under which the Milestone Payment was reduced to \$1,418, of which \$709 was recorded as an intellectual property intangible asset during 2023 and was paid on January 31, 2024. The remainder was due upon receipt of the MDR Certification for the product provided that it was obtained prior to December 31, 2024, which was not achieved. The asset purchase agreement was further amended in 2024 acknowledging the expectation that the MDR Certification would not be obtained. Pursuant to the amendment in 2024, the MDR Certification achievement criteria under the asset purchase agreement was extended for two years.

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 osteoarthritis (“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 during the years ended December 31, 2024, 2023 and 2022 totaled \$18,764, \$14,035 and \$14,712, respectively. These royalties are included in cost of sales within the consolidated statements of operations and comprehensive loss.

As part of a supply agreement entered on February 9, 2016 and subsequently amended 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 an additional 5 years 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.

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, 2024 the Company had three LOCs outstanding for \$2,200 and as of December 31, 2023, the Company had three LOC outstanding for \$2,200.

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 \$250 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. Refer to *Note 2. Significant accounting policies* for further information regarding revenue recognition. As previously discussed in *Note 1. Organization*, SonicOne revenue was reclassified from Restorative Therapies to Surgical Solutions on a retrospective basis as its capabilities to remove devitalized or necrotic tissue and fiber deposits more closely align with Surgical Solutions’ soft tissue management. SonicOne revenue reclassified for the year ended December 31, 2023 and 2022 totaled \$6,833 and \$6,845, respectively, for the U.S. reporting segment and \$299 and \$281, respectively, for the International reporting segment. The Company had product sales to one customer totaling \$59,742 primarily in the U.S. reporting segment during the year ended December 31, 2024, representing 10.4% of total net sales. There were no customers representing 10% or more of net sales during the years ended December 31, 2023 and 2022.

The following table presents the Company’s net sales disaggregated by major products within each segment as follows for the years ended December 31:

	2024	2023	2022
U.S.			
Pain Treatments	\$ 234,936	\$ 197,954	\$ 194,830
Surgical Solutions	167,706	141,888	133,052
Restorative Therapies	104,167	110,018	127,369
Total U.S. net sales	<u>506,809</u>	<u>449,860</u>	<u>455,251</u>
International			
Pain Treatments	26,353	22,847	21,495
Surgical Solutions	21,549	19,715	15,232
Restorative Therapies	18,569	19,923	20,139
Total International net sales	<u>66,471</u>	<u>62,485</u>	<u>56,866</u>
Total net sales	<u>\$ 573,280</u>	<u>\$ 512,345</u>	<u>\$ 512,117</u>

14. Segments

As previously discussed in *Note 2. Significant accounting policies—Accounting pronouncements recently adopted*, the Company adopted the provisions of ASU 2023-07, which required enhanced disclosures concerning significant segment expenses that are provided to the CODM and included within each measure of segment profit or loss. 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 CODM and (iii) it has available discrete financial information. The Company's CODM is its President and Chief Executive Officer, who uses Segment adjusted EBITDA to make decisions regarding the allocation of resources, assess performance and to develop annual budgets and forecasts.

The Company's two operating segments are U.S. and International, which also represent its reportable segments. Both segments sell the Company's portfolio of products to healthcare institutions, physicians, patients, distributors and dealers. The Company does not disclose segment information by asset, as the CODM does not review or use it to allocate resources or to assess the operating results and financial performance.

The following table presents segment adjusted EBITDA reconciled to loss before income taxes for the years ended December 31:

	December 31, 2024		
	U.S.	International	Consolidated
Revenue	\$ 506,809	\$ 66,471	\$ 573,280
Adjusted cost of sales ^(a)	118,985	24,188	
Adjusted selling expense ^(b)	157,789	11,233	
Adjusted marketing expense ^(b)	24,235	3,004	
Adjusted general and administrative expense ^(b)	97,592	14,949	
Adjusted research and development expense ^(c)	13,139	41	
Adjusted other segment income ^(d)	(352)	(405)	
Adjusted EBITDA	95,421	13,461	108,882
Reconciliation to loss before income taxes			
Interest expense, net			(38,792)
Depreciation and amortization			(49,555)
Acquisition and related costs			(1,339)
Shareholder litigation costs			(13,802)
Restructuring and succession charges			57
Equity-based compensation			(10,058)
Financial restructuring costs			(351)
Impairments of assets			(36,357)
Loss on disposal of a business			(292)
Other items ^(e)			(7,519)
Loss before income taxes			\$ (49,126)

	December 31, 2023		
	U.S.	International	Consolidated
Revenue	\$ 449,860	\$ 62,485	\$ 512,345
Adjusted cost of sales ^(a)	109,889	25,760	
Adjusted selling expense ^(b)	140,278	11,908	
Adjusted marketing expense ^(b)	24,401	2,655	
Adjusted general and administrative expense ^(b)	86,108	12,285	
Adjusted research and development expense ^(c)	11,458	31	
Adjusted other segment income ^(d)	(942)	(348)	
Adjusted EBITDA	78,668	10,194	88,862
Reconciliation to loss before income taxes			
Interest expense, net			(40,676)
Depreciation and amortization			(57,365)
Acquisition and related costs			(5,694)
Restructuring and succession charges			(2,331)
Equity-based compensation			(2,722)
Financial restructuring costs			(7,291)
Impairments of assets			(78,615)
Loss on disposal of a business			(1,539)
Other items ^(e)			(13,740)
Loss before income taxes			\$ (121,111)

	December 31, 2022		
	U.S.	International	Consolidated
Revenue	\$ 455,251	\$ 56,866	\$ 512,117
Adjusted cost of sales ^(a)	109,961	19,847	
Adjusted selling expense ^(b)	147,772	11,291	
Adjusted marketing expense ^(b)	30,161	2,667	
Adjusted general and administrative expense ^(b)	93,565	10,397	
Adjusted research and development expense ^(c)	18,326	33	
Adjusted other segment (income) expense ^(d)	(1,047)	534	
Adjusted EBITDA	56,513	12,097	68,610
Reconciliation to loss before income taxes			
Interest expense, net			(12,021)
Depreciation and amortization			(55,398)
Acquisition and related costs			(21,731)
Restructuring and succession charges			(7,453)
Equity-based compensation			(17,585)
Impairment of assets			(10,285)
Impairment of goodwill			(124,697)
Other items ^(e)			(8,465)
Loss before income taxes			\$ (189,025)

(a) Adjusted cost of sales used in calculating segment Adjusted EBITDA excludes depreciation and amortization as well as the amortization of inventory step-up resulting from acquisitions.

(b) Adjusted selling, general and administrative expense used in the calculation of segment Adjusted EBITDA excludes certain acquisition and related costs, shareholder litigation costs, certain restructuring and succession charges, asset impairments, financial restructuring costs, equity-based compensation expense and other segment items—charges associated with strategic transactions, such as potential acquisitions or divestitures and transformative project to redesign systems and information processing projects.

- (c) Adjusted research and development expense used in calculating segment Adjusted EBITDA excludes depreciation and amortization, equity-based compensation expense and other items—charges associated with the discontinuance of MOTYS and certain regulatory costs.
- (d) Adjusted other segment (income) expense primarily consists of foreign currency transaction and remeasurement gains and losses and other certain nonrecurring items. Activity excluded for the year ended December 31, 2024 included previously unrealized foreign currency gains within the International segment resulting from the sale of the Advanced Rehabilitation Business. There were no excluded costs relating to other (income) expense during the year ended December 31, 2023. Costs excluded for the year ended December 31, 2022 included an impairment related to the investment in Trice Medical Inc. within the U.S. segment.
- (e) Other items primarily include charges associated with strategic transactions, such as potential acquisitions or divestitures and a transformative project to redesign systems and information processing. During the year ended December 31, 2024, other items primarily consisted of divestiture costs related to the Company's Advanced Rehabilitation Business, including transactional fees, transformative project costs and strategic transaction costs.
- During the year ended December 31, 2023, other items mostly consisted of strategic transaction costs, transformative project costs, transition and severance costs and expenses related to the discontinuance of MOTYS.
- During the year ended December 31, 2022, other items primarily consisted of costs related to the discontinuance of MOTYS, strategic transaction costs and public company preparation costs.

15. Discontinued operations

On February 27, 2023 the Company reached a Settlement Agreement with the Former Securityholders of CartiHeal that resulted in the transfer of 100% of the Company's shares in CartiHeal to a Trustee. Refer to *Note 4. Acquisitions and divestitures* for further details concerning the CartiHeal Settlement Agreement and its deconsolidation from the Company's financial statements. CartiHeal had no sales for the years ended December 31, 2023 and 2022.

The following table summarizes the major income and expense line items of these discontinued operations, as reported in the consolidated statements of operations for the years ended December 31:

	2023	2022
Selling, general and administrative expense	\$ 1,728	\$ 472
Research and development expense	396	2,087
Change in fair value of contingent consideration ^(a)	1,710	5,350
Depreciation and amortization ^(a)	4,264	11,405
Impairments of assets	—	64,500
Operating loss from discontinued operations	(8,098)	(83,814)
Interest expense, net ^(a)	4,889	13,774
Other expense (income) ^(b)	61,442	(22,714)
Other expense (income)	66,331	(8,940)
Loss before income taxes	(74,429)	(74,874)
Income tax benefit, net	—	(6,134)
Net loss from discontinued operations	(74,429)	(68,740)
Loss attributable to noncontrolling interest—discontinued operations	14,937	13,955
Net loss attributable to Bioventus Inc.—discontinued operations	<u>\$ (59,492)</u>	<u>\$ (54,785)</u>

(a) Depreciation and amortization, the change in fair value of contingent consideration and interest expense represent the significant operating non-cash items of discontinued operations.

(b) Other expense includes the \$60,639 loss on deconsolidation, of which \$10,150 was attributable to non-refundable payments. Total investing cash outflows included these non-refundable payments and \$1,356 cash on hand at disposal.

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 President and Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) promulgated under the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on this evaluation, our President and 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, 2024.

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 and for its assessment of the effectiveness of 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 is a process designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

In connection with the preparation and filing of this Annual Report, the Company's management, including our President and Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control—Integrated Framework (2013)*.

Based upon this evaluation, our President and Chief Executive Officer and Chief Financial Officer concluded that we maintained effective internal control over financial reporting as of December 31, 2024.

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 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report of Independent Registered Public Accounting Firm

This Annual Report does not include an attestation report on our internal control over financial reporting of our registered public accounting firm due to an exemption established by the JOBS Act for emerging growth companies.

Item 9B. Other Information.

During the quarter ended December 31, 2024, none of our directors or officers (as defined in rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" (as such terms are defined in Item 408 of Regulation S-K).

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 information regarding our directors as of March 1, 2025:

Name	Age	Position(s)
Robert E. Claypoole	53	President, Chief Executive Officer and Director
William A. Hawkins	71	Director, Chairperson
John A. Bartholdson	54	Director
Patrick J. Beyer	59	Director
Philip G. Cowdy	57	Director
Mary Kay Ladone	58	Director
Michelle McMurry-Heath	55	Director
Guido J. Neels	76	Director
Guy P. Nohra	64	Director
Martin P. Sutter	69	Director
Susan M. Stalneck	72	Director

Robert Claypoole joined Bioventus as our President, Chief Executive Officer and a director in January 2024. Please see Mr. Claypoole’s biography set forth in *Part I, Item 1. Business—Information about our Executive Officers of this Annual Report*. The Company’s Board of Directors (the “Board”) believes that Mr. Claypoole is well-qualified to serve on our Board considering the breadth of his experience across multiple global medical device markets and his extensive expertise in accelerating innovation, driving operational excellence, enhancing go-to-market strategies, and driving commercial execution and organizational effectiveness.

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 2001 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 served as a member of the board of managers of BV LLC from January 2016 until the time of our IPO. 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., Cirtex Medical Corp., Enterra Medical and Virtue Labs, LLC, each a privately-held life science company. Mr. Hawkins serves on the compensation committee of Biogen and chairs the ethics and compliance committee of MiMedx. Mr. Hawkins previously served on the Board of Directors of Avanos Medical, Inc. from 2015 to April 2021 and Immunor, Inc. from 2015 to 2021. Mr. Hawkins served on the Duke University Board of Trustees from 2011 to 2023, where he held the position of Vice Chair, and was appointed Duke University Trustee Emeritus in 2023. Mr. Hawkins also previously served as the Chair of the Duke University Health System board of directors. He is currently 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.

John A. Bartholdson was appointed as a member of our Board effective January 8, 2023. Mr. Bartholdson is the co-founder and has been a Partner of Juniper Investment Company, a private investment management firm that invests in publicly traded and private companies through concentrated ownership positions since its inception in 2007. Mr. Bartholdson has 25 years of experience leading and overseeing private and public equity investments. His experience includes extensive management oversight, service on multiple public and private company boards, and deep transactional expertise. Mr. Bartholdson presently serves as the Chairman of the board of directors of Lincoln Educational Services Corporation, a public company and a leading provider of career education and training services, and Theragenics Corporation, a private medical device company serving the surgical products and prostate cancer treatment markets. Previously, he served as a member of the board of directors of Obagi Medical Products, Inc., a public specialty pharmaceutical company, until its acquisition by Valeant Pharmaceuticals in 2013. In addition, Mr. Bartholdson has previously served on the board of directors of numerous private companies. Mr. Bartholdson was a Partner of Stonington Partners, where he worked from 1997 to 2011. Prior to that, he was an analyst at Merrill Lynch Capital Partners from 1992 to 1994. Mr. Bartholdson received his Bachelor of Arts from Duke University and his Master of Business Administration from Stanford Graduate School of Business. Mr. Bartholdson was selected to serve on our board because of his professional investor perspective on stockholder and related matters and his significant governance, finance, capital markets and transactional experience on multiple public and private company boards.

Patrick J. Beyer has served as a member of our Board since October 2021. Mr. Beyer was appointed President and Chief Executive Officer and a member of the board of directors of ConMed Corporation, a publicly held medical technology company, effective January 1, 2025. Prior to that, Mr. Beyer served as ConMed Corporation's Chief Operation Officer from April 2024 to December 2024, and before that as its President International and Global Orthopedics from October 2020 to April 2024. 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 Bachelor of Arts in Economics, Western Michigan University with a Master of Business Administration in Finance and Harvard Business School's Advanced Management Program. Mr. Beyer was selected to serve on our Board because of his extensive experience in international healthcare markets, his service as a chief executive officer and his broad business and public company experience.

Philip G. Cowdy has served as a member of our Board since September 2020. Mr. Cowdy has served as the Chief Business Development and Corporate Affairs Officer for Smith & Nephew plc, a medical equipment manufacturing company, since 2018. 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 served as a member of the board of managers of BV LLC from January 2012 to October 2017 and again from July 2018 until the time of our IPO, and 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. ("Hill-Rom"), a medical technology provider, from December 2018 to December 2021. Ms. Ladone previously served as Hill-Rom's Vice President, Investor Relations, July 2016 to December 2018. 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. Since March 2022, Ms. Ladone has also served on the board of directors of Inogen Inc., a publicly traded supplemental oxygen therapies provider, where she is a member of the audit and compensation committees. Ms. Ladone also serves on the board of directors of Kestra Medical Technologies, Inc., a privately held wearable medical device and digital healthcare company, where she has been the chair of the audit committee since September 2022, and of Novanta Inc., a publicly traded supplier of technology solutions service to medical and advanced industrial original equipment manufacturers since July 2024. Ms. Ladone holds a Bachelor of Arts in Finance and Economics from the University of Notre Dame. Ms. Ladone was selected to serve on our Board due to her significant finance and investor relations, talent management, and M&A experience at large healthcare companies.

Michelle McMurry-Heath, MD, PhD, has served as a member of our Board since January 2022. Dr. McMurry-Heath 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, from 2020 to 2022. Dr. McMurry-Heath was previously with Johnson & Johnson (“J&J”) from 2014 to 2020, where she served as Global Head of Evidence Generation for Medical Device Companies and then Vice President of Global External Innovation and Global Leader for Regulatory Sciences. Prior to her time at J&J, Dr. McMurry-Heath was a key science policy leader in government, conducting a comprehensive analysis of the National Science Foundation’s policies, programs and personnel. President Obama then named her associate science director of the FDA’s Center for Devices and Radiological Health where she served 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 also serves on the Board of Directors at publicly traded Revvity Inc., the former life sciences and diagnostics business of the company previously known as PerkinElmer, where she is a member of the audit committee. Dr. McMurray-Heath received her M.D./Ph.D. in Immunology from Duke University’s Medical Scientist Training Program, becoming the first African American to graduate from the prestigious program, and her AB in Biochemistry from Harvard University. Dr. McMurry-Heath was selected to serve on our Board due to her significant policy, regulatory, commercial healthcare and advocacy experience.

Guido J. Neels has served as a member of our Board since September 2020. Mr. Neels has been with EW Healthcare Partners (formerly Essex Woodlands), a healthcare growth equity and venture capital firm, since August 2006, where he is has served as Operating Partner since 2013. Prior to joining EW Healthcare Partners, 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 served as a member of the board of managers of BV LLC from May 2012 until the time of our IPO. Mr. Neels also currently serves on the board of directors of Axogen, Inc. and 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 served as a member of the board of managers of BV LLC, from May 2012 until the time of our IPO. Mr. Nohra currently serves as a member of the boards of directors of Spiral Therapeutics, Inc., a 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., Sanifit 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 served as a member of the board of managers of BV LLC from May 2012 until the time of our IPO. Mr. Sutter also currently serves on the board of directors of 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 Abiomed, Inc., Tissue Tech, Inc. and Suneva Medical, Inc. Mr. Sutter currently serves on the compensation and nominating and governance committees of MiMedx Group, Inc. and Prolacta Biosciences, Inc. and previously served on the compensation and nominating and governance committee of Abiomed, 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 diversified science and innovations public company and 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 served as a member of the board of managers of BV LLC from November 2018 until the time of our IPO. Ms. Stalnecker also currently serves on the board of directors of Leidos Holding, Inc. and Optimum Funds McQuairie. She also serves on the audit & finance committee of Leidos Inc. and the audit committee of Optimum Funds McQuairie. From 2009 to 2023, Ms. Stalnecker served on the Board of Trustees of the Duke Health System, where she was a member of the compliance, audit and finance committees. 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 qualifications as a financial expert, and her extensive treasury, governance, risk management and investment experience, and her service as a director of other public companies.

Additional information required by this Item concerning our directors is incorporated by reference from the sections captioned “Election of Directors,” “Corporate Governance” and “Committees of the Board” contained in our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024.

The information required by this Item concerning our Audit and Risk Committee is incorporated by reference from the section captioned “Committees of the Board-Audit and Risk Committee” contained in our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024.

Code of compliance and ethics

We have adopted 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 required by this Item concerning our executive officers is set forth at the end of Part I of this Annual Report.

The information required by this Item, if any, concerning compliance with Section 16(a) of the Exchange Act will be incorporated by reference from the section captioned “Delinquent Section 16(a) Reports” contained in our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024.

Item 11. Executive Compensation.

The information required by this Item is incorporated by reference from the section captioned “Executive and Director Compensation” contained in our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024.

Item 12. Security Ownership of Certain Beneficial Owner and Management and Related Stockholder Matters.

The information required by this Item is incorporated by reference from the section captioned “Equity-based Compensation Plan Information” and “Security Ownership of Certain Beneficial Owners and Management” contained in our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item is incorporated by reference from the section captioned “Certain Relationships and Related Party Transactions” contained in our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024.

Item 14. Principal Accounting Fees and Services.

The information required by this Item is incorporated by reference from the section captioned “Report of the Audit and Risk Committee of the Board of Directors” contained in our definitive proxy statement for our 2025 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2024.

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 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	3/31/2021	
2.2	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	
2.3	Asset Purchase Agreement, dated as of May 10, 2023, by and among Misonix, LLC, Solsys Medical, LLC, Bioventus LLC and LifeNet Health.	8-K	001-37844	2.1	5/16/2023	
2.4	Purchase and Sale Agreement, dated as of September 30, 2024, by and among Bioventus LLC, Bioness Inc., Bioventus Cooperatief, U.A., and Rehab Acquisition Corporation, III	8-K	001-37844	2.1	10/4/2024	
3.1	Second Amended and Restated Certificate of Incorporation of Bioventus Inc.	8-K	001-37844	3.1	6/17/2024	
3.1(a)	Certificate of Amendment to Amended and Restated Certificate of Incorporation of Bioventus Inc.	8-K	001-37844	3.1	6/17/2024	
3.2	Second Amended and Restated Bylaws of Bioventus Inc.	8-K	001-37844	3.2	6/17/2024	
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 Capital Stock.					*
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	
10.4(a)	Amendment No. 1 to Stockholders Agreement, dated June 19, 2024, by and among Bioventus Inc., Bioventus LLC and the Principal Stockholders.	8-K	001-37844	10.1	6/21/2024	

Exhibit no.	Description	Form	File No.	Exhibit	Filing Date	Filed / Furnished Herewith
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	
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	
10.8	Credit and Guaranty Agreement, dated as of December 6, 2019, by and among Bioventus LLC, certain Guarantor Subsidiaries party thereto, Wells Fargo Bank, National Association, as administrative agent and collateral agent and the lenders and other financial institutions party thereto.	S-1	001-37844	10.11	1/20/2021	
10.8(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	
10.8(b)	Amendment No. 2 to Credit and Guaranty Agreement, dated as of October 29, 2021, by and among Bioventus LLC, Oyster Merger Sub I, 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	
10.8(c)	Amendment No. 3 to Credit and Guaranty Agreement between Bioventus LLC, Guarantor Subsidiaries party thereto, Wells Fargo Bank, National Association, as administrative agent, dated July 11, 2022.	8-K	001-37844	10.1	7/12/2022	
10.8(d)	Amendment No. 4 to Credit and Guaranty Agreement between Bioventus LLC, Guarantor Subsidiaries party thereto, Wells Fargo Bank, National Association, as administrative agent, dated March 31, 2023.	10-K	001-37844	10.8(d)	3/31/2023	

Exhibit no.	Description	Form	File No.	Exhibit	Filing Date	Filed / Furnished Herewith
10.8(e)	Amendment No. 5 to Credit and Guaranty Agreement between Bioventus LLC, Guarantor Subsidiaries party thereto, Wells Fargo Bank, National Association, as administrative agent and collateral agent, and the lenders and other financial institutions party thereto, dated January 18, 2024.	8-K	001-37844	10.1	1/19/2024	
10.9^	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	
10.10^	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	
10.11^	Bioventus Inc. 2021 Employee Stock Purchase Plan.	S-1/A	333-252238	10.44	2/4/2021	
10.12^	Bioventus Inc. 2021 Equity Incentive Plan.	10-Q	001-37844	10.3	8/12/2022	
10.13^	Form of Notice of Stock Option Grant and Stock Option Agreement.	S-1/A	333-252238	10.47	2/10/2021	
10.14^	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit	S-1/A	333-252238	10.48	2/10/2021	
10.15^	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Agreement (2025).					*
10.16^	Form of Bioventus Performance Restricted Stock Unit Award Grant Notice and Agreement.					*
10.17^	Bioventus Inc. Non-Employee Director Compensation Policy.	S-1/A	333-252238	10.51	2/10/2021	
10.18^	Employment Agreement, dated as of February 9, 2021, by and among Bioventus Inc., Bioventus LLC and Anthony D'Adamio.	S-1/A	333-252238	10.55	2/10/2021	
10.19	Form of Indemnification Agreement.	S-1/A	333-252238	10.46	2/4/2021	
10.20	Lease Agreement, dated November 17, 2021, between Bioventus LLC and 7101 Goodlett Farms Parkway, LLC.	8-K	001-37844	10.1	11/22/2021	
10.20(a)	Amendment to the Lease Agreement, dated October 14, 2024, between Bioventus LLC and 7101 Goodlett Farms Parkway, LLC.					*
10.21^	Revised Employment Agreement, dated as of February 14, 2022, by and among Bioventus Inc., Bioventus LLC and Mark Singleton.	8-K	001-37844	10.1	2/28/2022	
10.22^	Bioventus Inc. Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Agreement Inducement Award.	S-8	333-264050	99.1	4/1/2022	
10.23^	Bioventus Inc. Notice of Stock Option Grant Inducement Award.	S-8	333-264050	99.2	4/1/2022	

Exhibit no.	Description	Form	File No.	Exhibit	Filing Date	Filed / Furnished Herewith
10.24	Settlement Agreement by and among CartiHeal (2009) Ltd., Bioventus LLC, Elron Ventures Ltd., and certain other parties detailed therein, dated February 27, 2023.	10-Q	001-37844	10.3	5/16/2023	
10.25†	Amended and Restated Exclusive Distribution Agreement No. 2, between Bioventus LLC and Seikagaku Corporation and dated as of December 22, 2020.	S-1	333-252238	10.9	1/20/2021	
10.26^	Consulting Agreement between Alessandra Pavesio and Bioventus LLC, dated as of January 1, 2023.	10-Q	001-37844	10.1	5/16/2023	
10.27^	Employment Agreement between Anthony P. Bihl III and Bioventus Inc., dated as of April 5, 2023.	8-K/A	001-37844	10.1	4/11/2023	
10.28^	Bioventus Inc. 2023 Retention Equity Award Plan.	8-K	001-37844	10.1	6/9/2023	
10.29^	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Agreement.	8-K	001-37844	10.2	6/9/2023	
10.30^	Employment Agreement, between Robert E. Claypoole and Bioventus Inc., dated as of December 19, 2023.	8-K	001-37844	10.1	12/21/2023	
10.31^	Form of Bioventus Inc. Inducement Award - Restricted Stock Unit Agreement.	8-K	001-37844	10.2	12/21/2023	
10.32^	Form of Bioventus Inc. Inducement Award - Option Agreement.	8-K	001-37844	10.3	12/21/2023	
19.1	Bioventus Inc. Insider Trading Policy, dated as of February 10, 2021					*
21.1	Listing of Subsidiaries					*
23.1	Consent of Grant Thornton LLP (Bioventus Inc.).					*
31.1	Certification of President and 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 President and Chief Financial Officer pursuant to Rules 13a-14(a)/15d-14(a) under the Securities Exchange Act of 1934, as amended.					*
32	Certification of President and 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.					**
97.1	Bioventus Inc. Compensation Recovery Policy, dated September 7, 2023.	10-K	001-37844	97.1	3/12/2024	
99.1	List of patents and pending patent applications directed to Bioventus Inc.'s material products.					*

Exhibit no.	Description	Form	File No.	Exhibit	Filing Date	Filed / Furnished Herewith
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.

- (c) *Financial Statement Schedules*. Schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission have been omitted because they are not applicable, not required or the information required is given in the Consolidated Financial Statements and notes thereto set forth above under *Part II, Item 8. Financial Statements and Supplemental Data*.

Item 16. Form 10-K Summary.

None

SIGNATURE

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

BIOVENTUS INC.

By: /s/ Robert E. Claypoole

Name: Robert E. Claypoole

Title: President, Chief Executive Officer and
Director (Principal Executive Officer)

March 11, 2025

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
<u>/s/ Robert E. Claypoole</u> Robert E. Claypoole	March 11, 2025	President, Chief Executive Officer and Director (Principal Executive Officer)
<u>/s/ Mark L. Singleton</u> Mark L. Singleton	March 11, 2025	Senior Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)
<u>/s/ William A. Hawkins III</u> William A. Hawkins III	March 11, 2025	Chairman
<u>/s/ John A. Bartholdson</u> John A. Bartholdson	March 11, 2025	Director
<u>/s/ Patrick J. Beyer</u> Patrick J. Beyer	March 11, 2025	Director
<u>/s/ Philip G. Cowdy</u> Philip G. Cowdy	March 11, 2025	Director
<u>/s/ Mary Kay Ladone</u> Mary Kay Ladone	March 11, 2025	Director
<u>/s/ Michelle McMurry-Heath</u> Michelle McMurry-Heath	March 11, 2025	Director
<u>/s/ Guido J. Neels</u> Guido J. Neels	March 11, 2025	Director
<u>/s/ Guy P. Nohra</u> Guy P. Nohra	March 11, 2025	Director
<u>/s/ Susan M. Stalnecker</u> Susan M. Stalnecker	March 11, 2025	Director
<u>/s/ Martin P. Sutter</u> Martin P. Sutter	March 11, 2025	Director

<u>Legal Name</u>	<u>Jurisdiction of Incorporation</u>
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
Misonix LLC (1)	Delaware
Misonix OpCo, LLC (4)	Delaware
Solsys Medical, LLC (4)	Delaware
Perseus Intermediate, Inc. (1)	Delaware
Bioness Inc. (5)	Delaware

- (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) Wholly owned subsidiary of Misonix LLC
- (5) Wholly owned subsidiary of Perseus Intermediate, Inc.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 11, 2025, 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, 2024. We consent to the incorporation by reference of said report in the Registration Statements of Bioventus Inc. on Form S-3 (File No. 333-282836), Forms S-8 (File No. 333-278100; File No. 333-276437; File No. 333-272740; File No. 333-271310; File No. 333-264050; File No. 333-263496; 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, 2025

CERTIFICATIONS

I, Robert E. Claypoole, 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/ Robert E. Claypoole

 Name: Robert E. Claypoole
 Title: President and Chief Executive Officer
 (Principal Executive Officer)

Date: March 11, 2025

CERTIFICATIONS

I, Mark L. Singleton, 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/ Mark L. Singleton

Name: Mark L. Singleton

Title: Senior Vice President and Chief
Financial Officer (Principal Financial
Officer)

Date: March 11, 2025

**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, 2024, as filed with the Securities and Exchange Commission on the date hereof (the Report), each of Robert E. Claypoole, President and Chief Executive Officer of the Company and Mark L. Singleton, 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/ Robert E. Claypoole

Name: Robert E. Claypoole

Title: President and Chief Executive Officer
(Principal Executive Officer)

/s/ Mark L. Singleton

Name: Mark L. Singleton

Title: Senior Vice President and Chief Financial
Officer (Principal Financial Officer)

Date: March 11, 2025